The single concept note details the applicant's request for Global Fund resources for a disease component for a three-year period. The concept note should articulate an ambitious, strategically focused and technically sound investment, informed by the national health strategy and the national disease strategic plan. It should represent a prioritized, full expression of demand for resources, and it should be designed and implemented in a way that maximizes the strategic impact of the investment. The single concept note for TB and HIV details the CCM's request for countries with high co-infection rates for the two diseases based on data from the World Health Organization.

SINGLE CONCEPT NOTE FOR TB AND HIV

Investing for impact against tuberculosis and HIV

Countries with overlapping high burden of tuberculosis (TB) and HIV must submit a single concept note that presents each specific program in addition to any integrated and joint programming for the two diseases[1].

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

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

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

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

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

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

Section 4: Implementation arrangements and risk assessment.

[1] For the 2013 WHO list of countries with high TB/HIV burden, refer to Annex 6 of the Instructions for the single concept note for TB and HIV.

SUMMARY INFORMATION			
Applicant Information			
Country	**India**		
Funding Request Start Date	**1 October 2015**	**Funding Request End Date**	**31 December 2017**
Principle Recipient(s)			
If the programs are to be managed as separate grants:			
Funding Request Start Date for HIV	**1 October 2015**	**Funding Request End Date for HIV**	**31 December 2017**
Principal Recipient(s) for HIV	**1. Department of Economic Affairs: National AIDS Control Organization 2. India HIV/AIDS Alliance 3. SAATHI 4. PlanIndia**		
Funding Request Start Date for TB	**1 October 2015**	**Funding Request End Date for TB**	**31 December 2017**
Principal Recipient(s) for TB	**1. Department of Economic Affairs: Central TB Divisio 2. The Union 3. World Vision India**		

FUNDING REQUEST SUMMARY TABLE

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

SECTION 1: COUNTRY CONTEXT

This section requests information on the country context, including descriptions of the TB and HIV disease epidemiology and their overlaps, the health systems and community systems setting, and the human rights situation.

1.1 Country Disease, Health Systems and Community Systems Context

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

a. The current and evolving epidemiology of the two diseases, including trends and any significant geographic variations in incidence or prevalence of TB and HIV. Include information on the prevalence of HIV among TB patients and TB incidence among people living with HIV/AIDS.
b. Key populations that may have disproportionately low access to prevention, treatment, care and support services, and the contributing factors to this inequity.
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 relevant to effective implementation of the national TB and HIV programs including joint areas of both programs.

a. Current and evolving epidemiology of the two diseases

India, with 1.23 billion people, has the second largest population in the world. An estimated half of this population is young adults who are economically productive. Between 2005 and 2010, rapid economic growth lifted an estimated 50 million people over the poverty line, yet an estimated 400 million are still living in poverty and the country accounts for one – third of the global poor. Tuberculosis (TB) and Human Immunodeficiency Virus (HIV) epidemics have been long associated with poverty and other social factors. Poverty manifests TB and increases HIV vulnerability through dismal living conditions such as overcrowding, limited livelihood choices, barriers to education, social exclusion, lack of awareness, and limited healthcare access. Conversely, TB and HIV through their manifold effects on patients' care-seeking behaviours and out-of-pocket expenditure contributes to poverty. Thus, any sustained initiative to bring down these epidemics will also greatly accelerate poverty reduction and improve human development efforts not only within the country but in the region and globally as well.

India with an estimated 2.2 million new cases every year accounts for the highest TB burden in the world (24% of global burden), causing 270,000 deaths annually. In addition there is a growing threat of drug resistant tuberculosis, which is both more deadly to patients and one-hundred times more costly to manage. India has the third highest burden of HIV with 2.1 million people estimated to be living with HIV, contributing to nearly 6% of the global burden. With an estimated 120,000 HIV-TB co-infected individuals, India has the second highest burden of HIV-TB co infections annually. TB remains the leading cause of death among People Living with HIV (PLHIV), with an estimated 36000 deaths in 2013.[2]

HIV Epidemic:

Low prevalence but high burden: India has an estimated prevalence of 0.27% among adults

[2]WHO. Global TB Report 2014

and 2.1 million people estimated to be living with HIV, of which 39% are women[3]. The sexual route continues to be the main mode of transmission, accounting for 88.7% of all reported cases. Parent to child transmission accounts for 5.4% of HIV cases and injection drug use for 1.7%. In 2011, about 116,000 new HIV infections occurred among adults. An estimated 14,000 infants acquire HIV eachyear,[4]indicating a continued and high level of transmission of HIV from infected mothers to their children.

Concentrated among Key Populations and geographies: The HIV epidemic is concentrated among Key Populations (KPs), with the highest prevalence among transgender (8.82%) followed by injecting drug users (7.14 %), men having sex with men (4.43%) and female sex workers (2.67%) (HSS2010). The five high prevalence states (Andhra Pradesh, Karnataka, Maharashtra,Tamil Nadu, and Telangana) account for 53% of all cases, and the states of Bihar, Gujarat, Uttar Pradesh, and West Bengal account for 22% of all HIV infections in India.

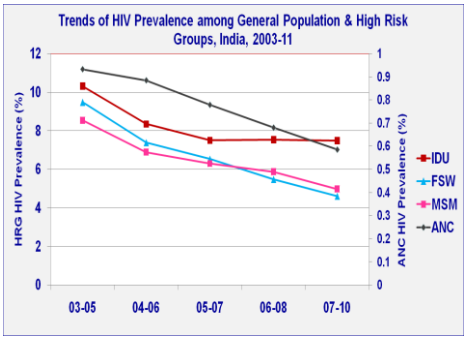
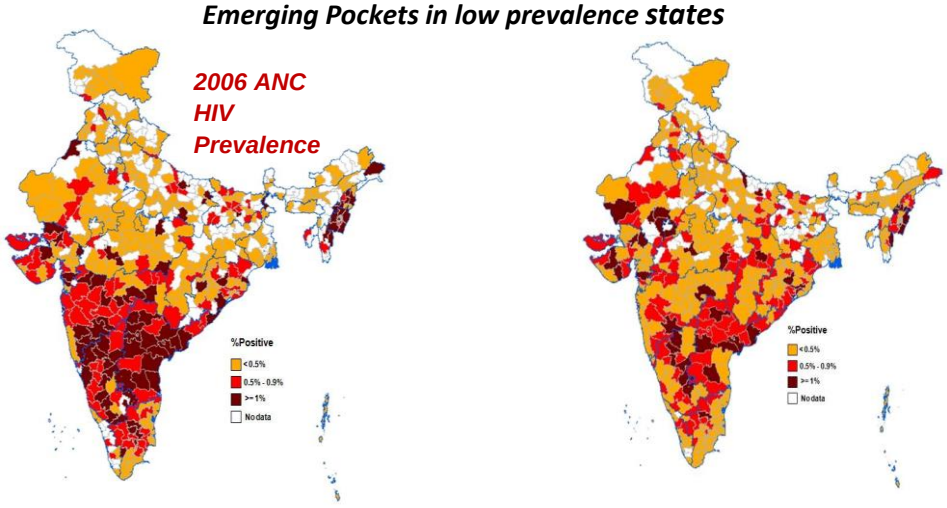


Figure 1: Declining HIV prevalence in India

Epidemic is on the decline in high prevalence states and certain key populations but on the rise in new geographies: India's HIV epidemic is on the decline, with a 57% decrease in new HIV infections between 2000 and 2011. All the high prevalence states show a clear declining trend in adult HIV prevalence, which is largely attributed to early and sustained response through targeted interventions, and substantial scale up testing and treatment services.In 2011, prevalence has reduced among FSW (5.06% to 2.67%), MSM (7.41% to 4.43%) PWID (7.23% to 7.14%) from year 2007 to 2012. However, it has been observed that in some of the previously low prevalence states of Arunachal Pradesh, Chandigarh, Jammu & Kashmir, Jharkhand, Kerala, Orissa, Meghalaya and Uttarakhand, have shown rising trends in adult HIV accounting for 31% of new infections. Accordingly there has been a reduction in the number of districts with high HIV prevalence (≥1% among pregnant women in Ante Natal Care) from 135 to 65 in high prevalence states, and an increase in HIVfrom 8 to 24 districts in low prevalence states between 2003 and 2011. (Ref: Map).

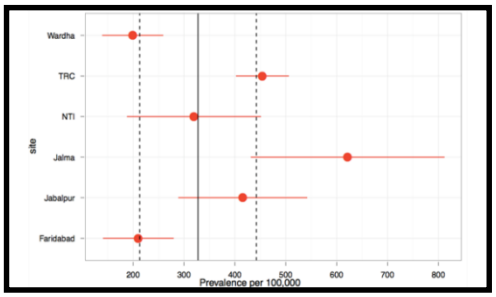
Emerging Pockets in low prevalence states



[3]NACO. (2014). *Annual Report 2013-14*. Pg. 11Retrieved from http://www.naco.gov.in/upload/Publication/Annual Report/Annual report 2013-114_English.pdf

[4] NACO. (2013). *National Strategic Plan: Multi-Drug ARV for PPTCT under National AIDS Control Programme in India*. Retrieved from NACO - 2013 - National Strategic plan.pdf

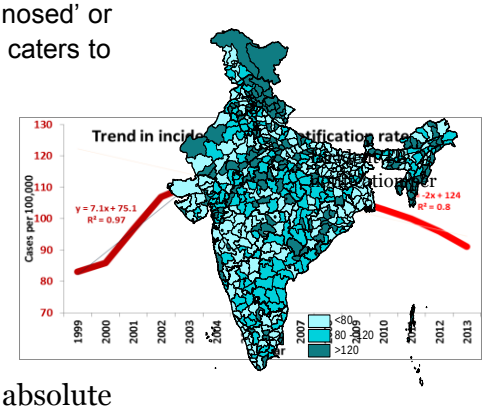
TB epidemic:



India has the highest burden of Tuberculosis, which remains a significant cause of suffering. Although incident cases have reduced from 216 per 100,000 in 1990 to 171 per 100,000 in 2013,while TB prevalence decreased from 465 to 211 per 100,000 population[5].There is still an estimated 2.2 million new cases and 270,000 deaths annually. The problem of TB in India is further compounded by the emergence of drug-resistant TB, and HIV-associated TB. It is also estimated that 1 million TB cases are missed by the national notification system every year. WHO estimations suggest an annual reduction of TB prevalence by 5%, mortality by 4.5% and incidence by 1.7% since 2003. The recent Annual Risk of TB Infection (ARTI) study (2009 -2010) also revealed a reduction in ARTI from 1.5 in 2003 to 1.1 in 2010. However, isolated sub – national studies indicate a high prevalence rate.[6]The TB prevalence study conducted by the program at 6 sites shows wide variation and indicates a heterogeneous prevalence of the epidemic (Fig 2). The current drivers of TB transmission are urbanization, overcrowding, and poor airborne infection control, coupled with host factors such as poor nutrition, HIV, Diabetes Mellitus, and tobacco use. The rates are much higher in certain marginalized and vulnerable populations such as tribals, urban slum dwellers, migrants, refugees, and in people living in geographically remote and difficult – to – reach areas.

Figure 3: Trend in incident TB case notificationrate

In 2013, India reported 1.4 million TB cases, of which over 1.2 million were incident TB cases (new and relapse). Thus, close to 1 million TB cases are either 'not diagnosed' or 'diagnosed but not notified' mostly by the private sector which caters to nearly 50% of TB cases[7].



Situational Analysis:National level

Ever since complete geographical coverage of the Revised National Tuberculosis Control Programme (RNTCP) was achieved in India, TB case finding efforts have increased (annual examination rates of TB symptomatics increased from 566 per 100,000 population in 2006 to >660 per 100,000 in 2014). In absolute numbers TB symptomatics examined have increased from 6 million to more than 8 million during this period. Rate of sputum smear positive cases diagnosed by microscopy increased by 20%, from 65 to 79 per 100,000 population by 2008, remained at that level till 2012, then decreased to 74 per 100,000 in 2013(Fig 3). The number and rate of all new (incident) cases notified in the country has steadily increased at the rate of approximately 7% per year (83 per 100,000 population in 1999, to 116 per 100,000 population in 2004), reflecting an almost 40% increase in half a decade. The incident TB case notification rate has decreased from 116 per 100,000 population in 2004 to 91 per 100,000 population in year 2013 showing a decline of 20%, almost 2% annually. WHO estimations suggest a decrease in TB burden in terms of prevalence, mortality and incidence by 55%, 50% & 20% respectively between 1990 and 2013 as per the Global TB Report[7]

Figure 2: TB Prevalence in India

[5]WHO (2014) *Global Tuberculosis Report 2014*, Geneva

[6]ICMR studies in Model DOTS project area of Tiruvellur, Gujarat state – wide study and NFHS data (2006)

[7]Wells WA, Ge CF, Patel N, Oh T, Gardiner E, Kimerling ME. Size and usage patterns of private TB drug markets in the high burden countries. PLoS One. 2011;6(5):e18964

Sub-national / Regional level: Though overall progress in TB control at national level appears to be on track as per Millennium Development Goals, the situation in different regions, areas and population groups is quite heterogeneous. Following are some of the highlights of the epidemiology of Tuberculosis across the country.

Geographic variation: In general, there is wide geographical variation in TB burden as well as programme implementation. For example, India's total notification rate is 114 per 100,000 population. But in certain districts it is as low as 32 (Mungeli, Chhatisgarh) and as high as 2,453 (Bail Bazar Road district of Mumbai). Also, programmatic efforts for case finding are also diverse with India's national average of 163 per 100,000 population per quarter which in certain districts is as low as 25 (Phek, Nagaland) and as high as 1,252 (Parel, Mumbai). Similarly incident TB case notification rate is different across the country.

MDR-TB: India is also the highest burden country for MDR TB in absolute terms, with an estimated 0.062 million (95% CI: 0.05 – 0.074) incident cases among notified pulmonary TB cases annually. Nearly 2.2% (1.9% - 2.6%) of the notified new pulmonary cases and 15% (11% – 19%) of the notified previously treated pulmonary cases have MDR TB. Cases of extensively drug resistant TB (XDR-TB) have also been reported from most states of India. However this estimate at country level masks important local variations such as high level of drug resistance in urban areas such as Mumbai**.** After complete geographical coverage of MDR TB services, MDR notification rates continue to be very high in certain areas such as Sikkim (340 per million), Mumbai (220 per million), Arunachal Pradesh (94 per million), Delhi (84 per million), as against the national average of 27 per million population. MDR rates are very low in areas like Puducherry (14 per million), and Tamil Nadu (21 per million), with both states having good examination rates. The graph shows, this diversity in drug resistance across the country.The graph shows, this diversity in drug resistance across the country.

TB–HIV co - infection: Tuberculosis and HIV synergistically form a deadly duo, often leading to unfavourable outcomes in patients co-infected with these diseases. Approximately 120,000 HIV associated TB cases emerge in India annually[8], out of which an estimated 42,000 die each year, making India the second highest burden country for people living with these co - morbidities. Case fatality rate among the notified HIV positive TB patients in India is about 13% which is 4 times higher than that among HIV negative TB patients. It is estimated that nearly 5% of TB patients are co – infected with HIV, however the epidemiology is heterogeneous. While HIV is a concentrated epidemic primarily in certain states and districts and emerging in others, the TB epidemic is comparatively more uniform and hence the programmatic priorities are based on the geographic need for both programmes. Reported proportion of HIV detection amongst TB patients is also variable with a range of 0%-45% across the country (districts of Bagalkot, Bijapur, Belgaum in north Karnataka and Sangli, Satara and Solapur in southern Maharashtra report high HIV among TB patients). TB-HIV activities are being prioritized in the geographies where both HIV as well as TB prevalence is high.

Urban TB & private sector: There is very high TB notification under the public sector in larger cities (Delhi 300 per 100,000 population, Mumbai >250 per 100,000 population) as well as in the private sector, with studies suggesting upto 70% of patients seeking care from the private sector in large cities, whose facilities have an annual case load of >700 per 100,000 population. The ARTI study[9] suggests very high TB transmission in urban slums of Delhi with ARTI of 3.2%. Populations of the urban poor are more affected by TB due to stress, poverty, malnutrition and overcrowding at both residence and at many workplaces. There is a large proportion

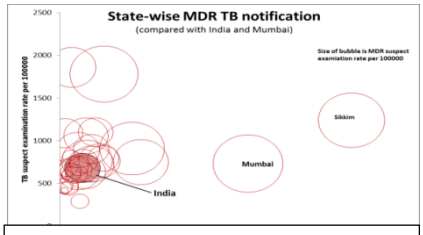


Figure 3: Statewise MDR TB notification

[8]WHO (2014) *Global Tuberculosis Report 2014*, Geneva

[9]RohitSarin etal

of patients being treated in the private sector, especially in urban areas, with diagnostic and treatment practices of unknown or poor quality. Recent efforts for TB notification from private sector have shown variable success and remains a major challenge to be addressed in TB control in India.

Special populations:A recent prevalence survey in tribal districts of Madhya Pradesh suggested TB prevalence of >500 per 100,000 population. Data from prisons in many states also suggest that TB rates are very high among prisons and congregate settings.Overall wide area wise variation is depicted in table below 1:

Table1 :Overall wide area wise variation

Parameter	Mean	Median	Lowest	Highest	India	Coefficient of Variation	Ratio of Highest: Lowest
Symptomatic examined per lakh population per quarter	171	158	25	1252	163	52%	49
Symptomatic examined per smear positive case diagnosed	10	9	4	87	9	62%	21
Annual total case notification rate per 1,00,000 pop	131	112	32	2453	114	92%	75
Notification rate per 1,00,000 population (private sector)	4	0	0	108	3	265%	*
MDR TB cases registered under RNTCP per million pop	35.7	21	2.7	340	27	167%	127
Proportion of all registered TB cases with known HIV status	63%	68%	0.0%	100%	50%	45%	*
Proportion of TB patients known to be HIV infected among tested	4.1%	2.2%	0.0%	49.9%	5.0%	118%	*
Proportion of TB patients known to be HIV infected among registered	2.9%	0.8%	0.0%	40.8%	2.6%	170%	*

The diverse TB epidemiology at sub-national levels necessitate need for specific actions addressing the local epidemiology. Development of a good TB surveillance system to understand the local and focal epidemiology is crucial for TB control in the country. RNTCP is moving ahead with development of case-based notification with systems and regulations for complete notification of all cases.

b. Key populations that may have disproportionately low access to prevention, treatment, care and support services, and the contributing factors to this inequity.

Within the country's population of 1.23 billion, a few population groups are more vulnerable and marginalized due to social inequalities that lead to exclusion and limit access to quality services. These groups are at higher risk of succumbing to HIV and TB, and need focused and enhanced

support. While there is some overlap between the two diseases for key populations, however due to key differences in transmission dynamics (airborne transmission for TB and predominantly sexual route for HIV) and differing epidemiology few population groups are unique for TB and HIV.

The primary KPs for HIV and critical to the epidemic include: Female sex workers (FSWs), Men who have sex with men (MSM), people who inject drugs (PWIDs), and Transgenders (TGs). Other vulnerable populations or those who could,'bridge' infection towards the general population include clients of FSWs,spouses and sexual partners of drug injectors, migrants, and long distance truck drivers. Targeted Interventions (TI), implemented with the support of donors ,such as the World Bank, GFATM, USAID , DFID as well as with others have been central to the National AIDS Control Programme (NACP) through its four- five–year phases to date, making India a forerunner in mounting a large-scale public health response to HIV prevention needs of KP's. However, it is an established fact that these KP's continue to have limited or less than optimal access to critical services such as HIV testing, diagnosis, treatment and continuum of care due to social inequities, stigma and discrimination, and implementation challenges, though the influence of some of these factors have reduced considerably over time. There are also gaps in KP's specific data collection and utilization regarding the extent of access, retention in services and adherence to treatment. These issues are currently being addressed in a systemic manner through the National AIDS Control Organization (NACO) and the World Bank's five year co-funded project: National AIDS Control Support Project (NACSP). The NACSP facilitates access to services for the KP's through a nationally defined package of services for all KPs. Based upon data from 2013-2014 [Table 2],around 60 percent of the KP's reached by the program are undergoing testing for HIV with the exception of TG which is lower at 43.8% and there is progressive increase in the same. Recognizing that 40% or more of the population at risk is still not being tested, and that referral to health services needs to be generally reinforced, HIV testing strategies will be further diversified, including community based testing to increase accessibility to and uptake of HIV testing. Pilots have been initiated in select districts, such asthe district Thane under NACSP. The results from the pilots will guide further steps needed to increase testing uptake among KPs as well as implementing a 'test and treat' strategy for KP regardless of their CD4 Count.

Table 2: Coverage of Key population for HIV Testing 2013-14

		April 2013– September 2013				October 2013– March 2014			
Core Typology	Coverage	Number tested	% tested	Number found positive	% found positive	Number tested	% tested	Number found positive	% found positive
FSW	718,998	443,654	61.7	1,188	0.3	462,984	64.4	864	0.2
MSM	258,660	151,977	58.8	511	0.3	161,324	62.4	432	0.3
PWID	131,752	75,982	57.7	850	1.1	76,399	58.0	563	0.7
TG	13,200	5,782	43.8	53	0.9	6,956	52.7	51	0.7
Total	112,2610	677,395	60.3	2,602	0.4	707663	63.0	1,910	0.3

Key populations for TB: KPs who are at high risk for developing TB include those with co-morbidities such as PLHIV, diabetics, malnourished, tobacco users, contacts of TB cases, certain occupational groups such as those exposed to silica, and miners. KP groups with poor access to TB care include those who are socially marginalized, those living in congregate settings, urban slum dwellers, prisoners, elderly women, children, tribal populations/backward classes, migrants and refugees. An important key population group is individuals seeking care from the private sector, where the quality of care is variable. The spectrum of interventions to address these groups is being funded through India's domestic budget along with a World Bank credit, and is being strengthened and intensified for KPs including TB-HIV co-infected

individuals, urban slum dwellers, children, tribal populations/backward classes, and refugees through Global Fund support. It is further planned toalign with Migrant Strategy of National AIDS control program to reach migrants and cover them with TB services. Section 3.2 may be referred to for detailed strategies to cover key populations. Private sector engagement activities are important components of urban TB programme.

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

There is need to address barriers that impede access to health services such as existing legislation, human rights issues, gender inequalities, and lack of awareness.

Gender differentials: Gender inequality is reflected by program data where the male: female ratio of those diagnosed with these two diseases is approximately 1.5 - 2:1. While this may be partly due to biological factors; poor health seeking behaviour, and difficulty in accessing services especially for elderly women and stigma for younger women continue to play a major role. Issues such as lack of woman's economic independence, empowerment and autonomy also play a significant role in seeking health care services. The majority of HIVinfected women contract the disease from their spouses or partners, likely as a result of low power of negotiation for safer sex, deciding family planning options, or ignorance of partner's HIV risk behavior. Additionally, women living in low prevalence states are under–served with disproportionately low access to Prevention of Parent to Child Transmission of HIV services compared to higher prevalence states, because of unavailability of counselling and testing services at the sub-district level. However, both the TB and HIV programmes are trying to address the issue of access by decentralising to sub-district level to bring services closer to clients and making services more patient friendly.

Human Rights: Stigma and discrimination within local communities and by health care providers lead to inequitable access to care for TB and HIV. Gender norms, punitive laws and socio–cultural attitudes around morality and sexuality play an important role in defining access to services especially for high risk groups such as tribals, slum dwellers, migrants, MSM, TG, FSW and PWID.[10]Rigidity within the health system such as fixed timings for health care also acts as a deterrent to health seeking behaviour for men as well as women.

d. The health systems and community systems context in the country, including any constraints relevant to effective implementation of the national TB and HIV programs including joint areas of both programs.

India has made significant strides in addressing the requirements of HIV and TB, through NACP and RNTCP respectively, which have also come together to address cross cutting issues. Strong country ownership is reflected by the availability of sizeable domestic funding. However, additional resources are still required to leverage and sustain the gains in reach and quality of services, as well as to integrate the programs at various levels, with a clear client focus. India's request under the New Funding Model (NFM) for infrastructure improvement, deployment of better diagnostics, drugs, provision of technical and HR support, development of mechanisms for M & E, linkages between public and private sectorsand enhanced collaboration and integration of TB-HIV will strengthen health systems and community systems nationwide. Innovative approaches for Health Systems Strengthening (HSS) and Community Systems Strengthening (CSS) will strengthen efforts towards universal access to TB and HIV treatments and can significantly improve programme qualityand save lives. Both national programmes have a long and good track record of partnering with a wide variety of stake holders on all critical issues, including top-level government officials, the private sector, bilateral and multi-lateral partners, academic institutions, civil society organisations including those who represent

[10]UNAIDS. Evidence to Action, UNDOC, UNFPA & UNDP. (2013). Punitive laws hindering the HIV response in Asia and Pacific. July 2013.

affected communities, families and patients. Inclusive programming is practiced and is now part of India's response and internationally recognized for its efforts in working with community systems

Health Systems: The Central Government issues policy decisions and provides guidance and limited resources; however program implementation is a responsibility of the state governments. The states do not have uniform capacity, commitment or resources, which leads to varying levels of program implementation. Some of the key challenges faced in delivery of quality services in TB and HIV include poor health infrastructure, inadequate human resources and sub optimal logistics systems. Further, the private sector which caters to more than three fourths of India's population remains largely unorganized and unregulated. Lack of security and inadequate financing mechanisms results in significant out-of-pocket expenditure, driving patients and families into debt and poverty. These two national programs, within the ambit of the National Health Mission (NHM), have made efforts to strengthen health systems through the provision of human resources, strengthening health infrastructure, capacity building and commodity assistance. India with an investment in health of 4.5 per cent of the GDP is significantly short of the modest norm of 6.5 per cent of GDP suggested by the World Health Organization (WHO) for this category of countries. Even more distressing is the fact that the state contribution as the public health expenditure at 1.2 per cent of the Gross Domestic Product (GDP) — resulting in being amongst the lowest for any country on the globe. Only 25 per cent of the total population is covered by some form of health insurance (public or private) in India[11].

Community systems: The community engagement for HIV services has matured over the last two decades and has been successful and has been essential to overall programme delivery and effectiveness as well as improvement in the lives of the infected and affected populations. Many communities, especially of sexual minorities and sex workers, have played key advocacy roles to protect their rights through establishing networks and forums at national and state levels. The networks have developed linkages at central and local levels with relevant government agencies. Community and civil society are part of policy making and implementation of the HIV program. India's response for key populations is implemented via civil society organizations (CSOs) with an increasing amount of funding from domestic sources. Community strengthening is one of the critical activities in Targeted Interventions (TIs). The PLHIV networks, civil society, and CBOs have been actively participating in the care, support and treatment programs especially for psychosocial support, loss-to-follow-up tracking, community support group meeting, and coordinating with national programs on issue related to supply chain as well as quality of services at NACP facilities including demand generation. They are fully involved in planning, implementation and monitoring of the National Strategic Plan and are also members of various Technical Resource Groups established by NACO. However, efforts for setting up community systems are evolving within the TB program. Project Axshya, implemented by The Union and World Vision, along with the national programme, undertake initiatives like the establishment of District TB Forums, empowering of TB-affected communities, development and dissemination of TB Patient Charter and engaging community system and care-givers in TB care and control. However, both these programs are challenged in sustaining and monitoring these networks for effective public health outcomes. There is still a need to further strengthen and empower communities to demand, access, deliver and monitor services.

Some additional constraints are listed below:

- There is limited capacity both in terms of infrastructure and skilled human resources in health systems. Historically the health system had a rural focus and delivery and development of

[11] *Long overdue initiatives for the health sector – challenges for the new government _ Independent commission on development and health in India*

urban health services has been ad hoc and fragmented. The central government is now focusing on urban health through the National Urban Health Mission(NUHM).

- The vast geography, the large number of commodities used in each program, the issues pertaining to quality, and ensuring sufficient inventory without compromising on transparency and accountability in public procurement remains a challenge for both programs. The Central Government has since established an independent decision making body called Centralized Medical Supply Services (CMSS) to streamline procurement and supply chain management.
- The decentralized nature of service delivery on an ambulatory basis by frontline health workers for both programs poses special challenges in terms of early identification, documentation, and management of adverse drug reactions. Both TB and HIV programs have entered into a Memorandum of Understanding (MoU) with Pharmaco-vigilance Program of India to document, monitor and manage adverse effects at community level.
- India is well recognized as a global leader in the manufacture and supply of Quality Assured Anti-TB and ARV Drugs. However there are issues related to domestic procurement of drugs, which are now being addressed by strengthening the Central and State level Drug Regulatory Authorities and engagement with manufacturers to align and comply with the International drug quality standards.
- Elimination of TB and HIV will not be possible without addressing other determinants of health, and interventions have to extend beyond the health sector, such as provision of safe and well ventilated housing, control of environmental pollution, improving nutritional status of the general population, life style modification to increase healthy behavior, work place interventions, introduction of protective legislation etc. This calls for cohesive response across various ministries and stakeholders. Both the TB and HIV programs have engaged with various Ministries such as Labor, Consumer Affairs, Public Distribution System, Telecommunication, Education, Social Justice, Rural Development, Defence, Women and Child among others. This coordination needs to be strengthened and sustained.

Both National Programs identified co–infections as a challenge to deal with and rolled out services for TB-HIV co–infected patients in 2000. These efforts were gradually scaled up to cover the entire country by 2012 and intensified TB-HIV mechanisms are now in place. However, only two thirds of TB patients know their HIV status, and there is still sub–optimal identification and referral of TB suspects among PLHIV. While Isoniazid Preventive Therapy (IPT) is a national policy, it remains to be implemented at scale. For early diagnosis of TB and MDR TB amongst PLHIV, CBNAAT has been recommended as a front line diagnostic test with plans for nationwide scale-up. The daily treatment of TB for PLHIV is being rolled out in HIV congregate settings. Lessons from these initiatives will shape the future response to this co–epidemic.

1.2 National Disease Strategic Plans

With clear references to the **current** TB and HIV national disease strategic plan(s) and supporting documentation (including the name of the annexed documents and specific page reference), briefly summarize:

a. The key goals, objectives and priority program areas under each of the TB and HIV programs including those that address joint areas.

b. Implementation to date, including the main outcomes and impact achieved under the HIV and TB programs. In your response, also include the current implementation of TB/HIV collaborative activities under the national programs.

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

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

e. Country processes for reviewing and revising the national disease strategic plan(s). Explain the process and timeline for the development of a new plan and describe how key populations will be meaningfully engaged.

a. The key goals, objectives and priority program areas under each of the TB and HIV programs including those that address joint areas.

HIV

The National AIDS Control Programme of India is currently in its fourth phase (2012-2017). The guiding principle of the NACP-IV continues to be emphasis on three ones- one Agreed Action Framework, one National HIV/AIDS Coordinating Authority and one agreed Monitoring and Evaluation system. The other principles followed are equity, gender, respecting rights for PLHIV, Civil Society Organization (CSO) representation and participation, improved public-private partnerships, along with evidence-based and results oriented program implementation.(For details refer to NSP of NACP IV at Annexure 1)

Goal: Accelerate reversal of HIV infection and integrate programme response.[12]

Objectives: The main objectives are: (1) Reduce new infections by 50% of 2007(Baseline NACP III),and (2) Provide comprehensive care andsupport to all PLHIV and treatment services for all those who require it.

Key Strategies:(1) intensifying and consolidating prevention services with a focus on High Risk Groups (HRG) and vulnerable populations (2) expanding IEC services for (a) general population and (b) high risk groups with a focus on behavior change and demand generation (3) increasing access and promoting comprehensive care, support and treatment (CST) (4) building capacities at National, State and district levels and (5) strengthening and use of Strategic Information Management Systems.

Priority programme areas: preventing new infections, PPTCT, outreach and behavior change for KP, capacity building, comprehensive CST, decentralizing services, strategic use of information for program planning. Cross-cutting areas of focus are quality innovation, technical support, and integration, leveraging partnerships, stigma and discrimination.[13]

The priority areas identified under the programme are supported by resources from domestic budget, the World Bank credit , other donors and development partners and few activities areas are being further strengthened by resources from Global Fund through this NFM proposal. The current proposal specifically aims at strengthened focus on increasing access and promoting comprehensive care, support and treatment, capacity building, strengthening HIV-TB collaborative activities and strengthening systems for linkages, quality care at service delivery points and strengthening monitoring and evaluation of services and community systems strengthening.

Tuberculosis

The Revised National Tuberculosis Control Program (RNTCP) has entered into an ambitious National Strategic Plan (NSP) 2012-17 as part of the country's 12th Five year plan. The theme of the NSP 2012-17 is "Universal Access for quality diagnosis and treatment for all TB patients in the community" with a target of "reaching the unreached". The NSP is backed by Government of India's (GoI) commitment for substantial increase in the investment for TB control, with a three-fold increase in budgetary allocation. (For details refer to NSP of RNTCP at Annexure 2)

Goal: The goal of RNTCP is Universal Access to quality TB Care for all TB patients in the community.

Objectives: Specific objectives include: (1) To reduce the incidence and mortality due to TB, (2) To prevent further emergence of drug resistance and effectively manage drug resistant TB, (3) To improve outcomes among HIV-infected TB patients, (4) To involve private sector on a scale commensurate with their dominant presence in health care services, and (5) To further

[12] NACO & DAC. (n.d.). *National AIDS Control Programme Phase-IV (2012-2017)*, Page 3. Retrieved from http://www.naco.gov.in/upload/NACP - IV/NACP-IV Strategy Document .pdf

[13]NACO, & DAC. (2014). *Annual Report 2013-2014.* Retrieved from http://www.naco.gov.in/upload/Publication/Annual Report/Annual report 2012-13_English.pdf

decentralize and align basic RNTCP management units with National Health Mission (NHM) block level units within the general health system for effective supervision and monitoring.

Priority program areas are strengtheningand improving quality of basic DOTS services, further strengthening and aligning health systems under the umbrella of National Health Mission, deployment of improved diagnostics at field level, expanding early diagnosis and treatment for TB, drug resistant TB and TB-HIV, expanding efforts to engage all care providers, strengthening urban TB control, addressing key at risk populations, improving communication, outreach, and social mobilization, and promoting research for development and implementation of new tools and strategies.

The priority areas identified under the programme are supported by resources from domestic budget, a World Bank credit, while a few activity areas is being further strengthened by resources from Global Fund through this NFM proposal. The current proposal specifically strengthens focus towards improving access to early diagnosis and treatment of TB and Drug Resistant Tuberculosis (DRTB) services, improving access and outcomes among HIV-infected TB patients, improving access and outcome amongst at risk population (social and clinical: urban, tribal, pediatric, migrant and refugee), engaging with providers outside RNTCP for public health impact for TB control, and generating evidence for guiding future policy for better TB care and control.

Joint TB/HIV National Framework

Existing TB/HIV Collaborative activities consist of the strong RNTCP-NACP coordination mechanisms at national, state and district level with joint: Monitoring and evaluation (M&E), training of field staff, operational research, and implementation of basic infection control measures.

Goal: The goal of TB-HIV collaboration is to prevent TB among HIV infected individuals and to reduce the impact of HIV co-infection among HIV-positive TB patients.

Objectives: The specific objectives of TB-HIV collaboration are early diagnosis of TB among PLHIV through intensified case finding at high HIV congregate settings, prevention of airborne TB infection within these centers, decentralization of HIV diagnosis through RNTCP network of designated microscopy centers (DMCs), prevention of development of TB among PLHIV, improving access to ART, Cotrimoxizole Preventive Therapy (CPT) and Anti-TB drugs and improving outcomes among co-infected patients with better treatment adherence strategies. To ensure adherence for both TB and HIV treatment, there needs to be social and economic support mechanisms in place.

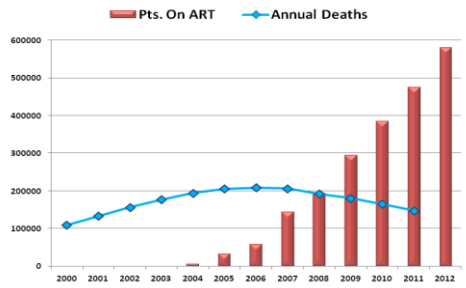
Priority program areas are early and improved diagnosis of TB and rifampicin resistance through deployment of rapid diagnostics, establishing F-ICTC at all RNTCP DMCs for expanding HIV diagnosis, HIV testing among chest symptomatics in high HIV settings, strengthening collaborative mechanism, scale up of IPT implementation, expanding access to care, capacity building and operational research.

b. Implementation to date including main outcomes and impact achieved

HIV

In order to control the spread of HIV/AIDS, the Government of India is implementing the National AIDS Control Programme (NACP) as a 100% centrally sponsored scheme. The first National AIDS Control Programme was launched in 1992, followed by NACP-II in 1999. Phase III of NACP, (2007-2012) launched in July 2007, had the goal to halt and reverse the epidemic in the country by scaling up prevention efforts among High Risk Groups (HRG) and general population, and integrating them with Care, Support and Treatment services. Consolidating the gains made during NACP-III, the NACP-IV(2012-17) was launched to accelerate the process of reversal and to further strengthen the epidemic response in India through a planned and well defined integration process over the period 2012-2017 .

Implementation to date: A total of 16283 ICTCs are functional across the country. During 2013-14, 13.4 millionpeople received counseling and testing services at these sites. Efforts are underway to include testing in all TB sites as well as some community level organizations.Similarly coverage of key populations (FSWs, MSM and IDU) against estimates was 80%, 68% and 75% respectively[14]is planned to be increased. There are 1436 functional ART centres /Link ART centres across the country wherein currently 0.8 million PLHIV are receiving free first line and 10223 PLHIV are receiving second line drugs.Trends show that with decentralization, the proportion of women and children accessing ART is increasing. Nearly 67% of PLHIV receive ART against the estimated needs (based on CD4 cut off of 350). This is being addressed through better access to HIV testing facilities and bridging the gap in linkages of those found positive with ART centers. Global Fund grants have made a significant contribution by supplementing the efforts of the national programme by supporting the scale up and strengthening of prevention, testing, care support and treatment services and have resulted in high impact. The programme is laying considerable emphasis on regular analysis of data pertaining to the retention cascade, with clear strategies to plug the losses at different stages of the cascade and this is monitoring at facility, district, state and national levels. The National AIDS Control Organisation has adopted "Option B +" and initiated lifelong ART (using the triple drug regimen) for all pregnant and breastfeeding women living with HIV, regardless of CD4 count or WHO clinical stage or duration of pregnancy. A total number of 9.752 millionpregnant women were tested for HIV during 2013-2014, of which 12,008 pregnant women were found to be HIV positive, out of which 10,085 (84%) Mother-Baby (MB) pairs were provided ARV for prevention of mother-to-child transmission of HIV.



*Outcome/Impact:*Wider access to ART has led to a 29% reduction in estimated annual AIDS-related deaths between 2007 and 2011 (Fig 5). It is estimated that the scale-up of free ART since 2004 has saved over 150,000 lives (2011).The current pace of scale-up of ART services is estimated to avert an additional 50,000 – 60,000 deaths annually in the next five years. India has demonstrated an overall reduction of 57% in estimated annual new HIV infections (among adult population) from 274,000 in 2000 to 116,000 in 2011(Fig 6), reflecting the impact NACP's scaled-up prevention interventions.

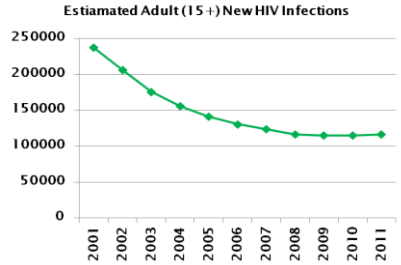


Fig**6: 57% Reduction in New Infections (2000-**

eaths due to HIV

[14]NACO& DAC. (2014). Annual Report 2013-2014. Retrieved from http://www.naco.gov.in/upload/Publication/Annual Report/Annual report 2012-13_English.pdf.

TB

Implementation to date: TB was declared as a global health emergency in 1993. In the same year, India established the RNTCP as a small pilot project. This project was scaled up nationwide from 1997 to 2006. In its second phase (2006-11), RNTCPsought to improve the quality and reach of services, and reach global case detection and cure targets. These targets were achieved by 2007-08.For quality diagnosis and treatment 13000 DMCs and 650000 DOT centres have been established in the country. Uninterrupted supply of quality assured drugs is ensured by timely procurement, a robust supply chain management system and issuing drugs in patient-wise boxes ear marked to each patient. Programmatic Management of Drug resistant TB services were initiated in the States of Gujarat and Maharashtra in 2007 by March 2013 the entire country was covered for services of PMDT. Sixty-two C/DST laboratories, 119 CBNAAT and 122 DR TB centres and 50 link DR TB centres have been established till date to support and implement PMDT

Outcome/Impact: RNTCP has evaluated over 70 million persons for TB and treated more than 17 million TB patients, saving 3 million lives. On an average 1.5 million cases are put on treatment annually. Treatment success rate of 88% has been achieved among NSP for the year 2013. About 3.8 million presumptive Drug Resistant TB cases were screened at around 50 certified C&DST labs across the country and more than 47,000 MDRTB and about 700 XDRTB cases were treated through 111 DRTB centres.

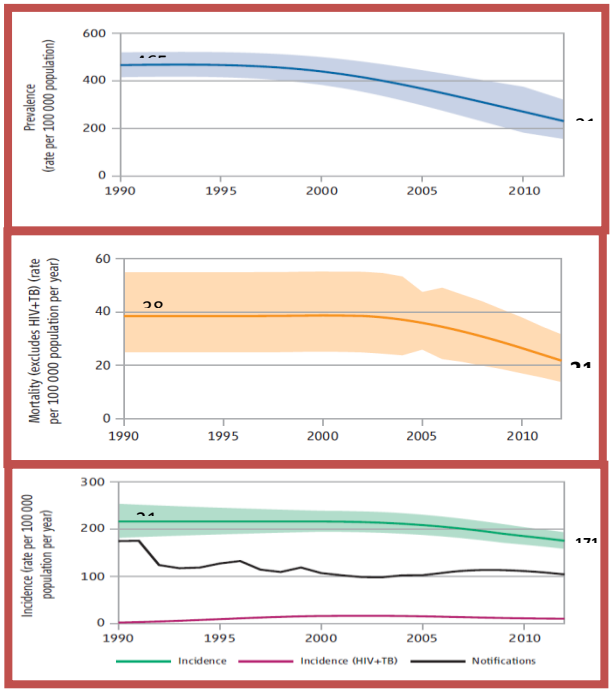


Figure 7: Estimated TB Incidence, Prevalence *and Mortality. India 1990-2013*

India is well on its way to achieve all TB related MDGs (Figure 7)[15]. Global Fund has been supporting the RNTCP for last one decade in critical areas such as TB care and treatment, laboratory scale up, and PMDT scale up, and has substantially contributed to reducing TB prevalence, incidence and mortality. There is compelling evidence that the tide has turned for TB. The burden of TB has begun to fall, and there are now fewer TB-related deaths each year than the year before.

TB/HIV

The RNTCP and NACP have significantly expanded joint TB/HIV services to all states in India. The main interventions have been to reduce TB among all PLHIV and to have PLHIV regularly screened for TB including all TB cases counseled and tested for HIV.

*Implementation to date:*TB-HIV activity coordination started relatively early in India in 2001, in the high HIV burden states. The early activities were primarily joint training of health staff in TB-HIV and cross-referrals. Expansion of these activities was then extended to eight additional states. In 2007, the first National Framework for Joint TB-HIV Collaborative Activities was developed which endorsed a differential strategy reflective of the heterogeneity of the TB-HIV epidemic. A package of essential TB-HIV interventions was implemented in all states. Concurrently an "Intensified TB-HIV package of services", was implemented in states with high TB burden. In 2009, it was decided to implement the full spectrum of "Intensified TB-HIV activities" nationwide and the entire country was covered with this intensified package by 2012. This expansion was

[15]WHO (2014) *Global Tuberculosis Report 2014*, Geneva

accompanied by strengthening of joint monitoring and evaluation, with specified national TB-HIV programme indicators and performance targets. Currently a strong coordination mechanism exists for TB-HIV with provider initiated HIV counseling and testing (PITC) and this is accessible to all presumptive TB cases. All PLHIV have access to Anti-Retroviral Therapy (ART) and co-trimoxazole preventive therapy (CPT). Isoniazid preventive therapy (IPT) is a national policy for all PLHIV who do not have active TB (estimated at 50% of those newly enrolled in HIV care).

Outcome/Impact: TB-HIV coordination is incrementally improving. As per Global TB report 2014, 63% of TB patients know their HIV status, and 95% of HIV positive TB patients receive CPT, and 88% receive ART. As shown in table3 below HIV –TB collaborative activities are reaping results and India is performing relatively well on HIV-TB indicators when compared to global averages However, TB-related outcomes have remained poor among PLHIVs with treatment success rate of less than 80%.

Table 3: Comparisonof HIV testing for TB patients and treatment for HIV-positive TB patients Global average with India

Country/ Region	% of Notified TB Patients with known HIV status	% of TB Patients with an HIV Test result Who were HIV-positive	% of Notified HIV-positive TB patients Started on CPT	% of Notified HIV positive TB Patients Started on ART
Global	48	18	85	70
India	63	5	95	88

c. Limitations and lessons learned

HIV

As of the last round of HSS, efforts are largely on track to meet the HIV related Millennium Development Goal (MDG). In NACP-III, the programme focused more on saturating coverage. Now NACP-IV needs to advance towards focusing on ensuring higher quality of services under interventions while sustaining the coverage. The data and programme review suggests the following challenges and limitations:

Emergence of the epidemic among certain key populations amid issues of access by key populations: The coverage of key populations (FSWs, MSM and PWID) against estimatedsizes of these population was 80%, 68% and 75% respectively. However, data shows emerging epidemics among Transgender and PWID. There is therefore need to focus on the KP's with innovative prevention strategies to reduce the transmission risks. Furthermore, the access of KP remains limited to HIV testing, diagnosis treatment and care for HIV. There are also gaps in specific data regarding retention and adherence. This is being covered under the national programme with domestic and World Bank funding.

Emerging Epidemics in certain low prevalence states and districts: Regions with different maturity levels of the epidemic require differentialstrategic emphasis, resources and services. Rising HIV trends in some States in North and Eastern India, especially due to migration, drug use and limited access to services is a concern. In addition, there is lack of strong public health systems and human resources in these States with an emerging HIV epidemic. This has necessitated the need for a greater focus on prevention as well as need for scale up of services to improve accessand serve the underserved.

Limitation pertaining to Universal Access to Treatment: Presently 67%of PLHIV receive ART against the estimated need (based on CD4 cut off of 350). This calls for better access to testing treatment services. Further WHO 2013 guidelines recommends for early ART initiation. Expanded eligibility for ART will provide new opportunities to save lives, improve clinical outcomes, act as prevention tool by reducing transmission risks and therefore lead to decreased HIV incidence. New recommendation will have implications for laboratory services, supply

systems for ARV drugs and other commodities, service delivery systems and available financial resources. NACO has in principle agreed to these recommendations but issues related to finance and logistics need to be worked out before implementing these recommendations in the programme

Low coverage of PPTCT programme: Against the 38,000 estimated positive pregnancies each year, the programme is able detect only 40%. Poor knowledge and health seeking behavior, lack of involvement of spouses and family members, and inadequate access to PPTCT services closer to their residence have led to poor coverage of PPTCT services. Furthermore there are linkage losses at every stage of retention cascade from detection to care of the exposed infant. There is need to strengthen coordination with RMNCH and also with private sector facilities which caters for nearly 4.25 million deliveries annually. Based on discussions with the RCH programme, mechanisms are now being established to substantially upscale HIV testing for pregnant women and detect all HIV positive women for timely intervention

Limitation pertaining to early linkage to testing and treatment: There are still delays in linking to testing and treatment due to low level of awareness and poor referrals from the general health system. There is also poor engagement with HCP both in public health system and the private sector on early suspicion and referral for HIV testing. Around 20% of PLHIV reaching ART centres have CD4 count less than 100.

Limitation pertaining to scale of CD4 testing facilities: Presently only 276 CD4 machines are available for 456 ART centres. In order to scale up treatment services in new emerging pockets, and to saturate all re-categorized A, B & C districts with ART services, will require additional CD4 machines at the sub-district level and in districts with new emerging epidemics. CD4 testing facility (particularly point of care equipment) should be deployed up to the Link ART Centres (LAC).

Delayed detection of treatment Failure and low uptake of Second Line ART: The ART programme in India is more than a decade old but second line uptake is low. The programme has adopted for targeted viral load testing only for individuals with suspected immunological failure. Immunological failure is often detected very late, leading to continuation on failing regimen, accumulation of mutations and compromised future options. Presently the program has only 9 viral load testing labs which is a huge limitation.

Strengthening retention in care:NACP- IV needs to advance towards focusing on ensuring higher quality of services under interventions while sustaining the coverage. Early diagnosis and timely treatment, retention in care continuum, early initiation and bridging the gaps in leaky retention cascade continue to pose challenges for the programme. There is need to strengthen supportive supervision mechanisms and capacity of staff on quality care and strengthen outreach activities through (CSCs)

Need to strengthen Supply ChainManagement: Supply chain management of commodities such as test kits and ARV drugs, require trained manpower, infrastructure, hardware and a robust IT-based system to monitor movement of drugs from suppliers to consumers. The program needs to improve in all these areas to strengthen supply chain management and prevent stock outs.

Stigma, discrimination and community strengthening and ensuring social protection schemes for people infected and affected with HIV/AIDS through mainstreaming of HIV/AIDS with other ministries: Stigma and Discrimination still prevails against vulnerable populations, as well as persons and families infected and affected with HIV, especially at the work place, in healthcare settings, educational institutions, and society at large.

Involvement of Health system: Larger integration of NACP within general health system of country is needed to ensure sustainability. There is need to address the challenge of competing priorities and varying capacities of health systems in different states to provide access to quality HIV/AIDS prevention, care and treatment services**.** Recently the Department of AIDS Control was merged within the Ministry of Health and Family Welfare (MoHFW). NRHM has created programme management structures at the block, district and state levels. Hence, opportunities exist to strengthen the involvement of the programme within the general health system in order to utilize management structures developed by NRHM to handle administrative and fiduciary functions.

Implementation Challenges: There are several challenges related to implementation due to limited resources both human and financial despite having policies in place .Early linkage to testing, care and treatment and a leaky retention cascade remains a challenge.

Health Information and M&E: The Monitoring and Evaluation tools at ART centres are both paper based and electronic (PLHA software). However there are challenges in regard to generation of output reports from the present software. NACO has initiated the process to integrate this into the overall Strategic Information Management System (SIMS). It is felt that strengthening patient recording and reporting system at ART centres , minimizing duplication, and having a robust monitoring mechanism for ART centres is required in order to provide good quality services. An effective IT-based case reporting and patient tracking system linked with biometrics as well as with the Unique Identification system of the Government of India (UIDAI), will help in systematizing patient tracking, regularity of treatment during travels, improved forecasting of essential commodities under NACP, and strengthen supply chain management.

TB programme:

RNTCP has been hailed as one of the most successful public health programme in the country and has been consistently achieving global benchmarks of New Smear Positive (NSP) case detection and treatment success for the last several years. It is also on track to meet all TB related MDGs. However despite these successes the data and programme review suggests the following challenges and limitations:

Public services not perceived as patient friendly: About half to three fourths of patients first report to a private provider for relief of TB symptoms. The timings of health centres, the location and distance of public sector health facilities, long waiting times, behaviour of the health staff etc. are some of the barriers which need to be addressed to render these services more attractive to patients.

Limitations pertaining to treatment: Directly Observed Treatment Short-course (DOTS) can drive patients to the private sector because they think DOTs is an invasion of privacy, inconvenient, and increases out-of-pocket costs borne by the patient. There is need for aligning the clinic timing, place and observation site to patients' convenience, and making the process more respectful and flexible. Both provider and patient incentives need to be re-visited to improve patient adherence on DOTS.

Health system involvement: The integration between the health systems and the programme has been achieved in the provision of services. However it is limited in other operational areas such as administration, financial management and monitoring and supervision. This has affected the quality of implementation because of the multiple administrative, financial and operational functions to be carried out by field level staff. Also numerous staff vacancies within the health system render it extremely weak. NRHM has created programme management structures at the block, district and state levels. Hence, opportunities exist to strengthen the involvement of the programme with the health systems in order to utilize management structures developed by

NRHM to handle administrative and fiduciary functions. There is also an opportunity to further decentralize field units to make them co-terminus with the block level structures of NRHM. Further, the health system leadership at the different levels can be divested the regular supervisory role of programme implementation as in the case of other diseases.

Ineffective and delayed diagnosis*:*Around half of all patients with TB seek care in the private sector, and private healthcare providers are often the first point of care even for patients who are eventually treated in the public sector.[16]Studies reveal average patient delays in seeking care of 66 days and visit at least 3 providers before they are correctly diagnosed. Diagnosis still relies on smear microscopy, which misses many TB patients. Those TB patients with negative results often drop out before clinical diagnosis and may still be infectious.

Gaps in capacity in diagnosing and treating all incident cases of MDR TB: Though the PMDT services have been scaled up to cover the entire country, there still exists a gap between availability of diagnostic services and those eligible to receive those services. Laboratory capacity needs to be strengthened, particularly for drug susceptibility testing (DST) for second-line drugs at MDR TB diagnosis, and follow-up cultures for treatment monitoring to achieve universal access to DST guided treatment. Further, treatment outcomes remain sub-optimal (~50%) with high loss to follow up rates. The systems for treatment support need to be strengthened for optimal treatment adherence and favourable treatment outcomes.

Large unregulated private sector: The private sector is the first point of contact for health services for the majority of the population in India. This is common for both urban and rural areas. Further undiagnosed and mistreated cases continue to drive the epidemic such that TB remains an enormous public health problem. Despite increasing attention to improving the quality and access to diagnosis in the public sector, case detection trends have plateaued during the past few years. There are still an estimated 1 million cases going unreported annually. This underscores the need for strengthening engagement with the private sector, use of new technologies, and improving strategies for early diagnosis and treatment. The main limiting factor is poor understanding of the dynamics of patients' behaviour and private providers. The differential treatment practices across public and private sectors also contribute to this gap. Universal access will not be achieved without private sector involvement.

Managing TB in urban areas: In rural areas, the RNTCP has been able to develop a structure for programme implementation because of the established rural health infrastructure under the general health system. In urban areas, however, there is no established health structure. National Urban Health Mission which was rolled out in 2014 is still in its early stages. Until the urban health infrastructure develops, the programme needs to establish its own structure and also forge effective partnerships with the private sector to make quality-assured services available. Strategies to track patients put on treatment (especially migrant urban slum dwellers) need to be evolved.

ACSM: Advocacy, Communication, and Social Mobilization (ACSM) activities have not been positioned as creating demand for TB services. Also, it has not strategically developed to bring about desired behaviour change in order to increase uptake of services and adherence to treatment to improve success rates. This function needs to be strategically positioned within the RNTCP as an enabler to creating a supportive environment for the achievement of programme objectives.

Access issues for key populations: Marginalized and vulnerable individuals within the society are at higher risk of developing TB. Over the years, control efforts have focussed on biomedical interventions; however, there exists certain socioeconomic and cultural barriers that

[16]Hazarika, I. Role of private sector in providing tuberculosis care: evidence from a population-based survey in India. *J Glob Infect Dis*. 2011; **3**: 19–24

prevent the full utilization of diagnostic and treatment services available. Strategies need to be developed to improve access and outcomes among key and at risk populations**.**

Limitations related to Paediatric TB*:* Diagnosis and management of childhood TB offers challenges including obtaining specific biological specimen, non-availability of child friendly formulations, pill burden and supervision of treatment. Further limited ability of the mother in recognizing symptoms early and seeking help due to dependence on others for mobility creates additional challenges in accessing care. Programme needs to strengthen service delivery component for this key population group.

Implementation Challenges: There are several challenges related to implementation due to limited resources both human and financial despite policies being in place. Tracing contacts of infectious TB patients, screening them and offering preventive therapy to those who need it, is sub-optimal and needs strengthening.

TB/HIV

Inequitable distribution of infrastructure in TB-HIV services: The TB-HIV infrastructure both physical and human resources is well developed in high HIV burden states and weak in other parts of the country. This has led to poor programme performance in many low HIV burden states. There is a need for strengthening services across all states as a rising trend of new HIV infection is now being observed in hitherto low HIV prevalence states.

Poor outcomes in co-infected patients: Mortality still remains high in these patients. There are delays in diagnosis of HIV, TB and TB-HIV resulting in compromised treatment outcomes. The programme is now rolling out rapid diagnostic tools and strategies, daily anti-TB regimen to improve outcomes. These new initiatives need to be closely monitored, evaluated and scaled up based upon evidence for public health impact.

Poor Airborne Infection Control Practices: Poor ventilation and infection control has been observed in most HIV care settings possibly resulting in increased TB transmission rates. Airborne infection control measures may need structural changes in existing infrastructure and are resource intensive and have been accorded a low priority by the general health system. These need to be strengthened.

Lessons Learnt:

DOTS: DOTS has been an extremely successful strategy and needs to be taken forward in the next phase of the programme. The quality of provision of DOTS needs to be addressed through patient support mechanisms.

Availability of diagnostics: The availability of sputum microscopy has been adequately increased. The arrangements for transportation of sputum from suspects need to be strengthened in order to increase case finding. Newer rapid molecular diagnostics need to be scaled up for early diagnosis; addressing certain key at risk populations and moving towards DST guided treatment.

Structure set up: The structure for implementation of the programme has been established right from the field level upwards. The reduction in population norms for effective supervision needs to be rapidly scale up for effective implementation.

Well defined information system: The information system is well established and the reporting units provide information within specified time periods. The programme has rolled out real time web based system and all reporting now need to be real time at all levels. There remains a need to strengthen this system and use information for real time feedback, monitoring and follow up.

Availability of guidelines and protocols: The programme has developed guidelines and protocols for every aspect and the providers are trained on these guidelines. This has standardized service provision across the programme and facilitates maintenance of quality. The recently developed "Standards of TB Care in India" which are uniform for both public and private sector need wider dissemination.

Review mechanisms: Marginalized and vulnerable individuals within the society are at higher risk of developing TB. Over the years, control efforts have focussed on biomedical interventions; however, there exists certain socioeconomic and cultural barriers that prevent the full utilization of diagnostic and treatment services available. Strategies need to be developed to improve access and outcomes among key at risk populations.

Technical Committees: The programme technical committees (Diagnosis and Treatment, Operations Research, PPM, ACSM etc) as well as task forces at the zonal levels have been very useful. These bodies are functioning well and facilitating programme implementation. A high level oversight committee/governing board which can steer intensification of activities to make an impact in next five years need to be put in place.

MDR-TB: The programme has focussed on MDR-TB and it has developed protocols for treatment. is the programme is also in the process of developing laboratory capacity for strengthening this component. Structural arrangements for early diagnosis and treatment of MDR-TB patients have been put in place. The programme however needs to address issues around management of drug-resistance other than MDR-TB.

Trained human resources: The programme has been able to develop a pool of well-trained service providers at all levels, and efforts to retain and maintain this level of training needs to be included in the programme. There is need to develop a long-term human resource development plan to address issues of sustainability of the programme**.**

TB and HIV activities are increasingly coordinated: At National level, a National Technical Working Group (NTWG) is in place, comprised of key officials from NACP and CTD dealing with TB-HIV collaborative activities and experts from WHO. At the state level and district level, State Coordination Committees (SCC)/District Coordination Committees (DCC) are in place to ensure smooth implementation and regular review of TB-HIV collaborative activities. Challenges to implementation remain and require strengthening.

d. Areas of linkage with the national health strategy

HIV Program

Since 1997, HIV Counselling and testing services for HIV infection, PPTCT, STI Clinics, ART centres, and blood banks have been placed in healthcare facilities, at stand-alone sites and in the community at various levels of the public health system in India (including State, District, Sub-district and village/community levels). However, this infrastructure is not uniform across low and high HIV prevalence settings. NHM and NACO coordinate planning and implementation of activities and provide the requisite infrastructure, manpower, equipment and service delivery components. These elements are also an integral part of services provided at all government health facilities including PHC/CHC. At each of these health facilities, a standardised service delivery protocol is followed. Free counselling, testing, and drugs are provided to the patients, medical and paramedical staff are trained, and monthly reports are submitted from these facilities in the existing Health Management Information System (HMIS). Laboratory services are not confined to HIV testing, but are overarching and have an impact on other interventions included under prevention, care, support and treatment, STI management, blood safety, procurement and supply chain management. Convergence has been strengthened at the national level through constitution of a joint working group and development of a national operational

framework for service delivery at health facilities. National operational guidelines and training modules for medical officers and paramedical staff have been developed and disseminated as per the standardised curriculum. During the later phase of NACP-III, the PPTCT program expanded services in collaboration with the National Rural Health Mission (NRHM) and piloted provider-initiated testing and counselling services in Primary Health Care (PHCs) centres of Category A and B districts through the facility-integrated ICTC model. The program also piloted sub-centre level HIV screening through front line health workers in high prevalence districts.

TB Program

RNTCP falls under the purview of National Health Mission (NHM), and is embedded in the General Health System. District program management is integrated completely with district health management units for MIS, M&E and fund flow. The most peripheral health institutions (PHI)under in the general health system, caters to approximately 20,000-30,000 population, are provided with referral linkages, specimen containers, recording and reporting materials, drugs, training to the medics and paramedics including their community link workers. Designated microscopy centres for diagnosis of TB are established in one of these institutions, where the adjacent 2 to 3 facilities are linked to ensure coverage of DMC for 50,000 to 100,000 populations. For management of MDRTB/XDRTB cases the DMCs act as the points for collection of sputum samples and transportation for diagnosis at DST laboratory and PHIs act as the treatment administration centres, thus bringing DRTB services to patients' premises. At the health block level, which caters approximately to 200,000 to 250,000 population, a TB unit is established, which serves as the most peripheral program management unit of RNTCP. It additionally provides opportunity for inter-program collaboration as it is the most peripheral program management unit for all disease control program including non-communicable diseases including HIV/ AIDS through integrated planning.

a. Country processes for reviewing and revising the national disease strategic plan(s)

HIV Program

The strategy and plan for NACP-IV (2012-2017) was developed through an elaborate and extensive process. The process has adopted an inclusive, participatory and widely consultative approach with 15 Working Groups and 30 sub-groups covering all thematic areas involving around 650 representatives from central and state governments, representatives of key population communities, people living with HIV/AIDS, civil society, subject experts, experts from NRHM and other government departments, development partners and other stakeholders. Regional and state level consultations, e-consultations and special studies/ assessments were also undertaken to develop the strategic plan. Evidence generated from operational research and program data form basis for mid-term revision of NACP strategy. Further, NACO has Technical Resource Groups for various thematic areas which deliberate on latest global and national evidence and guidelines for updating in program policy. Community and civil society are part of all TRGs at NACO.

TB Program

The process of development of NSP for RNTCP involves a consultative process through formation of working groups along the different thematic areas to be covered in the NSP-RNTCP. Each working group is provided with background materials to facilitate discussions. There were eleven working groups for development of NSP 2012-17 and each of the groups met for about 4-5 times during the period May2011-July 2011 and finalized their recommendations.

The background material to facilitate discussions is drawn from monitoring and reviewing the operational processes of current plan. The first level of review is through MIS, initiated monthly at the most peripheral institution and validated by the program supervisors. The TB units submit

quarterly reports on case finding, case holding, and infrastructure, resources and program management. Composite indicators are developed to monitor input, through put and output of program at TB Unit, district and state levels. Districts and states are monitored at national level through quarterly reports, with the same composite indicators. Presently, the program is fast migrating into real time monitoring through intelligent deployment of information, communication and technology (ICT).Based on the information through these processes of supervision, monitoring, evaluation, specific intervention visits, periodic reviews, special reviews, analysis of MIS, and gaps are identified in focus areas.

A consultative process is initiated with 100-150 national experts and state/district program managers with representation from all stakeholders including civil society. The NSP working group drafts the new strategic plan, which passes through the process review by the Core Group. The Core Group reviews the recommendations of the working groups from the point of view of feasibility, cost as well as the suitability in the overall framework of programme priorities. Based on the decisions of the Core Group, the individual sections of the draft NSP-RNTCP are prepared. A panel of external experts then reviews the drafts in order to synchronize the NSP-RNTCP with the developments of TB Control in other parts of the world. The members of the ministry also review the drafts NSP and then approve it with changes if required. Once approved, it enters the next cycle of review and revision from the most peripheral program implementation unit to national program management unit. A key feature of the development process is the extensive consultation with diverse stakeholders and time devoted to strategic thinking on critical issues.

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

In order to understand the **future** plans for joint TB and HIV planning and programming, briefly describe:

a. Plans for further alignment of the TB and HIV strategies, policies and interventions at different levels of the health systems and community systems. This should include a description of i) steps for the improvement of coverage and quality of services, ii) opportunities for joint implementation of cross-cutting activities, and iii) expected efficiencies that will result from this joint implementation.

b. The barriers that need to be addressed in this alignment process.

a. Plans for further alignment of TB and HIV strategies, policies and interventions at different levels of the health systems and community systems.

TB HIV collaborative activities - Governance and Program Management

Both national programmes have made significant progress regarding TB and HIV joint planning and programming. The Joint National TB/HIV Policy Framework (Annexure 3),revised in 2013, aims at strengthening coordination between RNTCP and NACP at national, state and district levels. This mechanism seeks to ensure reduction in morbidity and mortality due to HIV/TB, decrease burden and impact of TB in HIV patients and reduce the risk of HIV in TB patients. The RNTCP and NACP have significantly expanded joint TB/HIV services to all states in India to ensure early detection and treatment of HIV-TB along with TB prevention. The main interventions have been to reduce burden of TB among all PLHIV by implementing 3Is (ICF, Infection control, and IPT) in HIV settings and to reduce the burden of HIV in patients with presumptive and diagnosed TB, their families and communities, by providing HIV prevention, diagnosis and treatment. Provider-initiated HIV counselling and testing (PITC) is accessible to all presumptive TB cases. All PLHIV have access to Anti-Retroviral Therapy (ART) and co-trimoxazole preventive therapy (CPT). Isoniazid preventive therapy (IPT) is a national policy for all PLHIV who do not have active TB.

At National level, the National TB-HIV Coordination Committee (NTCC) is headed by the administrative heads from both programmes. The National Technical Working Group (TWG) comprised of key officials from NACO, CTD and other stakeholders, helps in identifying bottlenecks in policy, program design and service delivery, explore solutions to address the

bottlenecks and holds oversight responsibility to the joint implementation of activities.[17]Similarly at the State and District levels, State level Coordination Committees, State Technical Working Group and District level Coordination Committees are in place to ensure smooth implementation and regular review of TB-HIV Collaborative activities.[18] This Coordination is facilitated by appropriate Human Resources: TB-HIV collaboration is a part of the RNTCP and NACP and hence, all staff involved in the programme are involved in TB-HIV activities as well. In addition, a few dedicated staff are assigned for improved supervision and monitoring.

A joint monitoring of TB-HIV interventions is already in place wherein officials from both programmes jointly review field level implementation and take appropriate corrective measures. This joint review is being further strengthened through joint regional reviews and experience-sharing by implementing officials, partners and technical agencies. These regional reviews also create opportunities for cross learning among implementing states.

Steps identified for the improvement of coverage and quality of services

i. **Establish and strengthen the mechanisms of collaboration and joint management** between HIV programs and TB-control programs for delivering integrated TB and HIV services preferably at the same place and time;

a) State Technical Working Group and Coordination committees in all Districts will be strengthened by designating Nodal Persons for TB HIV co-ordination from both RNTCP and the HIV/AIDS program at State and District levels, and strengthening joint review and monitoring of TB HIV collaborative activities at State and District levels by Program Managers of RNTCP and HIV/AIDS.

b) This coordination mechanism is proposed to be further strengthened by an innovative approach "Go→Connect HIV TB". This approach will focus on utilization of these new proposed posts of supervisors under NFM for strengthening these linkages, through a weekly review of all new PLHIV enrolled in ART centres. Another approach to prevent linkage loss would be putting up different coloured dots on the white card of patients at ART centres (e.g. if TB is suspected, a red dot to be put on white card: then a yellow dot if Tb test is positive, a green dot when ATT is started and another coloured dot when ART is initiated).

c) It is proposed to have one HIV/TB treatment coordinator for every 5 ART Centres and attached Link ART Centres (15 LACs) to provide TB/HIV linkage at ART facilities. The role of the HIV/TB Treatment Coordinator will be to provide linkage for TB/HIV at ART centres and Link ART centres in terms of Intensified TB Case Finding among PLHIV, infection control, INH preventive therapy, data recording and reporting, Supply Chain Management, patient counselling,and follow up. This mechanism will strengthen coordination and supportive supervision of HIV-TB collaborative activities in HIV settings

d) There is a plan to establish F-ICTC in all Designated Microscopy Centres (DMC) where HIV screening facility will be available. This will help to improve low HIV testing coverage among TB patients in low HIV prevalence areas.

e) *Joint programming and monitoring:* HIV-TB collaborative activities will be rolled out at ART Centres as a **single window point** for care and treatment as well as for TB diagnosis and management. The Programme has already started a pilot for CBNAAT testing, Daily ATT and ART and alignment of standardised and harmonised recording and reporting systems at 30 high load centres as single window service. Based on lessons learnt, it is planned to scale up the project in all high HIV settings.

ii. **Intensified TB case-finding and early initiation of ATT and ART**

[17]RNTCP,& NACO. (2013). National Framework for Joint HIV / TB Collaborative Activities. Page 5 Retrieved from http://www.naco.gov.in/upload/NACP - IV/18022014 BSD/National Framework for Joint HIV TB Collaborative Activities November 2....pdf

[18]RNTCP,& NACO. (2013). National Framework for Joint HIV / TB Collaborative Activities. Page 6 Retrieved fromahttp://www.naco.gov.in/upload/NACP - IV/18022014 BSD/National Framework for Joint HIV TB Collaborative Activities November 2....pdf

There exists a gap in early identification, screening and referral of presumptive TB among PLHIV, resulting in delayed diagnosis of TB and poor outcomes of subsequent treatment. Both programmes are focussing on strengthening active screening for symptom complex for TB. Further it is planned to rapidly scale up the use of rapid diagnostics like CBNAAT,which are being procured under RNTCP as a part of its NSP, for early and accurate diagnosis of TB and Rifampicin resistance in PLHIV. CBNAAT testing will help to detect cases, which otherwise would be missed during routine diagnostic procedures and provide opportunity for prompt treatment initiation; minimizing linkage loss. All ART Centres will be linked to a CBNAAT testing facility in a phased manner. The Programme has already taken the decision to start daily ATT for co-infected patients to achieve better outcomes. ATT will be provided through ART Centres.

iii.Prevention of TB in PLHIV

a) GoI has taken the policy decision to roll out isoniazid preventive therapy (IPT) for prevention of TB among PLHIV, and this is being implemented in a phased manner. The drugs and logistics support is provided through the domestic budget, whereas GF NFM would support the capacity building of human resources for successful implementation of the strategy.
b) TRG NACO has recommended the adoption of WHO guidelines regarding revision of eligibility criteria for ART initiation. Early initiation of ART will reduce progression of HIV infection as well as TB among PLHIV. Support for rollout of this strategy is being sought under NFM.
c) *Airborne Infection Control Measures at HIV care settings: This* has been identified as an area of increasing importance. It is planned to roll out airborne infection control practices at all ART Centres. However the General Health System needs to be geared up to take up the issue for implementation.

iv. Reduce the burden of HIV in patients with presumptive and diagnosed TB, their families and communities by providing HIV prevention, diagnosis and treatment.

Provider Initiated HIV testing and Counselling (PITC) among presumptive TB cases is a nationwide policy. As compared to TB services, which are mostly decentralized and integrated into the general health system, HIV services remain largely centralized. Thus, this gap between RNTCP and NACP infrastructures results in suboptimal linkages. Overall at country level 6724/13232 (51%) of the Designated Microscopy Centres (DMC's) have co-located HIV testing facilities, however intrastate variations are evident (15% to 95%). An operational research study instituted by Central TB Division showed very high yield of HIV among presumptive TB cases (7 to 10%) in high HIV prevalence settings and this intervention contributed significantly in detection of new HIV infection in the study area (by up to 35%). All DMCs will be upgraded to also function as F-ICTC where HIV screening facility will be available, using existing facilities and manpower. The kits for HIV testing will be supported by NACP as a part of its NSP. This will go a long way in reducing the gap between those referred for HIV testing and those actually undergoing the test.

v. Alignment of TB and HIV strategies at the level of the Community System and involvement of community systems for ICF and referral linkages

The present efforts to identify co-infected cases are in the form of intensified case findings (ICF) in HIV and TB service delivery sites and cross-referrals between the two sites, necessitating additional efforts at the community level to improve notification of co-infected individuals. To assist the country in reaching a larger number of co-infected individuals, RNTCP, NACP and its partners have adopted the following interventions across the project:

a) Establish partnership with district-level networks of PLHIV to engage them in TB control activities and subsequently improve detection of TB cases.

b) Engage around HIV prevention projects in TB care and control activities in collaboration with State AIDS Control Society (SACS) and State TB Cell (STC) of all states.

c) Expansion of HIV-TB services into CSCs for Intensified TB case finding, referral of presumptive TB cases among PLHIV and their family members for TB testing during outreach, strengthening linkages of TB-infected PLHIV to ART centres and ensuring their retention in care and treatment adherence. These would be achieved using Outreach Workers (ORWS) who will work as a medium for community outreach and focused-group discussion. All the PLHIV and family members of the PLHIV registered in CSCs would be provided with Verbal screening through community-based Intensified Case Finding Approach (ICF). Those eligible would be sent for screening at the TB testing facility.

vi. Adapting models of TB/HIV care for high risk groups such as people who inject drugs and migrants

PWID:At present, it is estimated that in India there are currently close to 200,000 people who are injecting drugs. The high risk of HIV among people who share contaminated equipment to inject drugs is well established. Recent data suggest that the HIV prevalence among people who inject drugs is 9.19% in India. Similarly People Who Inject Drugs (PWID) are at high risk of contracting TB whether or not they are HIV positive because of poor living conditions, promiscuity and frequent stay in prisons (WHO bulletin 2013; 91:154-156). India is also rolling out "targeted interventions" for people who inject drugs and has access to PWIDS. These are community-based services (often staffed by people who use or formerly used drugs) with government providing financial and technical support. The 'targeted interventions' (TIs) take a harm reduction approach to HIV prevention (including free syringes and needle exchange), offer limited clinical services at drop-in centres (STD screening and treatment, treatment of abscesses), and sometimes OST. Clients are linked to other services via accompanied referrals. Some of the TIs are now also offering some limited TB/HIV services. However, human and financial resource constraint limits the number and coverage of services. A case study[19] on HIV-TB collaboration for PWID in India suggested that Prevention, diagnosis and treatment of tuberculosis among people who use illicit drugs require effective models of integrated delivery of HIV, hepatitis and harm reduction services that respect human rights. This can be through a one stop service approach or through string linkages and referrals. Regarding the proposed interventions for HIV-TB collaboration for PWID, following HIV-TB collaborative activities planned to be implemented:

- Joint Planning : Multi-sectoral coordination of TB and HIV services for drug users at the local and national level ,including health and criminal justice
- Case-finding protocol for TB and HIV for any facility or organization working with drug users. CBNAAT testing offers an opportunity to expedite the diagnosis of TB in this population group.
- TB infection control in congregate settings including health care facilities and prisons.
- Ensure access to all appropriate treatments for drug users (TB therapy, antiretroviral therapy, treatment for STDs, hepatitis B or C & drug dependency) in accordance with guidelines
- Isoniazid preventive therapy (IPT) to prevent active TB in drug users living with HIV once active TB is reasonably excluded
- Comprehensive HIV prevention services for drug users and health care staff

The proposed HIV-TB collaboration is /will be strengthen to improve the diagnosis of TB, HIV and co-morbidities among PWID.

[19]published in HATIP/issue 159/28 May 2010

Migrants: Migrants are at higher risk of getting TB as well as HIV. While data on internal migration and its effect on TB in India is limited and NACP has devised the migrant intervention strategy with specific reference to linking migrants with services and information on HIV prevention, care and support at Source (at their villages), at Transit (places like rail or bus stations where large number of migrants board trains or buses to travel to their places of work) and at Destinations (the places of work). DAC has identified 122 districts with high outmigration (based on the 2001 Census) across 11 States which are on priority for starting up community level migrant interventions. Interventions like awareness campaigns and health camps for strengthening Migrant Interventions were implemented at source villages accounting for the major bulk of migration, as well as at the major transit points. Modelling of migrant interventions across important corridors is being undertaken. Employer-led models and migrant tracking systems are also being piloted. It is planned for collaboration between the 2 programmes to synergize HIV and TB prevention among migrant and to improve TB detection among migrants (irrespective of their HIV status).

Opportunities for joint implementation of cross-cutting activities

The existing systematic structures will be leveraged for enhanced collaborations between the two national programmes and hence implementation of activities uniformly across the country, thus bringing efficiencies into program management. It also will ensure problem solving at the local level, and foster innovations to overcome hurdles.TheDepartment of AIDS Control has now been merged with the Ministry of Health and Family Welfare, and both programmes now report to the Union Secretary (Health). This is likely to bring more synergies in planning, coordination and implementation of the joint programme.

Collaboration through sharing facilities: The TB program is facilitating the establishment of HIV testing facilities in all Designated Microscopy Centres, using existing facilities and manpower.[20] Similarly, it is planned to consider all ART centres as PHI for initiating ATT in PLHIV.Both programs also plan to explore the feasibility of using common platforms for CBNAAT testing for TB and viral load testing for HIV.

Collaboration in referral and outreach systems*:* The programmes already have mechanisms for referral of all TB patients to ICTC, provision of CPT to HIV-infected TB patients, and referral of HIV-infected TB patients to ART centres for initiation of ART. The community systems available under both programmes will further be harnessed and strengthened for ICF, linkages, retention in care continuum, outreach and contact tracing, especially in key populations for HIV and TB.

Collaboration through Information systems and M & E:Coordinated and integrated recording and reporting mechanisms complement the data systems of both programmes and helps to avoid duplication of effort. Joint planning, supervision, monitoring and review are conducted through joint TB/HIV visits to states/districts and joint program reviews conducted at national and state levels.

Opportunities to leverage the well-established programmatic platforms*:* There is delayed diagnosisof HIVwhen CD4 counts are significantly low, resulting in sub-optimal outcomes. RNTCP has a better visibility and reach with private providers (through IMA, CBCI projects, PPP schemes) which can be very well be leveraged by NACP for sensitising private providers for PITC for HIV, referral to NACP facilities, UWP etc. This will lead to timely diagnosis and treatment of HIV as well as HIV/TB co-infected patients and better treatment outcomes. Similarly, RNTCP does not have sufficient evidence and mechanisms to reach migrants and

[20]RNTCP & NACO. (2013). National Framework for Joint HIV / TB Collaborative Activities.Page 9 Retrieved from http://www.naco.gov.in/upload/NACP - IV/18022014 BSD/National Framework for Joint HIV TB Collaborative Activities November 2....pdf

unorganised workers. With the changing epidemic of HIV in migrant populations, and high risk of TB in HIV infected individuals, the risk and prevalence of TB in migrants is expected to be high. NACP has a well-structured migrant strategy and employer-led models of interventions for unorganised workers which can be utilised by RNTCP.

Expected efficiencies resulting from these joint implementation

Better yield from Intensified TB case finding activitieswhich have beenrolled out in ICTC& ART centres across the country (currently this mechanism contributes to 4% additional TB notification to RNTCP).
Enhanced reach of HIV testing servicesthrough establishment of F-ICTCs at all DMCs. Availability of these services is gradually enhancing access to HIV testing services as this approach is expanded across the country.

Integrated TB management along with HIV care at ART centres: This will be a cost effective approach which will help reduce linkage loss, timely ATT and ART management, better outcomes in terms of morbidity and mortality, thereby reducing the burden on the health systems.

Integration of M & E systems: Standardised, comprehensive and harmonised recording and reporting systems for collaborative TB HIV activities have been developed. The M & E tools at ART centres LACs and ICTCs have been expanded to capture data on TB-HIV and this will be gradually integrated to MIS. This will avoid duplication and enable effective policy making and program planning. This will be periodically reviewed at district, state and national level. Joint monitoring and supervision will also add to program effectiveness.

***Efficient utilisation of resources*:** Collaborative mechanisms will lead to pooling of resources and avoid duplication of activities, thereby leading to cost efficiencies.

***Strengthen Health Systems*:** Joint efforts will contribute to strengthening infrastructure and capacity of the health systems which can also be leveraged for other programmes.

***Opportunities for cross learning*:** Both programmes are quite mature and acclaimed to be successful. Joint activities will provide opportunities to program managers to learn from each other.

The barriers that need to be addressed in this alignment process

India has two separate and strong national programmes which have evolved and matured over the last two decades. Moreover the transmission dynamics and disease epidemiology of the two diseases are different, calling for a differential strategy. While HIV is a concentrated epidemic, the TB epidemic is comparatively more uniform and hence the geographic as well programmatic priorities differ for both programmes. The organisational structure of service delivery is also more vertical for the NACP as compared to RNTCP. The challenge that needs to be addressed is going beyond the joint strategy for early detection and management of co-infected patients. The primary barrier that needs to be addressed is aligning service delivery of both programmes with the general health system under the umbrella of NHM and managing change given that the organisational climate of two programmes are currently dissimilar.

Another barrier is that the NACP infrastructure between low and high HIV prevalence settings is not uniform. For optimal collaboration, the infrastructure (both physical as well as human resources) have to match the demand for services. The scale of RNTCP programme testing network is comparatively huge as compared to HIV testing facilities. For patient-centric services, co-location of facilities is not adequate. Only about 51% of facilities offer both services. Further, there is a mismatch between increased access and coverage of HIV testing for TB patients and minimal access to antiretroviral therapy and other interventions for HIV-positive TB patients, including co-trimoxazole preventive treatment and HIV prevention. New emerging pockets of HIV in hitherto low prevalence states where the general health system as well as program scale

up is weak further adds to this challenge. Though both programmes have made significant investments in collaborative activities, there is need to strengthen planning and resources to quickly roll out national policies and evidence-based practices. Logistics and SCM have to match the scale of services. Non-harmonized, non-standardized and duplicative TB/HIV monitoring and evaluation systems need to be further streamlined for smooth implementation. At the implementation level, often well-intended national and state policies on collaborative action do not get implemented on the ground due to unclear communication and roles. Most of barriers articulated above are being addressed in the current proposal and will be closely monitored for seamless transition into practice.

SECTION 2: FUNDING LANDSCAPE, ADDITIONALITY AND SUSTAINABILITY

To achieve lasting impact against the diseases, financial commitments from domestic sources must play a key role in a national strategy. Global Fund allocates resources that are insufficient 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 TB and HIV national programs and how this funding request fits within these, 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.

a. The availability of funds for each program area and the source of such funding

As per the 12th five year plan (2012-17), the country has allocated an amount of USD 3,069 million towards HIV and TB services with an allocation of USD 2,236 million for HIV[21] and USD 833 million for TB[22].

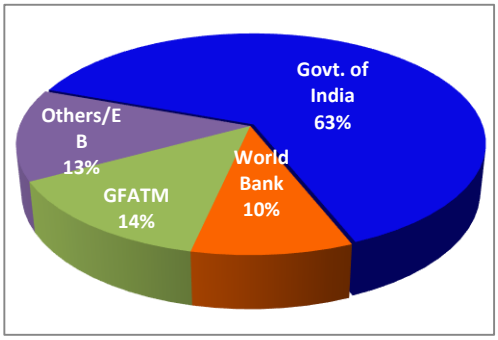


Figure 8: NACP IV - Sources of Funding

Availability and Sources of Funds for HIV

GOI under NACP-IV (2012-17) has earmarked an amount of USD 2,236 million. Under NACP IV 63% of the funds will be generated through budgetary sources of Government, 14% (USD 304 million from the Global Fund, 10% (USD 213 million from the World Bank, and 13% (USD 302 million through extra budgetary resources from other development partners (Figure 8).

Since prevention remains the integral part of the program strategy, component wise breakup of the NACP-IV budget indicates that 63% (USD 1,416 million) of the overall estimated budget is allocated for prevention services and 30% towards care, support and treatment services. The balance of 7% is bifurcated among the components of Institutional Strengthening and Project Management (4%) and the Strategic Information Management Systems (SIMS) (3%). This reflects that the primary focus of the government is towards prevention that has been the case in the previous phases of the NACP. Component wise budget for NACP is given as Table 4

Table 4:Budget for NACP IV (in USD.

Programme Components	2012-13	2013-14	2014-15	2015-16	2016-17	Total
Prevention						
FSW	25.22	26.40	29.28	31.23	31.84	143.97

[21]National AIDS Control Programme Phase-IV (2012-2017) Strategy Document (INR 13415 crores)

[22] RNTCP (2012-17),National Strategy Plan (INR 4500 crores)

MSM/TG	9.20	9.99	11.71	12.65	13.11	56.66
IDU	11.95	14.51	15.69	17.60	20.35	80.10
Migrants	5.92	9.35	10.84	12.00	13.00	51.11
Truckers	2.24	2.68	3.34	3.91	4.44	16.60
STRCs and TSU	6.70	7.34	7.74	7.94	8.15	37.85
Sub-total TIs	61.22	70.26	78.58	85.33	90.89	386.28
Link worker scheme	5.33	7.83	5.00	5.00	5.00	28.17
ICTC/PPTCT	50.83	46.83	47.67	59.30	59.56	264.19
STI	5.50	11.42	12.73	14.36	15.42	59.42
IEC	28.69	33.59	42.82	47.43	52.43	204.95
Mainstreaming	1.67	3.14	3.64	3.97	4.14	16.56
Condom Promotion	43.41	53.14	59.89	71.01	72.79	300.24
Blood Transfusion Services	27.67	26.59	25.58	28.79	27.84	136.47
Lab Services	3.34	3.55	3.93	4.30	4.58	19.70
Prevention Total	227.67	256.34	279.83	319.50	332.63	1415.97
Care, Support and Treatment	99.96	118.41	132.89	147.56	161.39	660.19
ISPM	15.38	17.24	18.94	20.67	22.72	96.62
SIMS	2.33	3.50	17.92	19.32	21.67	64.73
Total Budget	345.33	395.49	449.57	507.05	538.41	2235.84

As India is a concentrated epidemic with low HIV prevalence, prevention among key as well as general population remains a key focus. GFATM-supported interventions during NACP-III and NACP-IV contributed substantially in scaling up of prevention, testing, care and support services among key populations. NACP will continue to scale up implementation of prevention and testing services including targeted interventions, IEC, LWS, Condom Promotion, STI, Blood safety, and ICTCs. These services are adequately resourced through domestic budgetary support and the World Bank credit. GoI launched the National AIDS Control Support Project (NACSP) in August 2013, with an aim to target vulnerable risk groups including FSW, MSM, IDUs, truckers, and migrant populations. Of the project's total budgetary outlay of USD 510 million, the World Bank is providing interest free soft loan of USD 255 million. The programme aims at reaching out to hard-to-reach population groups at high risk with targeted prevention interventions through innovative approaches; increasing access to comprehensive care, support and treatment; expanding information, education and communication with a focus on behaviour change, demand generation and stigma reduction, further strengthening institutional capacities, and supporting the process of integration. The Project also envisages reaching out to the most vulnerable and marginalized population groups, increasing their access to and utilization of public health services, and reducing stigma and discrimination. The NACSP will contribute to three of the five strategies of the NACP IV: (i) the prevention component (USD 440 million), (ii) the behaviour change component, (USD 40 million) and (iii) the institutional strengthening component (USD 30 million). (For details refer to NACSP document Annexure 4).The project will ensure sustainability of various interventions implemented through civil society organizations under previous global fund grants as depicted in the Table 5 below:

Table 5: Sustainability of present Global Fund supported prevention activities beyond project

Global fund	Prevention projects	Project period	Key Interventions	How the activity will be sustained beyond Project
Rd7	LWS	September 2008 to August 2014	Linking rural Key population to HIV services	Currently under DBS transitioning proposed to TI NASCP project under World Bank.

Rd 9	Pehchan	October 2010 to September 2015	Strengthen community institutions and systems for MSM/Transgender / Hijra (MTH) communities.	Funded by GoI and WB for next 5 years.
Rd9	IDU	Oct-10 to Sep-15	Capacity building and enhancing quality services for IDU population	Will be integrated into existing TI programme of NACO.

All these activities are implemented through targeted interventions which are, and will continue to be implemented through civil society organizations for which there is a defined procedure. Civil society is fully involved in conceptualizing, designing and implementing interventions.

The programme is also implementing comprehensive HIV care services for all those who are in need and facilitates additional care and support systems, including for women and children. It will continue work to ensure improved access to CST services provided by the programme for PLHIV, to reduce HIV-related morbidity and mortality.

Availability and sources of funding in RNTCP

The approved outlay for RNTCP for the five year period 2012-17 is USD 833 million. Of the total available plan budget the World Bank (detailed project is attached at Annexure 5) credit constitutes USD 100 million; the Global Fund contribution is USD 261 million. The domestic budgetary support would form the remaining component of the plan budget. In due course of time and with increasing focus on addressing the epidemic with an intensified set of interventions these estimates have been revised recently through a national level consultative process. Partner agencies also provide nominal extra budgetary support in the form of technical assistance for identified activities. The revised outlay for the period 2012-17 and additional estimates for the year 2017-18 are presented in Table 6 below:

Table 6 :RNTCP Proposal (including all PRs)

PR wise & Sources of Fund					
A. Budget Requirement		2015-16	2016-17	2017-18	Total
CTD		353.64	388.15	405.18	1146.98
The UNION		20.43	14.17	3.00	37.60
WVI		4.06	3.74	3.12	10.92
Total Budget		378.13	406.06	411.30	1195.50
B. Available resources					
Support for TB	GFATM(SSF II)	9.32	0.00	0.00	9.32
	World Bank*	61.71	0.00	0.00	61.71
	GFATM(SSF II – Civil society)	8.00	0.00	0.00	8.00
	TOTAL Available	79.03	0.00	0.00	79.03
C. Gap		299.10	406.06	411.30	1116.47
Domestic Budgetary support**		187.86	229.78	332.91	750.56
Request under NFM	CTD	94.75	158.37	72.28	325.39
	The UNION	13.43	14.17	3.00	30.60
	WVI	3.06	3.74	3.12	9.92
	Total Proposal (including all PRs)	111.23	176.28	78.40	365.91

*World Bank commitment is up to 2015-16 only

** GoI is committed to support RNTCP within the overall approved plan outlay. It is also assumed that for the year 2017-18, which will be the first year of 13th FYP, the GoI will approve the allocation as proposed. Any gap in funding will be resourced through the additional WB credit / savings within the plan outlay of Ministry of Health.

The indicative funding in the table above is the full expression of demand for the period 2015-17. The committed funding under allocation component of GF NFM (USD 169.11 million for CTD, 20.95 million for The UNION and 7 million for WVI) would still leave quality unfunded demand to the tune of USD 156 million for CTD, 7 million an d 2.9 million for The UNION and WVI respectively. This quality unfunded demand may be considered for support from incentive funding. In case of any gap that is not supported through this proposal, the same will be attempted to be replenished through negotiations with WB for additional credit / DBS.

As may be seen, the proposed funding request to GF against the overall resource requirement is less than 30% assuming that NFM will meet the full expression of demand. Components such as FLDs, Program management, TBHIV are more or less adequately resourced and GF contribution to these components is less than 1/6th of the total outlay for these components (Table 7). It may also be noted that even for highly resource intensive activities such as PMDT and SLDs, the DBS contribution is more than half indicating strong country commitment.

Table 7: Component wise source of funding Table (FY 2015-16 to 2017-18)

Amount in Million USD

S No.	Categories	Total Requirement	Committed fund - WB	Committed Fund - GF (SSF Phase II)	NFM Proposal	Domestic sources*
1	Drugs FLD	104.43	13.69		13.15	77.59
2	PPM	91.17	0.00	0.37	21.23	69.57
3	PMDT (DRTB) Diagnostics	167.57	9.31	7.21	86.23	64.83
4	DRTB Treatment services SLD	383.22	35.53		129.85	217.84
5	Operational research	18.41	1.54	0.10	4.00	12.78
6	Technical Assistance	20.26	1.64	1.25	11.66	5.70
7	Others including TBHIV, Urban TB Control, Special population, Vehicles, Supervision & Monitoring, Civil up-gradation, Training, HR, Program management)	361.91	0.00	0.40	TBHIV 28.77 Urban TB Control 11.66 Special population (Tribal, Paediatric etc) 18.84	302.25
8	Civil Society	48.52	0	8.00	40.52	0
	Grand Total	1195.50	61.71	17.32	365.91	750.56
	Percentage	100%	5%	1%	31%	63%

b. Proposed Global Fund investment has leveraged other donor resources as follows:

Leveraging other resources for HIV:

NACP aims to accelerate the process of reversal and further strengthen the epidemic response in India through an integrated approach. The proposed Global Fund investment will supplement the consolidated efforts being made by NACP towards prevention and provision of comprehensive care support and treatment services through DBS/donor support. Several developmental partners like WHO, UNICEF, CDC, USAID, UNDP, BMGF and CHAI are providing extra–budgetary support/technical assistance. Therefore, the funding proposed under NFM leverage upon Domestic Budgetary Support of USD 902.56 million, WB Credit of USD 107.77 million and extra- budgetary support of USD 35.12 million during the project period. In addition in year 2017-18, USD 538.42 million is expected to be provided under domestic budgetary support. All the activities being undertaken through other resources do not form part of the proposal to avoid any duplication. In addition, the National programme has a long-standing relationship with several corporate foundations as well as public sector companies who conduct HIV prevention and treatment activities within their corporate initiatives including IEC, counseling, behavior change, condom programming, HIV testing and ART services. In addition,

several corporates support the program through drug donations (ONGC $3.2 million, Domestic Pharma industries $5 million). In addition, general health systems from states and corporations also contribute to the programme in terms of infrastructure, HR, services and laboratory. NACP is also working towards ensuring social protection of marginalized populations through earmarking of budgets for HIV among concerned government departments and has also signed an MoU with various other Ministries/Departments (Defence, Shipping, Road Transport & Highways, I & T, WCD, Youth affairs, HRD etc) for broader collaborations. Table 8 provides an overview of the budgetary and extra-budgetary support across different components.

Table 8: Overview of sources of budgetary support

	Budgetary Support	Extra-budgetary Support
TI	DBS, World Bank	BMGF, USAID, CDC, UNAIDS
STI	DBS	BMGF
Lab Services	DBS	CDC
Blood Safety	DBS	CDC
LWS	DBS, Global Fund	UNDP
ICTC	DBS, Global Fund	UNICEF, WHO
IEC/MS	DBS, World Bank, Global Fund	USAID, UNDP, UNICEF
Condom Pro.	DBS	Component
SIMS	DBS	CDC
CST	DBS, Global Fund	CDC, WHO , CSR initiatives

Leveraging other resources for Tuberculosis:

Since its inception, RNTCP has been supported through a World Bank credit, Global Fund grants and domestic budgetary resources. The programme has evolved and matured over the last 17 years and has seen incremental commitments from domestic budgetary support which has increased nearly five-fold from USD 168 million USD in 10th FYP to USD 833 in 12th FYP. The percentage share of domestic resources has also increased from <1% in 10th FYP to 61% in 12th FYP. The programme which started as small pilot projects in five sites in 1993 covering a population of 2.35 million has now evolved to cover the entire 1.23 billion population of India and is addressing all components of the Stop TB Strategy effectively demonstrating its capacity to leverage donor resources for an optimal public health response.

The goal of RNTCP in the 12th FYP is Universal Access to quality services for individuals with all forms of TB. The proposed Global Fund investment will supplement and consolidate the efforts of RNTCP towards reaching the unreached and reducing incidence and mortality due to TB. The programme also receives nominal extra-budgetary support from WHO, USG, UNITAID, BMGF and CHAI, primarily in the form of technical assistance. In addition, the National program has a long standing relationship with several NGOs and a few corporate foundations, as well as public sector companies who conduct TB prevention, testing and treatment activities within their constituencies. Further the entire implementation support at grass-root level is being rendered by the general health system of states that provide the infrastructure, human resources and institutional mechanisms.

Specifically the Global Fund support has leveraged on other funding sources as below:

- DR TB Scale up: UNITAID through EXPAND TB project is establishing 43 C&DST laboratories along with the committed support of laboratory consumables till Dec 2015. The proposed GF resources leverage upon these established laboratories and provide support for HR, M&E, Training. Further FIND with the support of USAID and technical assistance from WHO, conducted a feasibility study for roll out of CBNAAT in programmatic settings. UNITAID and EXPAND TB have also separately rolled out initial learning projects for DRTB scale up and have provided for 89 CBNAAT machines along with cartridge support for two years. Learnings from these projects are being leveraged with GF resources to further scale up the decentralized deployment of newer diagnostics.

  Procurement of SLDs: World Bank credit is supporting procurement of 29900 courses and DBS is supporting 38000 courses for DRTB patients. The NFM proposal leverages upon this to further scale up PMDT with support of 52800 courses.

- TB-HIV: PEFFAR through WHO is supporting deployment of rapid diagnostics in 30 high HIV congregate settings and roll out of daily regimen for co-infected patients. NFM proposal leverages upon electronic monitoring, and capacity building for the roll out of IPT, early detection of TB/DRTB, and PITC. Further the current proposal leverages upon strong established coordination and implementation mechanisms of the TB and HIV programmes.

- PPM: The National programme through domestic budgetary resources and the WorldBank credit supports partnership mechanisms at state and district level which is 70 million USD. Further many international

(BMGF, KNCV, USAID, CHAI etc.) and regional organizations (REACH, DFIT, TB Alert, RK Mission, TB Association, etc.) support partnerships through their own dedicated budgets. The current proposal leverages upon the complementarities offered by these partners.

- Advocacy and Coordination: USAID through its Challenge TB project and BMGF are supporting roll out of Urban TB models of care and high level advocacy initiatives with stakeholders. The domestic sources and WorldBankcredit also supports a dedicated media agency and PPIAs. NFM resources further build on these interventions and takes them to scale.
- Operational research: NFM further builds on existing OR initiatives of the program and partners, thus would support the program in evidence-based policy decisions.

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

HIV

NACP envisages to reduce new infections by 50% and provide comprehensive care, support to all PLHIV with treatment services for all those who require it.Based on the limitations discussed in section 1.2c, the program needs to scale-up prevention as well as treatment component in view of the demand for quality services and epidemiological shifts in disease As discussed in Section 2.1a,Funding Landscape, the GoI has provisioned for all financial needs for prevention; targeted interventions, blood transfusion services, condom promotion, and STI treatment services. As this forms the bulk of the budgetary allocation in NACP-IV, funds have not been requested for in the concept note but there will be no reduction in these activities. However, to achieve the objectives of the NACP of universal access to quality treatment, it is required to further upscale and strengthen the existing systems. In this context, WHO has issued revised global guidelines for ART initiation and monitoring in 2013 and the program has agreed in principle to accept most of the recommendations. This will help reduce HIV-related morbidity, mortality and incidence of Opportunistic Infections (OIs), particularly TB in PLHIV. It is also proposed that priority will be given to key populations while initiating ART at higher CD4 cut off of 500. Around 60,000 PLHIV among key populations will be covered. The programme also proposes to pilot a 'test and treat' strategy including community-based testing for key populations. However, adoption of these revised guidelines adds to the overall ARV drug requirement in the country. It further necessitates the need to strengthen ARV service delivery mechanisms, lab capacity for monitoring of patients on ART, supply chain systems for ARV drugs and other commodities, quality assurance systems, and enhanced supervision and monitoring of the programme. This would require significant additional funds. Also, there is financial gap for the outreach component of the programme, and involvement of the private sector to strengthen PPTCT.

Out of the total requirement of USD 1,946 million, an amount of USD 1,046 million has already been committed under domestic resources, the World Bank, current the Global Fund grants and extra budgetary support from other donors. Out of the remaining amount of USD 900 million, an amount of USD 538 million on current scale is likely to be met by Government, leaving a gap of USD 362 million for which Global Fund is being requested to support under this NFM (Table 9). The current Concept Note is prepared for USD 250.8 million as allocation amount (including an estimated saving of USD 18 million from previous Global Fund grants) and an above allocation of budget request of USD 111.82 million. This sums to an overall request of USD 362 million. This quality unfunded demand may be considered for support from incentive funding. In case of any gap that is not supported through this proposal, the same will be attempted to be replenished through negotiations with DBS or any other donor support.

Table 9: Component wise funding gap for HIV Amount in million USD

Component	Requirement	Available	Funding Gap	Additional Requirement to be met from		
	From 2015-2017	Under NACP		Domestic*	NFM-Allocation	NFM-Above

						allocation
Prevention (TI, STI,ICTC,IEC, PPTCT Blood safety, LWS, mainstreaming, TB-HIV)	1,010.67	652.13	358.54	332.63	17.98	7.93
CST	769.23	308.95	460.29	161.39	208.71	90.19
ISPM	93.74	43.39	50.35	22.72	15.92	11.70
SIMS(M&E,SI, ICT&Research)	72.32	40.98	31.34	21.67	7.67	2.00
Total	1,945.96	1045.45	900.51	538.41	250.28	111.82
Percentage		**54%**		**28%**	**13%**	**6%**

* GoI is committed to support NACP within the overall approved plan outlay. It is also assumed that for the year 2017-18, which will be the first year of 13th FYP, the GoI will approve the allocation as proposed. For any gap in funding , attempts will be made to resource them through the additional DBS allocation/WB/other donor support.

TB

RNTCP is currently implementing all components of Stop TB Strategy. Basic DOTS services which were rolled out in 1997 were scaled up to cover the entire country by 2006. TB-HIV services were rolled out in the year 2000, PMDT services in 2007. These were then scaled up to cover the entire country by 2013. However despite significant gains made by the programme, several challenges remain. The current rate of decline in incidence is too slow. RNTCP will not be able to reach Global TB elimination targets by 2050 with the current set of interventions. There is still delayed diagnosis, poor treatment outcomes in TB-HIV, and drug resistance among TB patients. 40% of estimated drug sensitive TB patients, 60% of estimated TB-HIV and DR-TB patients are still outside the reach of the programme. There is poor access to services by the marginalized and vulnerable populations. There are significant gaps in the programme andthese are being addressed through multiple, complementary sources offunding.

Table 10 given below may be seen in conjunction with Table no 5. in section 2.1c. As is evident in both tables, the program areas which have significant funding gaps are SLDs, PMDT diagnostics, TBHIV, PPM, Key Populations and Urban TB Control. The planned actions to address these gaps are enumerated in Table 10 below:

GoI is committed to provide quality TB services to all sections of the society irrespective of caste, gender, creed or economic status. The shortfall in funding, if any, to support any of the program areas noted above, including drugs and logistics, will be mobilized through additional WB Credit and/or domestic budgetary resources.

Table 10: Component wise – funding gap for TB program

Serial No.	**Categories**	**Total Requirement**	Available	NFM -Allocation	NFM - Above Allocation
1	Drugs FLD	104.43	91.28	13.15	0.00
2	PPM	91.17	69.94	15.01	6.22
3	PMDT (DRTB) Diagnostics	167.57	81.34	47.69	38.54
4	DRTB Treatment services SLD	383.22	253.37	57.54	72.31
5	Operational research	18.41	14.41	0.00	4.00
6	Technical Assistance	20.26	8.60	7.72	3.94
7	Others including TBHIV, Urban TB Control, Special	361.91	302.64	TBHIV- 15.40	13.37
				Urban TB Control 6.79	4.87

	population, Vehicles, HR, Supervision & monitoring Civil upgradation, Training)			Special population (tribal, paediatric) 5.82	13.02
8	Civil Society Proposals	48.52	8.00	29.95	10.57
	Grand Total	1195.50	829.58	199.07	166.84
	Percentage	100%	69%	17%	14%

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

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

b. Compared to previous years, what additional government investments are committed to the national programs (TB and HIV) 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.

HIV funding: During Eleventh Plan period (April 2007 to March 2012), domestic funding for the NACP was of the order of Rs. 1116 crore (about USD 186 million). However, for Twelfth Plan period (April 2012 to March 2017), Government has approved an amount of Rs. 8505 crore (USD 1417.5 million) under domestic funding. Under NACP IV, the Government of India has increased their commitment and augmented their funding allocation to 63% against 12% in NACP III. This is a substantial increase in the plan expenditure in terms of the activities that are expected to be financed by the government and represents the bulk of the resources required under NACP-IV.Government plans to incur expenditure partly on prevention activities partly on Care support Treatment, Institutional Strengthening & Project Management and Strategic Information Management System out of domestic funding. Blood transfusion services, Condom promotion, counseling and testing services, PPTCT mainstreaming activities, Strategic Information

Management Services and institutional building activities are the major areas where government plans to allocate its resources.

Realization of these commitments and its tracking: Government reviews the requirement on yearly basis and allots the requisite funds through annual union budget. Midterm reviews are also made and wherever required additional budget are passed through revised estimates processes. The expenditure incurred is entered, tracked and controlled through two software packages viz. Computerized Financial Management Package and Centrally Plan Scheme Monitoring System

TB Funding:

The Government of India (GOI) accords the highest priority to TB control and is committed to supporting the TB control activities for as long as it takes to achieve a situation where TB ceases to be a major public health problem in the country. The Government of India is committed towards its funding to RNTCP. The total outlay for RNTCP during 10th FYP was USD 168 million. In the 11th FYP this was increased to USD 358 million, while in the 12th FYP the approved outlay is USD 833million. The increase in RNTCP funding in absolute terms is in line with planned scale up of activities. In per capita terms, during the 12th Plan, average annual central government spending on TB control is proposed to be about US$ 0.18, which represents a tripling in absolute terms from the 11th Plan average. Further it may be noted that the domestic budgetary resources has also increased from 0.5 million USD in 10th FYP to 508 million USD in 12th FYP.

Table 11. Central government health spending on RNTCP during 10th, 11th and 12th Five Year Plan

Five Year Plan	Years	RNTCP Budget in US $ Million	RNTCP Budget in US $ per capita per year
10th	2002-2007	168	0.03
11th	2007-2012	358	0.06
12th	2012-2017	833	0.17

DOTS implementation, human resources for other than 9 identified GF supported states, operational expenses like maintenance, ICT initiatives and infrastructure expenses in all the states and union territory are funded from government sources.Further the National Health Mission of GoI supports infrastructure upgradation, health system strengthening, and human resources beyond RNTCP.

The commitments towards RNTCP from GoI and other donors are monitored on a regular basis. RNTCP submits annual Budgetary Estimate for the upcoming financial year where funding to RNTCP from all sources is mentioned. Moreover, based on spending in the first half of the year, a six-monthly re-estimation of budgets is conducted mid-financial year in September/October. Subsequently, reports are shared with the Department of Economic Affairs. Further achievements against physical targets are regularly monitored through standard M&E protocols of the program and regular common review missions.

The assessment of the completeness and reliability of financial data reported, including any assumptions and caveats: The reported financial data is reliable. These data are audited by the respective State Health System, State National Health Mission Societies, and Auditor and Comptroller General, before being compiled at the national programme management unit. These data are published in the form of an Annual Report of CTD as well as MoHFW, Annual Health Survey- GoI and made available in the public domain. No assumptions are made for the past years whereas logical assumptions are made for future requirements. Actual performance in the proposed areas may depend on the external environment, including the political and administrative changes at state level and capacity differentials of the individual state health systems.

SECTION 3: FUNDING REQUEST TO THE GLOBAL FUND

This section details the request for funding and outlines how the investment is strategically targeted to achieve greater impact on the diseases and health systems. While the investments for both the HIV and TB programs should be described, the applicant should also provide information on the expected impact and efficiencies achieved from planned joint programming for the two diseases including cross-cutting health systems strengthening as relevant.

3.1 Programmatic Gap Analysis

A programmatic gap analysis should be conducted for the six to twelve priority modules within the applicant's funding request. These modules should appropriately reflect the two separate disease programs in addition to cross-cutting modules for both programs such as Health System and Community Systems Strengthening.

Complete a programmatic gap table (Table 2) for 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 (Table3).

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 in the narrative section below.

HIV

The country aims to intensify and consolidate prevention services with focus on key populations as well as the general population, and in promoting universal access to comprehensive care, support and treatment services. Though there has been massive scale up of prevention interventions as well as testing and treatment facilities over the last decade, challenges in the program remain, such as reaching the unreached both for testing and treatment, delayed testing and diagnosis, gaps in the retention cascade, with linkage loss at each stage of the care continuum. There is need to scale up, strengthen and decentralize service delivery mechanisms to improve coverage especially for key populations, women, rural populations and people living in hard to reach areas. Globally more than 50% of new infections are among KPs. The Targeted Intervention programme among KPs in India has a very important component of creating an enabling environment including community support so that access to testing and treatment can be enhanced without any coercive approach. Given the substantial HIV burden among key populations, it will be difficult to reach the 90-90-90 global target without dramatically expanding access to evidence- and rights-based HIV testing and treatment for these groups. Reaching 90-90-90 targets for key populations will not only demand service innovations and enhanced political commitment, but also establishment of an enabling environment and implementation of critical enablers to extend the reach, acceptability and impact of services. The programme plans to implement community-based testing and treatment at some pilot sites. It is important to reinforce combination prevention approach among KPs which is also reflected in existing TI package of services. These interventions are a part of theGoI/World Bank funded NACSP which adequately covers these activities. Hence,additional funds for these activitiesare not proposed under this NFM.

The changing face of the HIV epidemic, emergence of new pockets in newer geographic areas and limited access to services, have further necessitated the need for greater scale up of services to improve service access and serve the unserved. Moreover, the general health system in these areas are traditionally weak, and therefore the programme needs to supplement service delivery mechanisms under health systems. To prioritize interventions, the programme has done a recategorization of districts based on HSS data, program data from TI, ICTC, PPTCT and vulnerability of the districts due to migration and other risk factors. It is planned to set up ICTC/F-ICTC at least up to community health center level (CHCs) in all low prevalence states and saturate all A & B category districts with ART centres, and all C and select D (tough geographic

terrain) category districts with LACs. This decentralization is being done through DBS. The programme also needs to address quality-related issues of coverage saturation, retention in care, treatment adherence, data systems and use and quality assurance at all service delivery points.

The WHO's new 2013 guidelines on The Use of Antiretroviral Drugs for Treating and Preventing HIV Infection recommend a CD4 threshold of 500 for initiation of HIV treatment. As an important step towards getting to zero AIDS-related deaths, the programme is planning to adopt WHO guidelines for ART initiation and monitoring. Expanded eligibility for ART will provide new opportunities to save lives, improve clinical outcomes, act as a prevention tool by reducing transmission risks, and therefore lead to decreased HIV incidence. At the same time, this poses challenges to the national programme in terms of need for increased resources as well as implementation, and need to strengthen service delivery and monitoring mechanisms. It is proposed that priority will be given to key populations while initiating ART at higher CD4 cut off of 500. The programme also proposes to pilot the 'test and treat' strategy, including community-based testing for key populations to prevent transmission risks and reduce new infections significantly. The objective is to make ART available to all KPs who are tested HIV positive. The ART programme in India is more than a decade old but second line ART uptake is low. Immunological failure is detected very late, leading to continuation on failing regimen, accumulation of mutations and compromised future treatment options, thus necessitating the need for viral load monitoring for preventing emergence of drug resistant strains[23]. India is committed to PMTCT and the elimination of paediatric HIV and has rolled out lifelong ART for pregnant & breastfeeding women. However, PMTCT access, linkage and engagement ofthe private sector still remains a concern. Further there is need to strengthen health systems for ensuring quality HIV care and management in terms of infrastructure, capacity of HCPs both in public and private sectors for HIV diagnosis and treatment, and supply chain management. To focus on quality of services, there is need to build and sustain the capacity of staff engaged in testing and treatment services through enhanced supportive supervision. Programmatic gaps for HIV are listed in Table 12 below:

Table 12: Programmatic Gap Analysis for HIV

Gap	Challenge/Underlying factors	Strategies
Module: Treatment Care and Support		
• Gap in universal access to treatment • Delay in detection and ART initiation	• Currently ART coverage is around 67% against estimated need • Need for additional resources to expand eligibility criteria for ART initiation • Presently all ARVs are funded through Global Fund. In scale up plan, GoI will spend increasing domestic budget on ARV drugs contributing progressively to 20%, 50% & 70% of total requirement • Nearly 25% of the estimated population is still undetected • Delay in detection and ART initiation	• Early initiation of ART for robust immunological response thus reducing risk death, incidence of TB and transmission risk. • Decentralization of HIV testing up to CHC level in newer geographies and community based testing to improve access to testing services • Geographic prioritization for Scaling up of treatment services in new emerging pockets and to saturate all recategorized A, B & C

[23]Gonzalez-Serna, A., et al. "Performance of HIV-1 drug resistance testing at low-level viremia and its ability to predict future virologic outcomes and viral evolution in treatment-naive individuals." *Clinical infectious diseases* 58.8 (2014): 1165-1173.

• delayed diagnosis of treatment failure and low uptake of second line ART	• Low access to treatment in low prevalent states with emerging new pockets of infection • Leaky retention cascade with losses at each stage of care continuum • Only 256 CD4 machines are available for 1442 treatment facilities, necessitating sample/patients to travel. This leads to linkage loss and delayed initiation of treatment and poor monitoring. • Mismatch in testing & treatment sites. To reduce the gap NACO has initiated concepts of Facility integrated ART centre, Link ART centre and facility integrated ICTCs. • Insufficient supervision and mentoring mechanisms • Presently targeted viral load testing is done for all those showing immunological/clinical failure to 1st line ARVs. Late detection of failure leads to accumulation of mutation, compromised future treatment options and increase mortality.	Category districts with ART services. • Deployment of CD4 testing facility up to LAC, particularly point of care equipments • Training of all health care providers on HIV suspicion and PITC. • Strengthening capacity building and Supportive supervision for quality of services at ART sites- retention in care, OI management, HIV-TB coordination, ADR, drug logistics, referrals to other necessary services. • Scaling up care & support Centres to provide supportive services and outreach services to PLHIV in Pre-ART care as well as on ART • Scale up of viral load testing in a phased manner as a routine monitoring tool for PLHIV on ART.
Module: PMTCT		
• Coverage of HIV Testing and counselling among pregnant women is low at 49%, and as low as 10% among those accessing private health facilities or delivering at home. • Linkage loss at each step care continuum in PPTCT including care of exposed child.	• Inadequate community based services to those delivering at home (3.8 million) • Poor knowledge and health seeking behaviour, lack of involvement of spouses and family members, and inadequate access to PPTCT services closer to their residence • Even though majority of the private sector facilities routinely test the pregnant, very few facilities are willing to care for HIV+ pregnant women and the majority are not aware of and/or do not adhere to the national guidelines on PPTCT and don't report to the government.	• Strengthening community systems for PPTCT care continuum • Outreach services for linkages with PPTCT and RMNCH services, psychosocial support pregnant woman, spouse and family • Strengthening of HIV screening at sub-centre level (being done through DBS) • Engagement with private sector for sensitisation on PPTCT , reporting and referral linkages PPTCT care

	• Lack of engagement with private sector which caters for nearly 4.25 million deliveries annually. Majority of these facilities are not aware of and/or do not adhere to the national guidelines on PPTCT and don't report to the government.	
Module :HIS &M&E		
• Gaps in information systems • Need for better monitoring and supervision • Insufficient OR to guide programme policy • Limited systems and processes for reporting, analysis and monitoring of Adverse Drug Reactions (ADRS) due to ART	• Insufficient IT based monitoring systems for patient tracking • Limited capacity in data analysis and interpretation of HCP • lack of Drug resistance monitoring • HCP at ART Centres not capacitated in monitoring, grading, managing,recording and reporting ADRs	• IT based case reporting and patient tracking systems linked with UID • Strengthening M & E systems at ART Centres • Cohort analysis for survival outcomes • Strengthening of Pharmacovigilance programme Drug resistance monitoring for acquired and transmitted drug resistance • Supportive supervision • Strengthening of OR on program priority areas
Module: Program Management		
• Implementation and ensuring quality of services and reporting	• Need to strengthen Program management systems	• Strengthening Human Resources for Technical Assistance and Programmatic Management.

TB programme

The country envisions universal access to care for all forms of TB including DR-TB and HIV associated TB. Though incidence of TB has been declining, approximately one million cases are missed, i.e. a third of global estimates for missed cases. As discussed in section 1.2c, the major reasons identified for this gap includepoor engagement with the private sector, inadequate systems to cover key populations, and limited reach of the programme in difficult and hard to reach areas. Lack of awareness in the general population about TB prevention and care also restricts access to health services, thus contributing to missed cases. Further, treatment practices in the private sector are suboptimal, resulting in poor patient outcomes and continued transmission of disease.In addition, poor treatment practices outside RNTCP, poor case holding and lack of follow up has fuelled the DRTB epidemic in India, along with emerging new chains of transmission. The estimates for MDR TB cases are approximately 99,000 annually, including 62,000 MDRTB among notified pulmonary TB cases.The programme has considerable gaps in capacity for diagnosing and treating MDR TB. Diagnosis of TB and DR-TB in the paediatric population and PLHIV is especially challenging in view of the difficulty in obtaining an

appropriate sample for testing, and poor sensitivity of existing diagnostic technology. Geographic and social inequities further add on to the access issues in key and vulnerable populations. To address the these gaps, an integrated three–prong effort is required: i.) strengthening public health systems for early TB diagnosis and quality anti-TB services ii.) developmentof community systems for generating awareness, demand generation and capacitating the community for improved health seeking behaviour and contact tracing; and iii) strengthening engagement with the private sector for early diagnosis, notifications, management as per standards of TB care in India.Programmatic gaps for TB programme in India are enumerated in Table 13 below:

Table 13: Programmatic Gap Analysis for TB

Gap	Challenges/underlying factors	Strategy
Module : TB Care and Prevention		
• Undiagnosed and missing TB cases • Inappropriate treatment practices / poor treatment outcomes outside RNTCP • Poor access to TB care services in urban areas • Poor access to TB care services by key populations • Low detection of Paediatric TB cases	*Health Systems* • Patients not accessing the public health system, or accessing the systems late • Lack of quality care in private sector: Inappropriate and irrational treatment and lack of focus on treatment compliance • delayed diagnosis in both the private and public sector •Inadequate systems in Urban TB •Poor access to prevention and treatment services for vulnerable and marginalised populations including tribal, refugees, migrants, unorganized work and other marginalized population • Lack of engagement with private sector on a scale commensurate with their dominant presence *Community Systems* • Low awareness of TB prevention and care and related public services • Low and inappropriate Health Seeking Behaviour • Insufficient community systems to reach vulnerable populations, includingmigrants, unorganized workers and other marginalized population.	• Detect and mobilize symptomatic earlier through outreach, communication, and social mobilization. • Active screening for TB among socially and clinically-vulnerable populations—e.g. slum-dwellers, contacts of TB cases, diabetics, smokers • Widespread deployment of new higher-sensitivity TB diagnostic tests will detect more people early and accurately • Effective engagement of private providers will capture TB cases at their initial point of care, reducing delay and transmission • Improved patient- friendly treatment in both the public and private sectors will enhance universal access • Greater involvement of civil society is predicted to yield reductions in stigma, improvements in access and improvements in case finding by reaching the unreached. • Developing local inventories of vulnerable groups to deploy innovative targeted case-finding activities by strengthening community systems • Strengthening Human Resources for Technical Assistance and Programmatic Management. • Strengthening Operation Research to address the enormity

	• Lack of treatment literacy and continuum of care among patients • Lack of psychosocial support to TB patients and their family members.	of RNTCP and inform policy decision.
Module :MDR TB		
•Sub-optimal Diagnostic Capacity to reach out all DRTB Cases •Sub-optimal resources to address and manage all DRTB cases •Sub-optimal treatment outcomes.	**Health Systems** • Decentralization of DR TB treatmentcentres to the peripheral level. • Insufficient rapid diagnostics at district and sub district levelsin order to the need of the population in terms of disease burden • Insufficient capacity interms of human resources to implement, monitor and supervise PMDT scale up • Insufficient facility based counseling services **Community Systems** • Attrition of diagnosed MDR cases before treatment. • Ensuring compliance to treatment • Limited supportive services to patients and their families leading to poor outcomes. • Lack of support for prevention, treatment and continuum of care.	• Establishment and upgradation of additional DRTB sites and establishment of Airborne Infection Control measures • Establishment of CBNAAT labs in each district for improved Case Detection and Diagnosis • Establishing additional C-DST labs for follow up cultures of patients under treatment and for second line DST • Intensified supervision and monitoring of laboratory services • Strengthening Human resources (additional manpower and capacity building) for implementation, supervision and monitoring of PMDT services • Enhancing patient support systems by strengthening community care delivery

TB HIV- Cross Cutting

As discussed in section 1.3, the joint collaborative efforts towards diagnosis and management of HIV /TB co-infected individuals, reducing overall burden of HIV –TB in the country need to be strengthened and intensified.

Table 14: Programmatic Gap Analysis for TB-HIV

Gap	Key challenges /underlying factors	Strategies
Module :TB/HIV		
• Sub-optimal detection of HIV-TB co-infection • Delay and difficulty in diagnosis and	• Low HIV testing coverage among TB patients in low HIV prevalence areas • Sub-optimal linkages of HIV positive TB patients to the ART centres due to low number of ART	• Collocation of F-ICTC screening services at all DMC • Strengthening provider initiated HIV testing and counselling to all

management of HIV-TB co-infection • Sub-optimal treatment outcomes • Poor access to TB preventive services to PLHIV	and Link ART centres in low HIV prevalence areas • Drop out of patients during cross – referrals • Sub optimal symptomatic screening for intensified case finding among PLHIV especially for key populations • Non– availability of newer , more sensitive diagnostic technologies to detect TB in PLHIV • Overcrowding and limited air borne infection control practices at ART centres • Sub optimal monitoring system for TBHIV activities at treatment facilities • Sub optimal Programmatic collaboration at the implementation level. *Community Systems* • Lack of awareness about TB/HIV prevention and care • High level of stigma for TB and HIV • Inappropriate and poor health seeking behaviour • Lack of systems for community care delivery	presumptive TB cases, TB patients and their contacts. • Decentralisation and scale up of ART services • Single window services for HIV management and TB diagnosis and treatment • Strengthening 4 symptom complex screening in all HIV settings through trainings and supportive supervision • Deployment of better, rapid, sensitive diagnostic technologies for TB, collocated at ART centres which will give prompt and accurate results and lead to early treatment initiation and minimise linkage loss, particularly in cross referrals • Implementation Airborne Infection controlin congregate HIV settings. • Early initiation of ART(at CD4 count < 500) to reduce risk of TB and its progression • Strengthening joint programme management • Strengthening monitoring and supportive supervision for HIV /TB activities by positioning treatment coordinator • Strengthening and utilising community systems for HIV-TB • Strengthening community level linkages between both programmes • Symptomatic screening and contact tracing during outreach activities by ORWs, for key populations in particular

HSS

Table 15: Programmatic Gap Analysis HSS

Module : HSS	Key Challenges/ underlying Factors	Strategies
• NACP faces challenges of greater integration in the general health systems. • Lack of infrastructure for expanding ART services • Poor air-borne infection control practices at health care facilities • Poor capacity of general health system to monitor and supervise TB and HIV control activities • Uneven distribution of diagnostic capacity for TB and DRTB • Lack of adequate and properly maintained ware houses, weak cold chain monitoring mechanisms at State level, regional level and SDPs	• Over-burdened health systems with competing priorities • Insufficient capacity for HIV care and management with focus on KPs • Poor engagement with HCP both in public health system and private sector. • Varied levels of health infrastructure across the states • Ownership of general health system for air borne infection control practices • Establishment of additional programme management units (TU) • Enhancing access to laboratory services across all geographies. • Varied levels of capacities in states for systems of SCM • Lack of infrastructure for SCM	• Strengthen a capacitate health systems for maintaining quality of care • Capacity building of HCP both in public health system & private sector on early suspicion and referral for HIV testing • Decentralisation and strengthening of infrastructure at SDP for testing (FICTC) and treatment (LAC) and their alignment with health systems • Capacitating general health systems for mainstreaming HIV care through Centres of Excellence in HIV care which serve as training and research institutes • Strengthening SCM at State and SDP level • Centralized Cold Chain monitoring • Infrastructure development for warehouses at State and regional level including cold storage systems • Sensitization and capacity building of general health system to plan and implement air borne infection control • Decentralization and alignment of basic programme management unit of RNTCP (TU) to block level within general health system • Scaling up of laboratory capacity

Table 16: Programmatic Gap Analysis CSS

Module: Community System Strengthening

• Linkage loss at various stages of care continuum • Stigma and discrimination against HIV and TB • Lack of community systems in new geographies of HIV epidemic • Poor community engagement to respond to burden of TB disease	• Lack of awareness within communities on the importance of testing and treatment. • Lack of access to services for socio-economically deprived rural and in certain geographies communities. • High level of stigma associated with KP's and with people living with HIV or TB • Inappropriate and poor health seeking behavior • Lack of appropriate community leadership to inform and motivate communities. • Lack of opportunities to engage with the public system in formal situation to make changes possible	• Formation of Community Advisory Board (CAB) for Monitoring and advocacy of care and support for both the programmes • Strengthening Greater and meaningful involvement of people living with the disease, including greater involvement of people living with HIV/AIDS (GIPA) • Strengthening community response to TB care (establishment of TB patient forums) • Leverage community strength to solve problems and challenges • Capacity building of state level network and district level network of PLHIV and KP's. • Mentoring and Organisational Support for PLHIV Networks • Sensitization and involvement of Panchayati Raj Institutions (PRIs)

3.2 Applicant Funding Request

Provide a strategic overview of the applicant's funding request for TB and HIV, including both the proposed investment of the allocation amount and the request above this amount.Include the specific elements related to joint programming such as health systems and community systems strengthening. Describe how the request addresses the gaps and constraints described in sections 1, 2 and 3.1.If the Global Fund is supporting existing programs, explain how they will be adapted to maximize impact.

The India CCM requests a full expression of demand aggregating to a totalof 728.01 million USD (USD 362.10m for HIV &USD 365.91m for TB) including the savings from existing grants.The proposed Global Fund support is critical in view of the high burden of both TB and HIV, and in addition the contribution that India can make in reducing the global burden and thus interrupting chains of transmission. The National Strategic Plan (2012-17) of the HIV programme had not envisaged revisions in global guidelines on ART and PPTCT thus increasing the needs for drugs, diagnostics and related delivery services. Similarly, the NSP for TB had not provisioned for scale-up of diagnostic and management services for drug resistant TB, engaging the private sector on a large scale, active case detection, or offering decentralized rapid molecular diagnostics to presumptive TB cases among PLHIV and other key populations.

For the last 3 years, India has been unequivocally focussing on various interventions and reforms that would lead towards Universal Health Coverage. It is with this intent that both the TB and HIV programmes seek the support of Global Fund to address unmet needs despite having domestic and external investments to address all key populations, targeted interventions and garnering other extra-budgetary support for key areas of need. Towards achieving Universal

Health Coverage, India has committed to the Global targets and revised WHO treatment guidelines for ART initiation, addressing at scale, drug resistant TB, broad engagements with the private sector, ensuring demand and subsequent access for HIV services, and vulnerable populations including pregnant women and other underserved populations.

The proposed Global Fund support will help the country strengthen community and health system issues, and enhance access to lifesaving TB and HIV drugs. The proposed support will ensure continuum of care and sustain and strengthen integration of TB and HIV programmes. The strategic approach follows a 'Test, Treat, Follow up and Prevent' lifecycle approach for both diseases. The proposal puts adequate focus on building demand and strengthening supply of treatment, care and support to communities and key/vulnerable populations in need. By integrating services for TB-HIV, and by enhancing awareness about prevention and treatment, it is envisioned that the communities receive single window services, making it convenient and cost effective for patients, and addressing retention in care continuum.

HIV Program

The national program proposes to carry forward the goals and objectives of NACP IV by consolidating and strengthening achievements for reduction in new HIV infections and scaling up the programme to enable Universal Access to care, support and treatment facilities.The proposal has been worked out keeping theprogramme gaps and underlying issues discussed in Section 1.2c and 3.1 in mind, as well as the funding gap discussed in section 2.1. The proposal aims to: i. Scale-up Antiretroviral Treatment for universal access to reduce morbidity, mortality, TB co-infection and prevention of transmission, ii. developing and strengthening health systems and community systems for linkages, retention and quality care The proposal also aims to address the gaps in the efforts towards elimination of paediatric HIV in India. To summarize, the programme will follow strategy of early testing (HIV, ART eligibility and treatment failure), timely initiation on appropriate treatment, follow up for retention in care continuum and prevention of transmission, morbidity and mortality through early diagnosis and treatment. It is pertinent to mention here that the entire budget for prevention and testing services will be borne by GoI.

Module 1: HIV Treatment, Care, and Support

For scaling up ART, there will be a funding gap in view of the roll out of WHO guidelines and strengthening of HSS and CSS for service delivery to reach more individuals, particularly geographies of emerging localized epidemics. This has led to a re-estimation of budgetary requirement for care and support and treatment component. Of the total budget of USD 769 million required for treatment, care, and support during 2015-2017, 62 % is expected to financed by GoI , 27% has been requested under allocation and 11% under above allocation. In addition, ART services (ART Centres, Link ART Centres, and Centres of Excellence) are an integral of the health system and support for specialized care, admissions, and all investigations, except CD4 count and viral load. Limited HR comes from the general health system. During India's 2013-2014 fiscal year, all ARV drugs were funded by the Global Fund. The GoI will expand domestic budgetary support for ARV drugs, contributing 20%, 50% and 70% of total requirement in years one (2015-2016), two (2016-2017), and three (2017-2018) of the implementation period.

Intervention 1.1: Antiretroviral Therapy (ART):

Expansion of Eligibility criteria for early initiation of ART and Scale up of service delivery :ART is a high impact intervention not only to promote survival of PLHIV, but also to prevent HIV transmission and active TB in PLHIV. In line with WHO 2013 recommendations, national guidelines on ART are being revised and patients with CD4 count <500 cells/mm3 will

be eligible for ART (previously 350 cells/mm3). In addition, To further expandthe priority population groups which are eligible for ART initiation irrespective of CD4 count, (pregnant women, children under five years of age and PLHIV with active TB), the national program is considering expanding this to key populations (FSW, MSM, TG, PWID) living with HIV as well as HIV positive partners in sero-discordant relationships. Pilots are underway and will be planned to enable India to make this policy decision and create an implementation strategy. India requests funding to NACO for ARV drugs to support treatment for existing patients as well as the expansion of treatment to patients with CD4 count <500 cells/mm3. TDF+3TC+EFC fixed dose combination (FDC) is the preferred first line regimen. To accompany the new treatment initiation eligibility, India will use domestic resources under the NACP-IV to expand treatment facilities from 1,350 ART centres to 2,100 in low prevalence states where new infections are emerging. The Global Fund investment will supplement India's existing domestic resources which support the majority of service delivery costs including human resources, infrastructure, HIV prevention for key populations and other vulnerable populations, and HIV testing services.

Intervention 1.2: Treatment monitoring

***Expansion of CD4 testing*:**A significant proportion ofPLHIV still reach ART Centres very late and there are gaps in HIV detection and ascertaining ART eligibility. Therefore it is proposed to enhance treatment monitoring capabilities through scale up of CD4 testing through Global Fund support to NACO. Currently, CD4 testing capabilities are only available at 276 ART centres and funds would expand testing to 576 centres. Point of care CD4 testing equipment would be deployed in low prevalent districts with emerging new infections which currently have limited access. This would address gaps between diagnosis and treatment and result in earlier initiation of patients on ART.

Viral Load monitoring:India has adopted targeted viral load testing for those with suspected immunological failure, which is often detected very late, leading to continuation on failing regimen, accumulation of mutations and compromised future treatment options. Presently, the program has 9 viral load testing labs and aims to scale up to 39, to save more lives and to lower the risk of emergence of drug resistant strains. India requests Global Fund support to NACO to expand viral load testing facilities to 39, resulting in increased uptake of second line ART to 5% of total PLHIV, and prevent transmission of drug resistant strains.

Interventions 1.3, 1.4 and 1.5: Treatment adherence, Pre-ART care, counselling and psychosocial support:

To bridge the gaps in retention cascade and ensure quality of both in pre-ART care and ART care, there is need to strengthen capacity of HR involved at ART centres and Link ART centres for monitoring, counselling and follow up of PLHIV especially in relation to newer guidelines and strategies. The NFM will supplement programmes efforts in this regard to complement the expansion of ART services through adoption of treatment initiation at CD4 < 500 cells/mm^3. India requests funding to continue activities implemented by India HIV/AIDS Alliance at 350 Care and Support Centers (CSCs) currently funded by the Global Fund. The interventions aim to link PLHIV registered at ART centers with adherence counselling, psychosocial support, support group meetings, and needs- based referrals and linkages for both medical and non-medical needs. Treatment literacy, OI management, building community's knowledge on treatment and capacity building of the providers in literacy provision will be integral part of the interventions. Outreach workers at the CSCs support ART centres in the follow-up of PLHIV for retention and care.The CSCs currently reach 350,000 registered PLHIV (21% of registered PLHIV) and will contribute to an increase in coverage of PLHIV in HIV care, earlier initiation of patients on ART and a reduction in loss to follow up.

Module 2: PMTCT

Interventions:Prong 1: Primary prevention of HIV infection among women of childbearing age

Prong 3 - Preventing vertical HIV transmission

Prong 4- Treatment, care & support to mothers living with HIV, their children

NACP-IV PPTCT program targets 14,000,000 pregnant women to be tested for HIV. Currently only about 70% of estimated pregnant women in India are enrolled into antenatal care (ANC) and less than 60% of all deliveries are institutional deliveries. Out of these, only about 30% of women know their HIV status due to suboptimal access to testing facilities. Further, there are linkage losses at each stage of the care continuum. Though GoI will continue to support testing, the proposed Global Fund support will further contribute to elimination of new infections through a focus on pregnant women and exposed children. Interventions by Plan India focus on linking the community and private sector with government public health facilities to improve HIV testing coverage among pregnant women, ART initiation and continuation and HIV testing and care for exposed infants. Private sector interventions implemented by SAATHI include establishing public-private partnerships with hospitals, training of staff, establishment and/or strengthening of data reporting systems and improved quality of reporting to GoI, and strengthening of linkages between private sector and government testing centres (ICTCs) and ART centres.

Module 3: Community Systems Strengthening

Intervention3.1 :Community-based monitoring for accountability: Community Advisory Boards (CAB) will be established at all Care and Support Centres (CSCs) as a mechanism for monitoring ongoing performance and quality of all services, activities, interventions and other factors that are relevant to HIV, including prevention, care and support services, financing of programs, and addressing the enabling environment including discrimination and gender-based inequalities, which constitute barriers to an effective response to the disease and to an enabling environment**.**This will include external board member including KPs.

***Intervention3.2: Advocacy for social accountability*:**In order to strengthen the enabling environment for PLHIV and key populations to have access to prevention, care and treatment services, advocacy initiatives at district, state and national levels play a significant role. Funds are requested for India HIV/AIDS Alliance to support interventions at district level, in support of CSCs to conduct sensitization meetings, awareness programmes to service providers in government sectors, private sector, community leaders and district level nodal officers under different line departments of the State government. In addition, funds will support Discrimination Response Teams (DRTs) formed in each of the districts to support a response to any incident of stigma or discrimination towards PLHIV. Funds will support State level advocacy initiatives to increase PLHIV access to social entitlements and social welfare schemes in order to impact change at the district level. At a national level, funds will support joint PLHIV and government meetings aimed at effect policy change to impact the national response for care, support, and treatment for PLHIV.

Intervention3.3: Institutional capacity building, planning and leadership development:The India CCM requests funds for India HIV/AIDS Alliance to build the capacity of local organisations at the district level in a range of areas necessary for them to fulfil their roles in service provision, social mobilization, monitoring and advocacy. This includes support in planning, institutional and organizational development, systems development, human resources, leadership, and community sector organizing. This will include capacity building of networks , CBOs for treatment literacy and positive prevention.

Module 4: Health Information and M&E

Interventions: Routine reporting : In India, due to rapid scale-up of ART, many ART facilities face challenges in monitoring of large cohorts of patients without adequate patient monitoring systems. Furthermore, many people are lost between HIV diagnosis, ART registration, and ART initiation, and a more effective system to monitor programme linkages needs to be developed. In response to this need, support is being requested to strengthen ICT-based system for patient monitoring to have real-time data for programmatic decision-making. It is proposed to be linked with a unique identification (UID) to improve the tracking of patients to facilitate their access to social welfare and financial schemes offered by the government and allow for patient mobility between sites so that treatment is not discontinued when they are travelling.

Analysis, review and transparency: The programme proposes to strengthen M & E systems, conduct periodic programme reviews, and field visits. The programme also proposes to strengthen capacity for data analysis and interpretation of data for program performance, and to study treatment outcomes while having a regular mechanism for data dissemination.

Surveys:IT based effective case reporting and patient tracking system linked with UID for ART centre. Operations research, outcome and impact evaluations, and cost benefit/effectiveness analysis of various interventions under NACP are also proposed to be conducted.Research studies will be conducted on identified priority areas under national HIV AIDS research plan phase II .The research activities will be done with the help of ICMR, PHFI , NIHFW and other capable institutions

Module 5: Program Management

Funds are requested for grant management, including human resources, office operational costs at NACO as well as for trainings of SR staff, supervision from PR to SR, and by SR to SSRs, coordination meetings with stakeholders (i.e. NACO, SACS, and various departments of government).

Activities budgeted under NFM and their outputs have been described in Table 17. PR wise interventions, outcomes and budget is given in detail at Annexure 6. Detailed proposals of PRs are given at Annexure 7.

Table 17 : Overview of funding request for HIV

Activities planned	Key outputs/gains	Allocation in USDm
Module: Treatment, Care and Support		
Allocation • Early initiation of ART for robust immunological response • Increase in coverage with ART specially for key populations • Scale up of service delivery • Deployment of PoC CD4 machines to prevent linkage loss especially in low prevalence and difficult geographic areas. • Improved monitoring of treatment through phased scale up of viral load testing.	• Nearly 1.35 million PLHIV receiving ART • 2150 ART Centres and Link ART Centres to be functional in recategorized B & C category districts • 300 PoC CD4 machines to be deployed • Priority groups (children, pregnant women, PLHIV on ART for > 5 years) receiving viral load testing • Improved uptake of second line treatment. Nearly 5% of total PLHIV on second line. • Improved retention in care at all stages	208.711

• Strengthening treatment adherence, counselling and outreach through continuation of 350 CSCs.	○ Detectionto enrolment:88% (currently 82%) ○ Baseline CD4 testing: 95% (currently 91%) ○ ART initiation: 90% (currently 83%) ○ On Treatment LFU: 8% (currently 10%) • Optimisation of first line regimen in the program to prevent transmission of drug resistant strains	
Above Allocation • Improved monitoring of treatment through scale up of viral load testing • Third line ART • Training of personal in CST facilities, viral load and POC training for LT. • Development of training tools and modules. • Expansion of 125 additional CSCs for strengthening treatment adherence, counselling and outreach.	• 80 % of PLHIV on ART receiving viral load testing • Above allocation investment will have impact on quality of services and will lead to early initiation of treatment and better retention • % of PLHIV imitated on ART with baseline CD count less than 100 will decrease from current 20% to 10% • Improved retention in care at all stages ○ Detection to enrolment: 90%(currently 82%) ○ Baseline CD4 testing: 97% (currently 91%) ○ ART initiation: 92% (currently 83%) ○ On Treatment LFU:7% (currently 10%)	67.24
Sub-total		**275.95**
Module:PMTCT		
Allocation Plan India**:** Improved access to PMTCT in 212 priority districts of 22 states where present PMTCT uptake is between 7% and 45 % as per 2013 (March) data • improved linkages to testing, counselling and treatment facilities • Follow up of exposed children • Linking PLHIV from ICTC to ART SAATHI: Improved PMTCT coverage in private sector in 235 high load districts across 11 states and 2 Union Territories by mapping of private hospitals, signing of PPP-MOU with selected hospitals, advocacy and sensitisation of professional medical associations.	• 70% of pregnant women will be tested for HIV through PMTCT services • 90% of HIV positive pregnant women will be linked to ART related to PMTCT • Percentage/Number of infants born to HIV positive women receiving a PCR for HIV within 2 months of birth – 85%	**6.12**

Above Allocation Plan India**:** upscale of PMTCT coverage in 193 priority districts of 10 states and 4 union territories. SAATHI: expansion of interventions in 106 high load districts across 5 states and 3 Union Territories**.**	• 80% of the pregnant women will be tested for HIV through PMTCT services • 95% of HIV positive pregnant women will be linked to ART related to PMTCT • Percentage/Number of infants born to HIV positive women receiving a PCR for HIV within 2 months of birth – 90%	**6.79**
Sub –total		**12.91**
Module :Health Information System and M&E		
Allocation • Strengthening of ICT based systems for patient monitoring and tracking • Evaluation and operation Research • Field Visit review Meetings/Workshops/National+ /Workshops/State level	• Patient tracking through IT based systems linked to UID • Supportive Supervision of SACS and SDPs	**7.67**
Above Allocation • DR monitoring including EWI-recurring • Monitoring of adverse drug reactions	• ADR and TDR surveys to be done at 20 sites • ART Centres will be trained on monitoring of adverse drug reactions.	**2.00**
Sub-total		**9.67**
Module: Community System Strengthening		
Allocation • Community-based monitoring for accountability • Advocacy for social accountability • Institutional capacity building, planning and leadership development:	• Formation of community advisory board for monitoring and advocacy of care and support. • Reduce stigma and discrimination • Strengthening GIPA • Capacity Building of State Level Network and District Level Network of PLHIV	**2.07**
Above Allocation		
Expansion of above activities	• Formation of Community Advisory Board proposed for 125 CSCs	**2.77**
Sub-total		**4.85**
Program Management		
Allocation • Technical and Program management staff • Oversight of programme (CSCs), technical support coordination meeting, training of PR, SR and SSRs, audit and end line assessment. • Oversight cost of CSCs	Adequate technical and managerial for program implementation, management and supportive supervision	**13.85**
Above allocation	Expansion of oversight of activity CSCs	**8.93**
Sub-total		**22.77**

Total Allocation (including TB HIV - USD 11.86m)	**250.28***
Total Above Allocation (including TB HIV - USD 1.14m and HSS USD22.95m)	**111.82**
Total (excluding TB HIV and HSS)	**362.10**

*includes savings USD18m

TB Program

The current proposal builds on the vision of TB control articulated in the national strategic plan 2012-17 and focuses on those interventions which have a high public health impact and leverages existing resources, thus providing value for money. The current proposal would support the scale up and strengthening of interventions for TB care and prevention, HIV associated TB, Drug Resistant TB, engagement with the private sector, and program management. This proposal is focused on vulnerable populations, conceptualized to accomplish early, rapid and complete diagnosis of TB among these populations by enhancing access to appropriate technologies, processes and systems, and to improve outcomes of treatment by ensuring access to good quality drugs and promoting treatment adherence. It does not overlook the significance of strengthening program management, meaningful engagement of all care providers and prevention of airborne infection. The vulnerable populations targeted are PLHIV, children, urban slum dwellers, tribal populations, migrants and refugees. The proposed interventions have the potential to interrupt the chain of transmission, prevent emergence of drug resistance, improve outcomes among drug resistant TB cases and accelerate decline in incidence of TB including HIV associated and drug resistant TB as well as reduce mortality.

Module 1: TB care and Prevention

Under this module, the proposal aims at strengthening efforts of government for high impact interventions towards universal access to TB diagnosis and care and reduction in morbidity & mortality through the following approaches. These interventions have been prioritized based on situational analysis, programmatic gaps, and funding gaps, to reach underserved and hard to reach populations/areas.

Intervention 1.1: Case Detection and Diagnosis:

Detect and mobilize symptomatic earlier for diagnosis, treatment and care through outreach, communication, and social mobilization:A large proportion of cases are still missed in the country due to a passive strategy leading to huge delays before diagnosis & treatment initiation of infective cases, which allows continued transmission of infection during the disease. Therefore, it is planned to have targeted interventions by prioritizing identification of TB cases (early) in high risk populations using systematic screening. It is further planned to create awareness about prevention (targeted cough etiquette and anti-spitting education) and care, related public services, and generate health-seeking behaviour through outreach, targeted ACSM activities and community mobilisation. UNION and WVI will work towards enhanced case finding and contact tracing, targeting vulnerable and marginalized populations. In addition, sensitization, training of health care providers both in private and public sectors will lead to identification of presumptive TB cases and their linkage to appropriate diagnosis and treatment.

Widespread deployment of new higher-sensitivity TB diagnostic tests:Current tools like sputum smear microscopy used for diagnosing TB have limited sensitivity (under 50% in most settings). Hence, there is a need to deploy newer and rapid diagnostics like CBNAAT testing which has a higher sensitivity and specificity, while providing results within 2 hours. It is planned to have CBNAAT machines in each district. In addition to the existing 140 machines, and 300

under the procurement process, it is planned to deploy 200 CBNAAT equipment (90 under allocation &110 through above allocation) for early diagnosis of TB including Paediatric TB, Geriatric TB, Extra Pulmonary, TB HIV, and Diabetic TB suspects across the country through this proposal.

Intervention 1.2: Treatment

The program is committed to free TB treatment for all those diagnosed with TB. The program is also piloting innovative strategies for patient- friendly treatment (daily regimen, use of FDCs, flexi-DOTs. First Line Drugs for all TB patients including paediatric in 9 states (traditionally being funded by GF) for nearly 4 million patients are planned to be procured under NFM. UNION and WVI will work towards ensuring treatment adherence of patients diagnosed in project districts through the provision of a treatment adherence package, including counselling, use of mobile technology (sms/IVRS), home visits and flexi DOT.

Intervention 1.3: Engaging with all Care Providers

***Effective engagement of private providers for case finding and notification, ensuring compliance with standards of TB care – either through referral to public sector facilities or improved case management within the private practices, in line with national guidelines*:** Private healthcare providers are often the first point of care even for patients who are eventually treated in the public sector[24]. The intention of universal access to TB care for all patients may remain a distant dream unless TB patients in the private sector are provided quality TB management services. This generates a strong need for engaging the private sector beyond traditional Public Private Mix (PPM) approach. Substantial gains in TB control have been achieved through this concerted outreach to other health sectors, particularly medical colleges, public ministries and NGOs. Operationalization of this approach is further facilitated by partnership options which are recently approved by Government of India-Guidelines for partnerships (Annexure 8).The programme plans to establish mechanisms for PPM by creating a National Technical Working Group (NTWG), create a PPM Technical Support Group (PPM-TSG) for the national and state levels, establish PPM coordinators at district level, and by creating Private Provider Interface Agencies (PPIA). To ensure robust engagement of the private sector, the Government of India along with the State Governments of Bihar, Maharashtra and Gujarat are engaged in a unique endeavour for piloting the Interface Agency models in three cities – Patna, Mumbai and Mehsana. The lessons learnt through these pilots will help develop models for national scale up for engagement of private providers in the country. The followingstrategies are planned to more actively improve TB diagnosis, treatment and reporting by the private sector:

- Defining provider universe and engaging them on win-win situation: Private providers to be line listed, mapped as per their potential and need. PPs are engaged on one to one basis as per mutual need without adversely affecting financial and other interest of both stakeholders. This will help increase program engagementwith a large number of private providers in case finding for TB and HIV, and ensuring that engaged private providers comply with TB case notification according to the routine data collection system
- Reimbursement of cost of drugs: It is envisioned that cost of anti TB drugs for patients in the private sector will be reimbursed by the Government of India, thereby enabling receipt of free treatment services and motivate patient to comply with the treatment. This will also strengthen the notification system,the TB surveillance system, and will promote and ensure compliance with best practices in management of these cases – either through referral to public sector facilities or improved case management within the private practices, in line with national

[24]Hazarika, I. Role of private sector in providing tuberculosis care: evidence from a population-based survey in India. *J Glob Infect Dis*. 2011; **3**: 19–24

guidelines.

- Use of ICT techniques for Reporting, Monitoring, Provision of services and adherence tracking: The NIKSHAY, the real-time web-based system of reporting, is in the process of being scaled up to address all components of the programme for recording, reporting, clinical management, default retrieval, adherence monitoring etc. A system of missed call alerts and SMS to ensure compliance is being developed for monitoring treatment success rates of cases managed within the private sector and incorporating this into the monitoring framework. Monitoring will be in terms of number of patientsenrolled and proportion of patients complying with treatment. A robust M& E Framework and indicators will ensure reporting on treatment compliance of these notified patients through sub-recipients as per agreed and pragmatic benchmarks. The performance of sub-recipients (IMA and CBCI) will be tied to these agreed benchmarks and the programme will also extend necessary support and to partners to ensure achievement of these benchmarks.

Intervention 1.5: Community TB care Delivery

Greater involvement of civil society is predicted to yield reductions in stigma, improvements in access and improvements in case finding by reaching the unreached:RNTCP has identified community participation as one of the key strategies to achieve the TB-related Millennium Development Goals. This participation includes DOTs and treatment support by community members, community education, and advocacy for support from local administrative organizations. India has several robust community-based institutional structures (e.g.Panchayat[25],GaonKalyanSamitis[26]and MahilaMandals[27]), and a rich tapestry of communitybased organizations (CBOs), operating even in the most difficult areas of the country. These organizations are rarely utilized in the fight against TB, and represent a tremendously under-utilized resource to strengthen programme implementation. Project Axshya, a civil society initiative in Global Fund Round 9, supported various activities to involve community and community based organizations for TB care and control. Based on the experiences and learnings from the four years of the Project Axshya implementation, the component of Community Systems Strengthening will be an integral part of the NFM project design. Various activities will be conducted based on the six components of CSS:

- Enabling environments and advocacy – including community engagement and advocacy for improving the policy, legal and governance environments, and affecting the social determinants of health.
- Strengthening Community networks, linkages, partnerships and coordination – enabling effective activities, service delivery and advocacy, maximizing resources and impacts, and coordinated, collaborative working. Networking and partnership development between community and other actors, for access to services, particularly for the most affected population groups.
- Resources and capacity building so that community activities and service delivery evidence-informed and based on community assessment of resources and needs by using the network to map community health & social support services and their accessibility to end users.
- Organizational and leadership strengthening - including management, accountability and leadership for organizations and community systems.
- Monitoring & evaluation and planning - including M&E systems, situation assessment, evidence-building and research, learning, planning and knowledge management.

[25]Local village council government structures, empowered to engage with district authorities.
[26]Village-level committees formed under the National Rural Health Mission (NRHM), entrusted with community-level planning and implementation of health and sanitation, with representation from the local government (*Panchayat)*, local health centre and community.
[27]Community-level federations of women, sometimes encompassing several women SHGs

- Developing capacity of community groups/TB Forums on understanding information available at the local level, analyse the information for monitoring of activities

The funding requested under the proposal for The Union and WVI will primarily contribute to CSS.

Intervention 1.6: Key affected populations

Reaching socially and clinically-vulnerable populations with TB diagnosis, care and prevention: Specific interventions have been planned to address socially and clinically-vulnerable populationsunder NSP of RNTCP which are being funded through domestic budget and World Bank credit. It is proposed to strengthen and intensify the strategies to improvise diagnosis, treatment enrolment, adherence, and retention in KPs especially in underserved and hard to reach areas.

Urban Slums:*Urban Slums:**:* Nearly 65.5 million (31%) of India's population lives in urban areasThe slums in these urban areas have high population density, poverty, poor housing, overcrowding and sanitation and are particularly vulnerable to health inequities, inadequate social protection, discrimination, human-rights violations and stigmatization and limit access to health care services.[28]Special slum schemes to improve TB control in urban slums have been devised under the programme which includes sputum collection and transportation and setting up patient friendly treatment services. The program is engaging with NUHM to implement TB prevention and treatment interventions in urban areas which will improve access to TB diagnosis and treatment. However, there are several paucities leading to poor access to urban populations, which calls for special attention, even redesigning the TB interventions, including developing infrastructure and patient-centric services.Traditionally public health infrastructure in urban areashas been inadequate leading todelayed diagnoses, ineffective treatment (regimen issues as well as loss to follow up especially of migrant workers) and poor contact tracing. Large presence of private practitioners in urban areas with largely unregulated management practices for TB care further compounds the problem by inappropriate treatments and poor compliance leading to poor treatment outcomes.

*Strategy:*The proposed high-yield package of interventions for urban TB control is a multi-pronged approach that attempts to address several gaps that the national program has already identified and outlined in section 3.1 of the CN. It is proposed to cover urban slums in 210 cities (tier 2 and tier 3 cities of NUHM) through this project for improving TB case finding and control. The interventionsaim at:

- Active case finding in urban slums by mapping high-risk and vulnerable groups, slums, unauthorized colonies/residences, community care-givers and private TB services (qualified providers, corporate hospitals and private labs performing TB diagnostics including rapid tests) and active case-search by trained community volunteers in the urban slums of high-risk groups and contact tracing. The programme proposes to build capacities of community care-givers to suspect TB, identify cases, refer them, then reward community care-givers for positive referrals, visit qualified doctors and hospitals to help and encourage them in TB case notification and incentivize private doctors for TB case notification.
- Increasing access to diagnostic services including newer tools and referral mechanisms: Referrals (including sputum collection and transportation) of presumptive TB cases for diagnosis. Deployment of CBNAAT machines in a phased manner for early diagnosis.
- Special strategies to address migrants: Workplace interventions for migrant labourers working in the unorganized sector. This is proposed to align with the Migrant strategy of the National AIDS Control Program to reach migrants and cover them with TB services.

[28]http://www.stoptb.org/assets/documents/global/hrtf/Briefing%20note%20on%20TB%20and%20Human%20Rights.pdf

- Private sector engagement:Engagement with the private sector through professional organizations such as IMA, CBCI and PPIA for promoting Standards of TB care for diagnosis and treatment and free drugs linked to notification
- Strengthening community systems: Facilitate community referrals for reaching presumptive TB cases and linking them to diagnosis and treatment services. Further is theprogramme proposes to strengthen counselling services to MDR-TB, TB/HIV co-infected and paediatric TB cases. The program will also engage influencers and opinion leaders within slum clusters to community mobilization and with corporates for mobilizing resources under the corporate social responsibility.

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Children:RNTCP has established the vision that no child should die of TB in India. Progress towards this vision will require strengthening of relationships and engagement with private paediatricians, improving access to diagnosis, deployment of new diagnostic tools and case-finding approaches, and development of more child-friendly treatment approaches and regimens. However, diagnosis and management of childhood TB offers challenges, including obtaining specific biological specimen, mismatch in demand and supply of rapid diagnostic tools, non-availability of child-friendly formulations, DRTB formulations, ensuring quality at intake of certain preparations, pill burden and supervision of treatment. Active tracing of child contacts of smear positive TB patients and screening for TB and INH prophylaxis is recommended by RNTCP. The uptake of INH chemoprophylaxis has been suboptimal and needs to be strengthened.

Strategy: A pilot study with use of CBNAAT for early and rapid diagnosis for TB and EP TB amongst paediatric suspects in 4 major metropolitan cities of India revealed that by involving pediatricians based out of private sector institutions and private clinics there was a threefold increase in detection rates.[29]Based on the results from this pilot, the national program has now prioritized the use of CBNAAT for diagnosis of all paediatric TB patients across the country. Making DOTS more flexible and patient-friendly is also being considered, such as alternative approaches for DOTS wherein the mother or caregiver of the child can be the DOTS provider and child-friendly drug formulations can be provided. Specific interventions proposed under NFM will supplement programme's efforts for prevention of TB infection in children through contact tracing, IPT, and early detection and treatment of TB disease in children. Community systems will be strengthened for reaching children with TB contacts for prevention, diagnosis and treatment. The counselling component for treatment initiation and adherence will also be strengthened.

***Tribal Population*:** 8.6% of India's total population is tribal (approximately 104 million). 8.6% of India's total population is tribal (approximately 104 million). This population lives in concentrations in various parts of the country, some of them being Chhattisgarh, Jharkhand, Uttar Pradesh, Assam, Rajasthan, Orissa and Maharashtra. Studies in tribal populations indicate high prevalence of tuberculosis infection and higher ARTI at 3.9% (95% CI 3.5 - 4.3) in these communities.[30,31] Their vulnerability is attributed to high rates of poverty, illiteracy, smoking, and alcohol use, as well as harsh and isolated living environments, poor access to healthcare and poor health seeking behaviour. The programme has sustained focus to provide effective and quality services for tribal populations It has made several special norms and guidelines for better implementation in the tribal areas which include more incentives, human resources and smaller population size for designated microscopy centres when compared to the norms for non-tribal areas. The gaps in service provision to the tribal population have been studied through the 'Social

[29]Pilot study – "Accelerating access to quality TB diagnosis for pediatric cases in 4 major cities in India under RNTCP"
[30]Rao, V. G., et al. "Tuberculous infection in Saharia, a primitive tribal community of Central India." *Transactions of the Royal Society of Tropical Medicine and Hygiene* 102.9 (2008): 898-904
[31]Rao, Vikas G., et al. "Pulmonary tuberculosis: a public health problem amongst the Saharia, a primitive tribe of Madhya Pradesh, Central India." *International Journal of Infectious Diseases* 14.8 (2010): e713-e716.

Assessment Study under the Revised National Tuberculosis Control Programme' in 2011. This study revealed that limited improvements on certain aspects of the programme were achieved (access to services and awareness among the community) due to impediments to effective implementation of the RNTCP services and achieving Universal Access. Insufficient community engagement, non- involvement of traditional healers, remoteness of tribal populations from health services, and lack of appropriate awareness-building measures, results in delay and incomplete accessing of programmatic services by tribal population. It is imperative that a clear defined implementation process and structural arrangements be built up to engage the community, involve traditional healers and improve awareness of the community, each of which has been identified to be continually deficient, and the foremost reasons for vulnerability of tribal populations to various health problems and the problem of Tuberculosis particularly.

Strategy: Under this project, targeted Intervention in 80 tribal districts of India is proposed to expand and strengthen TB Control in tribal populations, covering a total population of approximately 320 million. These interventions include mobile vans for digital X- ray, and sputum microscopy for Geographically Remote Places (Spatial Targeting) for enhanced case finding. Community workers would be identified and trained to create TB awareness in the community and also identifying TB suspects to promote early case-detection and treatment adherence in the tribal population, and overall improvement in the quality of the services. It is also proposed to improve awareness on TB and RNTCP services through community based ACSM activities. It is expected that these interventions will to lead to an additional case finding of 23,100 TB cases from the intervention population and more importantly improve the 'Standard of Care' among these extremely deprived populations.

Refugees: The annual TB incidence in the Tibetan population in 2010 was 431/100,000, which is nearly three times the India's annual incidence of 185/100,000 in 2010. Lack of awareness, skilled HCP and extremely large pool of latent infections is a major issue. Besides this MDR TB is an emerging threat.
*Strategy:*Interventions are planned to significantly reduce the burden of TB and MDR TB among the exiled Tibetan population at 20 locations in India through Tibetan Voluntary Health Association (TVHA) as SR for TB awareness and community outreach campaigns, active case detection and contact tracing in settlement and congregate institutional settings and Capacity building in terms of health workforce and infrastructure development

Prisoners:There are 1,336 prisons across the country, with turnover of nearly 3,000 prisoners every day. Prison conditions can spread the disease trough overcrowding, poor ventilation, and weak nutrition. The majority of prisons in India have DOTS centres on the premises, and a large number also have microscopy centres. Prison DOTS centres are included in the RNTCP referral for treatment and transfer system.The category of population in prisons varies, turnover is also high, there is inadequate and/or inaccessible medical care and repeated prison transfers, and these issues affect the continuity of provision of services. Prison referrals and transfers, are not sufficiently accountable to the system.

Strategy: Interventions in urban areas will also reach out to this population with a specific focus on IEC, regular periodic screening , sensitization of prison staff, linkages with CBNAAT and treatment services.

Intervention 1.7: Collaborative activities with other programmes and sectors

NUHM: GoI is working towards strengthening urban health infrastructure with corporations, councils in all the states to provide access to quality diagnosis and treatment through NUHM. The program is engaging with NUHM to implement TB prevention and treatment interventions in urban areas which will improve access to TB diagnosis and treatment.

National Health Programmes (NPCDCS, NTCP and NACP):

- **Clinically vulnerable groups** such as Diabetics (with burden of ~62 million adult population), tobacco users, people engaged in risky occupations (Pneumoconiosis, silicosis etc) are proven risk factor for TB. Available evidence and modelling studies show that DM accounts for 15% PTB. Drawing the lessons from TB/HIV collaboration, efforts are being made to collaborate closely with the National programme for prevention and control of Cancer,Diabetes, Cardiovascular disease and Stroke (NPCDCS) and National Tobacco Control Program (NTCP) . NPCDCS is also planning ambitiously to cover the entire country with its services. The collaboration would evolve closely in line with developments in NPCDCS. It is planned to link tobacco using TB patients requiring higher levels of counselling or pharmacotherapy with appropriate support services in the National Tobacco Control Programme.
- **Migrants** are at higher risk of getting TB as well as HIV.It is planned to collaborate with migrant strategy of NACP for reaching out to migrant populations with TB prevention and care. Interventions for migrants are not budgeted under NFM

Other Ministries and Departments: The RNTCP is engaging with the Ministry of Labour and Mining to identify high priority districts with stone crushing units / mining industry to develop specific guidelines to support persons with an occupational risk for TB and provide access, diagnosis and treatment services from the programme

Intervention (others)

Strengthening Human Resources for Technical Assistance and Programmatic Management:For continuing and enhancing technical capacity for ensuring quality of services, it is proposed thatsupport for NRLs and CTD be provided (through technical assistance from WHO). For Grant management, sstrengthening of NPMU by expansion of existing NPMU at CTD, 6 new positions will be added(Consultant QA, Consultant AIC, Consultant OR and 3 Consultants for PMDT). In addition, 2 National DRTB Consultants and National Lab Consultant,4 consultants for Planning and Donor Coordination,PPM, M&E and TB-HIV and 5 Finance team members are also proposed at CTD. For field level, support to 6 NRLs, and 28 DRTB Field Consultants is proposed. For strengthening PSM, one NPO (Drug Logistics) at WHO Indiaalong with 1 Senior consultant, as well as 2 Consultants at CTD. Two Programme Assistants for administrative and financial support are also proposed.TA with necessary support functions is budgeted under this proposal. Under this project funds will be released to WHO through split disbursement mechanism.

Strengthening Operation Research to address the enormity of RNTCP and inform policy decision:Operational research is planned in the following areas: to evaluate interventions to minimize missed opportunities in diagnosis of treatment of pulmonary TB under RNTCP, to ensure early treatment of TB patients 'Referral for Treatment' in RNTCP, evaluate interventions for active case finding in high risk groups (clinically and socially vulnerable populations), to prevent treatment interruptions and default especially in tribal, slum populations and hard to reach areas, improve treatment outcomes in the private sector and for early diagnosis of pediatric TB under RTNCP. ICMR will undertake research primarily on identified priority research needs areas of RNTCP through the identified institutes. This activity will also be undertaken in collaboration with various partners such as Medical Colleges, Business Schools, Universities, Departments of Economics, TISS and others.

Module 2: MDR TB

Intervention 2.1:Case detection and diagnosis: It is proposed expand use of CBNAAT for identifying Rifampicin resistance cases amongst MDR suspects including retreatment cases, MDR contacts, PLHIV). 200 CBNAATequipmentbeing proposed under this proposal will cater for case detection and diagnosis of TB

Intervention 2.2: Treatment: There is need to establish and upgrade additional DRTB sites for decentralized delivery of DR TB treatment, which is being done through DBS. The country is already implementing baseline second line DST to all diagnosed MDR TB cases in six states to curb amplification of drug resistance and to diagnose drug resistance early, thus reducing morbidity and mortality of DR. The TB programme will leverage on the experience of the baseline and second line DST implementation to expand access to DR TB patients across the country**.** A Study[32] in the country demonstrated treatment success rate of >88% among a cohort of MDR TB patients treated with DST guided regimen. The DST guided treatment has now been approved by the MoHFW and the country is planning a five site implementation pilot. This initial experience will then be leveraged to scale up DST-guided treatment across the country.

Under the NFM, strengthening of existing C&DST labs is proposed, as well as establishing 30 additional labs for achieving diagnosis of MDR, XDR and FU of diagnosed patients. Thirty negative pressure air handling units will be established. Six NRLs will be upgraded with gene sequencing. Two hundred additional CBNAATs will be deployed at different levels across the country. Gene Sequencing labs for discordance resolution will also be established.

Intervention 2.3: Prevention for MDR-TB: The activities proposed under module 1 for early detection and treatment, ensuring compliance with standards of TB care – either through referral to public sector facilities or improved case management within the private practices, and focusing on treatment compliance and completion will help in prevention of MDR TB. Further CBNAAT testing at treatment initiation in all MDR suspects and MDR contacts will help in timely identification and treatment of MDR TB. Psycho-social support to ensure adherence and successful treatment will also cut down the chain of transmission of MDR TB. Infection control practices at DR TB sites are also being strengthened. This intervention is not budgeted separately under this module except for implementation of AIC measures at DR TB sites.

Intervention 2.4: Engaging all care providers: Interventions for engaging have been discussed in TB care and prevention module which will extend for all forms of TB

Intervention 2.5: Community TB care delivery

Enhancing patient support systems: The treatment outcomes for MDR TB have been sub-optimal.It is increasingly recognized that counselling of patients, their families and care givers is important and vital for the successful completion of treatment. Effective counselling is critical to helping MDR-TB patients cope with the side effects of MDR-TB treatment, treatment adherence during the length of treatment, stress and the need for social support. It is proposed to expand provision of counselling and psychosocial support to MDR-TB patients and care giversthrough a dedicated counselor in each district. Further, this will help reduce attrition of diagnosed MDR cases before treatment. The community systems discussed under Module 1 will also provide support for case detection, referral, and ensuring treatment compliance and retention in MDR treatment through outreach and psychosocial support to patients and care givers.

Studies show the treatment success among among individuals with nutritional support is statistically higher than those with poor nutrition.There are several state/district level interventions currently going for nutritional and social support mechanisms through NHM, state government funds and through Corporate Social Responsibility (CSR) initiatives.

[32]Rajeev Soman*et.all*

The national programme has mechanisms of enablers and incentives for better uptake and enhancing quality of services. Incentives for supporting treatment completion have been revised recently to increase acceptability. There are several good models of social support mechanisms from the states of Chhattisgarh, Kerala and Gujarat, but the country lacks any uniform mechanism to support TB patients. Now with the national health policy revision and concept of National Health Assurance Mission, the national programme is advocating for social support mechanism to be put in place for TB along with other diseases.

Intervention 2.6: Key Affected Populations: Interventions for key populations have been discussed in TB care and prevention module, particularly use of CBNAAT testing for socially and clinically vulnerable groups to identify drug resistance TB.

Interventions: Others

- Intensified supervision and monitoring of laboratory services: Budgeted under module 1
- Strengthening Human resources (additional manpower and capacity building) for implementation, supervision and monitoring of PMDT services: Budgeted under module 1. Counsellors at District level for MDR treatment support are being proposed.

Activities budgeted under NFM and their outputs have been described in Table 18. PR wise interventions, outcomes and budget is given in detail at Annexure9. Detailed proposals of PRs and SRs is placed at Annexure 10. Detailed Lab scale up plan and PMDT scale up plan is attached at Annexure 11a & 11b.

Table 18 : Overview of funding request for TB

Activities	***Output***	***Budget in million USD***
Module : TB care and Prevention		
Allocation: • Scaling up and expanding the use of newer rapid diagnostics for Paediatric, EP, Urban, tribal and marginalized group, including KPs • Active case search in slums and KPs and improving access to rapid diagnosis, prevention and care and treatment through community based approaches • Effective engagement with Private sector • Strengthening HSS and infrastructure, HR for service delivery, community outreach and Programme management	• No of TB cases notified from urban slums & KPs including paediatric: 150000 • No of TB cases notified from the private sector: 350000	76.01
Above Allocation • Scaling up and expanding the use of newer rapid diagnostics for Diabetic TB suspects and geriatric population, Paediatric, EP, Urban, tribal and marginalized groups including KPs. • Additional active case search in slums and KPs and improving access to rapid diagnosis, prevention and C&ST through community-based approaches • Support additional notification from Private sector with sensitization of PPs, Labs, Unqualified practitioners • Strengthening HSS and infrastructure, HR for service delivery, community outreach and Programme management • Conduct TB community mobilization, advocacy, intersectoral coordination meetings	• No of TB cases notified from urban slums & KPs: 25000 • No of TB cases notified from the private sector: 250000	41.88

Module : MDR –TB		
Allocation: • Treatment of diagnosed DR TB cases and drugs • Strengthening existing and increasing 15 additional C&DST labs for achieving diagnosis of MDR, XDR and FU of diagnosed patients. • Expand use of CBNAAT for identifying Rif resistant cases amongst MDR suspects • Establishing Gene Sequencing for discordance resolution • Strengthening HR and programme management for DR TB (budgeted under TB care and prevention) • Strengthening labs for NABL standards (ISO 15189) at 20 labs • Counselling to the MDR-TB cases (registered and under treatment in RNTCP) to ensure treatment adherence and successful completion	• No of DR TB drug courses: 24,200 (WHO PQP) • No of DR-TB cases diagnosed and put on treatment 135000* • No. of NRLs with Gene Sequencing: 2 • Labs to be supported for NABL standards: 20 • DR TB counsellors: 209	105. 68
*The Global Fund would support 24200 drug courses, Additional 28600 courses have been requested in above allocation. In the absence of request from programme not been agreed upon and as the government of India is committed to provide treatment to those diagnosed, the same would be procured through domestic resources as per the approved quality standards of GoI which are at variance from WHO PQP		
Above Allocation • Additional DR TB drug courses • Upscale of C-DST labs for improving access for achieving diagnosis of MDR, XDR and FU of diagnosed patients. • Increasing of establishing Gene Sequencing at 2 additional NRLs for discordance resolution • Strengthening HR and programme management for DR TB • Strengthening labs for NABL standards (ISO 15189) at all labs • Counselling to the MDR-TB cases (registered and under treatment in RNTCP) to ensure treatment adherence and successful completion to cover the entire country	• No of DR TB drug courses: 28,600* (WHO PQP) • No. of additional C&DST lab15 • No. Of NRLs with Gene Sequencing: 2 • Labs to be supported for NABL standards: 20 • DR TB counsellors: 491	111.00
Total allocation (IncludingTB HIV - USD 17.38m)		199.06*
Total Above-allocation (including TBHIV module-USD13.96m)		166.84
Total budget (excluding TBHIV module)		365.91

*includes expected savings 32.18 from existing grants .

Counselorsfor MDR TB, FLD, HR for PPM and TB –HV are proposed for 9 states which have been traditionally funded through Global Fund. In other states, these activities will be carried through DBS. Rest of the activities proposed are for all states

Cross Cutting
TB HIV

The national programs have created linkages and implementation mechanisms to support cross referrals, counselling and treatment services. As stated in section 1.3 and 3.1, there is further need to strengthen systems both in terms of infrastructure as well as coordination. Some of the activities listed under gaps, such as co-location of HIV screening at DMC, developing M& E systems, joint review and meetings, are being catered through domestic resources. The independent scale up of both HIV & TB programs for prevention, care & treatment, in terms of infrastructure, capacity, laboratory and access will contribute to strengthening health and community systems to address the gaps regarding HIV-TB intervention. Therefore, such activities have not been reflected under budgeted cross-cutting interventions. It is proposed to increase the number of Regional Coordinators (1 RC for every 15 ART centres) with focus on HIV -TB activity. It is proposed to have one HIV/TB treatment coordinator for every 5 ART Centres and attached Link ART Centres (15 LACs) to provide TB/HIV linkage at ART facilities. Strategies have been discussed in detail under section 1.3. The activities and budgets proposed for strengthening these coordination mechanisms through the NFM grant are listed in the table below:

Table 19 : Overview of funding request for TB-HIV

Activities	***Output***	***Budget in million USD***
TB HIV collaborative activities by HIV Program		
• Collocation of F-ICTC screening services at all DMC (being funded through DBS)) • HIV testing for TB patients ((being funded through DBS)) • Single window services for HIV management and TB diagnosis and treatment • Decentralisation and scale up of ART services * • Early initiation of ART(at CD4 count < 500) to reduce risk of TB and its progression* • Strengthening 4 symptom complex screening in all HIV settings* • Strengthening joint programme management and supportive supervision* (* budgeted under care and Treatment module) Allocation • Strengthening monitoring and supportive supervision for HIV /TB activities by positioning treatment coordinator • Implementation Airborne Infection Control in ART Centres. • Strengthening and utilising community systems for HIV-TB • ICF through symptom screening and supportive mechanism for TB-HIV linkages	• Significant increase in identification of HIV-TB co-infected. • 95% of those detected as HIV-TB coinfected initiated on ART • Decreased risk of TB in PLHIV initiated on ART by 50% • Active TB case finding in PLHIV and linking them to TB diagnosis • Symptomatic screening and contact tracing during outreach activities by ORWs More than 42,000 PLHIVs registered in the CSCs would be referred for TB • Better retention in care continuum both for TB & HIV • Strengthening community level linkages between both programmes	**11.86**

through dedicated TB/HIV outreach worker at all 350 CSCs.		
Above Allocation • Intervention among Key Populations on TB (ICF, Referral for testing) through CSCs	• Detection of TB in key populations	**1.14**
TB HIV collaborative activities by TB Program		
• Strengthening Provider initiated HIV testing and counselling to all presumptive TB cases, TB patients and their contacts. (not budgeted) • Strengthening cross referrals • Strengthening joint programme management (not budgeted) **Allocation** • Deployment of CBNAAT labs collocated/linked with ART centres for Active case finding amongst High HIV settings using appropriate new diagnostic tools • Provide counselling services to co-infected cases for treatment adherence and successful completion • IPT prophylaxis-Training, supervision monitoring and electronic reporting of data • Strengthening community level linkages between both programmes	• Percentage of TB patients knowing their HIV status: 78% • No. of PLHIV offered CBNAAT: 250,000 leading to prompt TB diagnosis and timely initiation of ATT and ART • No. of PLHIV will have access to IPT: 650,000 • No. of additional CBNAAT machines access for PLHIV: 90 (through GF) will lead to prompt and accurate results and lead to early treatment initiation and minimize linkage loss, particularly in cross referrals	**17.38**
Above Allocation • Extending the activity in additional areas for Active case finding amongst congregate HIV settings using appropriate new diagnostic tools • Provide counselling services to co-infected cases for treatment adherence and successful completion	• No. of PLHIV offered CBNAAT: 250,000 • No. of additional CBNAAT machines access for PLHIV: 110	**13.96**
Total – Allocation		**29.24**
Total - Above Allocation		**15.10**

Health Systems Strengthening:

Module: Health & community workforce

Health Workers capacity building: Integration of both HIV and TB with the general health system is necessary for early diagnosis and prompt referral for appropriate treatment. Programs are supporting decentralization and strengthening of infrastructure (including laboratory) for testing of TB DMC/ FICTC) and treatment (DOTS centres/ LAC) and their alignment with health systems. Centres of Excellence in HIV care, and National Institutes for TB which serve as training and research facilities are working towards capacitating the general health system for mainstreaming HIV and TB care respectively. Under this project, it is proposed to conduct

widespread sensitization of HCP in the general health system for suspecting, diagnosing and management of HIV & TB in patients as per standards of care/referral/reporting to national programme support. Further it is also proposed for advocacy and sensitization of the general health systems for universal precaution and infection control measures.

Module: PSM

PSM infrastructure and development of tools:

The large number of commodities used in each program, the quality issues and ensuring sufficient inventory without compromising on transparency and accountability in public procurement remains a challenge for both programs. The Central Government has since established an independent decision making body called the Centralized Medical Supply Services (CMSS) to streamline procurement and supply chain management.It is expected that once functional, CMSS will ensure appropriate, uninterrupted, efficient and transparent planning, purchase and distribution of quality medicines for health products and technologies for all national health programs. However, considering the vast geographies, the variety of commodities used under national programmes and varying capacities of states, there is need to ensure appropriate storage and distribution of medicines and other health products, for example increasing storage capacity, transportation, hardware and software for the procurement and supply management system. Support is requested for funding for supply chain management to expand the IT-based inventory management system (IMS) which monitors HIV commodities including HIV test kits and ARV drugs and for HR support at SACS level. Expansion of this system will ensure better monitoring and flow of stockand efficiencies in the system, and improve outcomes for patients. Infrastructure development of warehouses at State and regional levels including cold storage systems with centralized monitoring are also proposed under NFM to ensure appropriate storage capacity.

Table 20 : Overview of funding request for HSS

Module : HSS		
Activities	**Outcome**	**Budget**
Above Allocation • Training of HCP in health system and private sector on diagnosis & management and referral of HIV & TB • advocacy and sensitization of general health systems for universal precaution and infection control measures • Strengthening of SCM mechanisms • Centralised Cold Chain monitoring • Infrastructure development of warehouse at State and regional level including cold storage systems	• Timely and appropriate diagnosis and management of HIV & TB in patients as per standards of care and there referral/reporting to national programmes. • Practice of universal precaution and infection control measures in health settings • Proper information systems at state levels and below for SCM • Proper storage capacity for all commodities related to programme and monitoring of storage conditions	22.95
Sub –total		22.95

Summary of FundingRequirement

Programme	**Allocation**	**Above allocation**	**Total**
HIV	USD250.28m	USD111.82m	USD362.10m
TB	USD199.07m	USD166.84m	USD365.91m

3.3 Modular Template

Complete the **modular template (Table3)**.Note that the template allows access to modules that are specifically relevant to TB and HIV components, in addition to modules that are cross-cutting for both diseases.

To accompany the modular template, for both the allocation amount and the request above this amount, explain:

a. The rationale for the selection and prioritization of modules and interventions for TB and HIV,including those that are cross-cutting for both diseases.

b. The expected impact and outcomes of the interventions being proposed. Highlight the additional gains expected from the funding requested above the allocation amount.

a. The rationale for the selection and prioritization of modules and interventions for TB and HIV, including those that are cross-cutting for both diseases.

Modules and interventions for TB, HIV and HIV/TB have been selected based on the situational analysis of programmatic gaps, so that Global Fund investments can supplement efforts of national programmes to yield gains and make non-duplicative broader impact in reducing disease burden and saving lives.

HIV Program

In line with the gaps and strategies indicated under Section 3.1, the module following modules and interventions have been prioritized. These intervention will help the national program towards realisation of global goals of Zero AIDS related death, Zero New infection and Zero discrimination.

Treatment and care: Early initiation of ART reduces risk of progression to AIDS and/or death, TB, development of non-AIDS defining illness and increases likelihood of immune recovery and reduces transmission risks. For a rapidly developing country like India with a high burden of HIV, scaling up antiretroviral therapy preserves and strengthens the health and well-being of adolescents, and working-age adults on which future economic growth depends. Investing in HIV treatment generates economic returns up to three times the investment, increasing productivity, preventing children from becoming orphaned and deferring health care costs associated with advanced HIV-related illnesses. Further, India's HIV epidemic is concentrated in a few key populations and geographies. Early treatment initiation will help to curtail the chain of transmission and prevent HIV from becoming an epidemic among the general population and newer geographies. Implementation of expanded eligibility for ART initiation (with CD4 <500) and improving access in emerging new pockets in hitherto low prevalence sates requires scale up and strengthening of care, support and treatment, in terms of infrastructure, capacity, laboratory, commodities, monitoring mechanisms and community systems, to ensure quality care and retention of PLHIV. Therefore, achieving universal access to HIV treatment under the 2013 WHO guidelines will require a modest increase in HIV spending. This investment will be money well spent, as analyses have demonstrated that treatment is both cost effective and potentially cost saving over time. Further, as reflected from studies[33], drug resistance is also emerging as a potential threat and may nullify the gains made by the HIV programme in terms of reversal of epidemic and ART scale up in India. The proposed scale up of viral load monitoring will help detect immunological failure earlier and prevent transmission of drug resistant HIV virus strains in the community. For all the interventions proposed under this module, priority will be given to key populations, children and pregnant women. These investments under this module will support the national program towards achieving universal access and goal of 90-90-90 by 2020 (90 % of estimated PLHIV diagnosed, 90% with diagnosed HIV receive ART, 90%

[33]Balakrishnan, Pachamuthu, et al. "HIV-1 drug resistance among drug-naïve and HAART treated patients in India: Current status." *Regional Health Forum*. Vol. 15. No. 1. 2011.

of PLHIV on ART have viral load suppression at 12 months). The activities under this module will help achieving the NACP target of 50% reduction in new infections by 2017.

PMTCT: NACP is committed to the elimination of paediatric HIV, and PMTCT is a priority area for the program so that every child born in the country is free of HIV and leads a healthy life. In this regard, the national programme has set up an ambitious target of reaching all estimated HIV positive pregnant women and has developed a national strategic plan for PMTCT. However, the coverage still remains low. The reasons for this remain varied, from low health seeking behaviour to lack of awareness and access to HIV testing and treatment services, low institutional deliveries, and lack of private sector sensitization. The programme has priortized interventions in high ANC HIV burden districts. There is need to scale up this effort by strengthening linkages with NHM, engaging with the private sector and bridging the gaps in the leaky cascade of the PMTCT care continuum. In order to meet its global commitment to the elimination of mother to child transmission (<5%), India continues to improve PMTCT coverage among pregnant women, and treatment and care services to mothers living with HIV. The interventions under this module will supplement the efforts of the national program by providing lifelong multidrug ART to all pregnant and breastfeeding HIV positive women in the country and care of HIV-exposed children, and help India to reduce vertical transmission by 70% (from 2011 baseline) by end of this project.

Health Information System and M&E:Given the proliferation of data sources and need for effective use of data, it is imperative to identify the opportunities to strengthen generation, management and dissemination of data for better programmatic decisions. Nearly 4% of the available budget of NACP is earmarked for HIS and M & E. With the massive scale up of the programme, there is need to strengthen ICT-based information systems for patient monitoring, tracking, reporting and pharmacovigilance.Comprehensive, accurate monitoring and evaluation of activities allows clear assessment of achievements and gaps, as well as monitoring changes in the disease epidemiology, allowing future policy and programming to better meet the programme needs. The development of an IT-based effective case reporting and patient tracking system linked with a unique identification number (UID) for ART centres will strengthen referrals and will reduce losses over the continuum of care of PLHIV in care and treatment, as well as among TB/HIV co-infected patients. As ART coverage continues to grow, the national programme should perform routine surveillance of transmitted and acquired HIV drug resistance to optimize programme planning and management and to inform antiretroviral therapy policy. There is need for robust evaluation systems for outcome as well as impact evaluations of various interventions. The research activities will be done with high capacity institute like ICMR, PHFI and other capable institutions. The programme also needs to fortify operational research to guide program policy and future directions and adoption of high impact interventions.

Community System Strengthening: It is necessary to empower community systems by establishing and implementing mechanisms for ongoing monitoring of health policies, performance and quality of all services, activities, interventions and other factors that are relevant to the disease. CSCs' community advisory boards proposed under this project will serve as the backbone of the programme's community systems strengthening and ensure that PLHIV voices are directly informing the programme's ongoing implementation at every level. Discrimination Response Teams in CSCs will track reports of stigma and discrimination against PLHIV and coordinate timely responses to such cases. These mechanisms play a crucial role in creating enabling environments for PLHIV to increase service uptake and improve their quality of life.

Program Management: : In order to manage the activities under the GF grant, each PR will establish appropriate human resources, financial, technical and programmatic operations through a Program Management Unit (CPMU) consisting of program officer, Technical officer

and regional coordinators .This module will add to the capacity of the program in terms of policy, planning, implementation, monitoring & evaluation and supportive supervision.

TB Program:

The goal of RNTCP in the 12th FYP is universal access to TB care, specifically reaching out and improving outcomes in HIV associated TB, DRTB and patients treated in the private sector. RNTCP envisions forend of the Tuberculosis epidemic and Zero deaths, disease and suffering due to tuberculosis by ensuring universal access to quality assured TB care. The proposal under NFM has been developed based on a comprehensive TB control strategy to establish priorities for action, based on needs, effectiveness, feasibility and resources. The proposal aims at targeted interventions to improve access and ensure adequate diagnosis, treatment and follow-up of TB cases, building on partnerships with other service providers. In line with the national strategy and gaps indicated under Section 3.1,the following modules and interventions have been prioritized:

Module :TB care and Prevention:

The interventions under this module are expected to lead to increased case detection, and improved treatment outcomes resulting in prevention of TB transmission and emergence of DR TB. Based on epidemiological scenario, situational analysis, programmatic and financial gaps following interventions,under this module, are being proposed to be covered through Global Fund support.Prioritization takes into consideration disease epidemiology , differentials in disease epidemiology across geographies, issues related to access and needs of KPs .Prioritization also considers evidence generated through OR and program implementation.Technical approach and rationale for priotization have been discussed in detail under section 3.2.

Case detection and diagnosis : To accelerate declining incidence, there is need to reduce diagnostic and treatment delays by using more prompt, sensitive and accurate technologies for case detection. Country wide scale up of rapid molecular diagnostics proposed in this project has the potential not only to increase case detection but also to cut time to diagnosis, thus interrupting the chain of transmission.

Engaging with all care providers : A wide gap between the estimated cases and those captured by the RNTCP mandates intensification of engagement with the private sector. Further the diagnostics and management practices of the private sector are sub-optimal, and there is poor follow-up of patients to their logical cure. Often patients receive unstandardized treatment regimen, default treatment, thus resulting into continued chain of transmission and possible risk of acquiring drug resistance.

Key Affected Populations: Urban slum dwellers, children, tribal populations, prisoners, migrants and refugees being socially marginalized, are at great risk of getting TB infection. Social or economic inequalities that lead to exclusion limit access to quality health and other services. In addition certain groups such as PLHIV, Diabetics, tobacco users, people engaged in high risk occupations (Pneumoconiosis, silicosis etc), TB contacts are clinically more vulnerable to TB due to related co-morbidities. The aim of TB free India cannot be achieved without focused and customized approaches for enhanced support to these groups. This includesadapting services to the needs specific to these groups to make services people-centered and improve accessibility, appropriateness, and availability, thus encouraging them to access public services. Innovative diagnostic and treatment structures are necessary to meet the needs of key populations, e.g. through community-based TB care and prevention, mobile outreach to remote areas, community-based sputum collection, sputum transport arrangements, etc. TB-HIV, Urban slum dwellers, children, tribal populations/backward classes, and refugees are being proposed to be covered through interventions in this projectwhereas rest of the key affected populations, the

interventions are being carried out through domestic budgetary sources and enhanced collaboration with other national health programmes. Geographic priotization for these interventions has been done in a needs based manner taking into consideration thesub-national analysis to identify areas inhabited by these KAPs so that theprogramme can extend its reach to the underserved areas as well as unserved populations. Detailed intervention have been discussed in Section 3.2 under TB care and prevention module (KPs).

The proposal aims also aims at pediatric TB component. TB infection and disease in children is a reflection of ongoing TB epidemic in adults Moreover, children who are infected today will break down to disease in subsequent years or adulthood thus perpetuating the TB epidemic.Children themselves cannot access health services as the recognition of symptoms of disease and help seeking behavior for these symptoms are a function of the knowledge and motivation of the parents and caregivers. Children are also more vulnerable to acquire infection during growth period and are also unable to negotiate infection control practices. Specific Interventions proposed under NFM for prevention of TB infection in children through contact tracing and IPT and early detection and treatment of TB disease in children will result in decreased transmissible pool of infection.

Community TB care Delivery:To reach the key and vulnerable population, capacity building for community-level service delivery is necessary strengthening for community-based interventions and outreach services for TB patients. The interventions planned for community systems strengthening will help to establish and implement mechanisms for ongoing monitoring of policies and performance and quality of all services, activities, interventions, including prevention, care and support services, financing of programs, and of issues and challenges that constitute barriers to an effective response to the disease and to an enabling environment.

Module: MDR TB:

The emergence of DRTB strains in the country and their continued transmission in the community due to poor and sub-optimal resources to diagnose and treat such cases, have the potential to reverse the gains made by the National programme in TB Control. There are recent reports of DRTB among treatment naive patients, thus indicating the need of addressing this impending threat of DRTB on war footing. The situation is further compounded by the highly resourceintensive nature of services to address this problem. The treatment of DRTB is not only very expensive but also very complex and lengthy. A large number of patients drop-out of treatment due to side effects, lack of social support, and thus continue to transmit the infection in the community. Recent analysis of program data from the upfront use of CBNAAT and subsequent modelling, has shown that 180,000 cases of MDR TB will be averted between 2015-2025, turning an increasing MDRTB epidemic into a diminishing one.

To cater for huge burden for DRTB in the country, it is proposed to scale-up diagnosis, care and management of DR-TB in 36 states/Union Territories of India resulting in the initiation of treatment of more than 60,000 annual cases of Drug Resistant TB (DR-TB) by 2019 and follow up management of all such cases. To strengthen supportive services, treatment compliance for better outcome, and provision of adequatehuman resources for counselling the MDR-TB patients during treatment is required.

Cross-Cutting Modules:

HIV –TB:

Though the HIV prevalence in India is low in adults, (0.27), due to large population this translates into high absolute number (2.1 million). TB remains the most common opportunistic infection among PLHIV, causing considerable morbidity and mortality and adversely affecting quality of life in these patients. An estimated 120,000 TBHIV co-infections emerge annually, making India the 2nd highest TBHIV burden country globally. Further the diagnosis of TB in PLHIV is challenging due to atypical presentation of disease, low sensitivity of smear microscopy and most

of the patients presenting with signs/symptoms of EPTB. The treatment outcomes in TBHIV co-infected patients are also poor sub-optimal with high mortality. Early detection of TB with the high sensitivity diagnostic tool reduces mortality and improves quality of life. This is further complicated by the drug-drug interaction between ARV and ATT which needs special skills for early identification and management. PLHIV being immune-compromised carry increased risk of contracting infection with TB bacilli due to its air-borne mode of transmission especially in congregate settings where both TB and HIV patients are managed. The 3Is strategy of Infection control, Intensive case finding and IPT among PLHIV have the potential for prevention of transmission of infection, reduction in development of active TB disease among those infected, and early detection of disease. Implementation of 3Is strategy would help the program in reducing the burden of TBHIV coinfection. To improve outcomes among HIV-infected TB patients, it is necessary to reach HIV TB coinfected patients with appropriate diagnostic tools and comprehensive management. In this regard, it is proposed to link all ART Centres with CBNAAT testing in addition to the efforts already being implemented by the programme. It is also proposed to start ART early in all PLHIV (CD4 count <500). Early initiation of ART reduces the risk of TB in PLHIV by 50 to 70%. Further, to prevent TB in HIV patients, it is proposed to provide support for INH prophylaxis and infection control practices.

HSS:

Health & community workforce: The states do not have uniform capacity, commitment and resources, which leads to varying levels of program implementation. Individually the programs, within the ambit of National Health Mission (NHM), have made efforts to strengthen the health systems through provisions of human resources, strengthening health infrastructure, capacity building and commodity assistance. Some of the key challenges faced in delivery of quality services in TB and HIV include poor health infrastructure, inadequate human resources and sub-optimal logistic systems. The decentralized nature of service delivery on an ambulatory basis by frontline health workers for both programs poses special challenges in terms of early identification, diagnosis and management for both diseases. Further, the private sector which caters to more than three fourths of the population remains largely unorganized and unregulatedTherefore, there is need to strengthen health systems for early and appropriate diagnosis, management and referral and linkages mechanisms by sensitizing the health care workers both in public as well as private sector. This will help to integrate both HIV and TB programmes within the general health system in the long term.

PSM: Given the vast geography, and the large number of commodities used in each program, the systems for SCM also remains a issue of concern for effective and continued service delivery. There is need to strengthen systems and infrastructure for procurement and supply chain management for ensuring quality and sufficient inventory.

b. **The expected impact and outcomes of the interventions being proposed**

HIV

Impact:

- Annual incidence of HIV infection:50% reduction in HIV incidence from 2007 baseline
- AIDS related mortality: 30 % reduction in mortality from 2011 baseline
- New HIV infections among children : 70 % reduction in mother to child transmission from 2011 baseline (14,000 children acquired HIV infection in 2011)

Table 21: HIV-Summary of interventions, expected outcomes and additional gains from above allocation amount

Intervention	Expected Outputs/ Outcomes	Additional gain from Above allocation amount

Module 1 :Care , Support and Treatment		
PR :NACO		
Scale up of Antiretroviral treatment for Universal Access • Expansion of eligibility criteria for ART initiation to save lives, reduce morbidity, TB co infection and transmission risks • Scale up ART services, particularly in erstwhile low prevalent states where new infections are emerging to improve access and strengthen retention cascade	▪ **Output:** no. of treatment facilities will be scaled up from 1350 to 2100. Facilities will be decentralized to sub district level ▪ **Outcome** : improve access to care , support and treatment 1.3 Million PLHIV will be put on ART by Dec 2017 ▪ 80 % of PLHIV against estimated need to be on ART	Third line ART &OI drugs **Output :** around 4500 pts will be put on 3rd line ART **Outcome:**reduced mortality & morbidity in treatment experienced patients.
Strengthening of treatment monitoring Deployment of POC CD4 equipment in low prevalence districts where the existing diagnostic facilities are limited and access is low, to bridge gap between testing and treatment, and start patients on ART early	▪**Output:** No. of CD4 facilities will increase from 276 to 576, covering all ART centres. This will decrease linkage loss. ▪**Outcome:** Increase in baseline CD4 testing from 92% to 97% and improved regular six monthly CD4 monitoring	Capacity building of staff engaged in ART on patient monitoring and retention in care
Strengthening of treatment monitoring Viral load testing The VL testing for patients on 1st line ART to be scaled up in a phased manner over a period of 3 years.	▪ **Output:**No. of viral load facilities will be scaled up from 9 to 39 over the project period. Viral load monitoring of PLHIV on ART for priority groups (patients who are on ART for 5 years, pregnant and lactating women, all children < 5 years of age) ▪ **Outcome:**Uptake of second line ART to increase to 3% of total PLHIV on ART from current 1.2%	Viral load monitoring of 80% PLHIV on ART ***Outcome*:** Timely initiation of second line ART to reduce transmission of drug resistant strains of HIV
PR :India HIV/AIDS Alliance		
Treatment adherence, counseling and psychosocial support Strengthening treatment adherence with continuation of already existing 350 CSCs. Need to be sustained and scaled up for 125 more CSC	▪ ***Output:*** 0.35 million PLHIV registered in the ART centre (both On ART and Pre ART) would be provided care and support services through care and support centres. ▪ ***Outcome:***Improve the quality of live of PLHIV with reduction in LFU from 8% to 5%	125 CSCs in addition to the 350 existing CSCs will increase in reaching more 20% clients, reduce LFU cases, and improve quality of live of PLHIV
Module 2 :PMTCT		
PR :PLAN India		

Prong 3: Preventing vertical HIV transmission: All pregnant women will be targeted to access PPTCT services in 212 high load districts in 22	**Outcome:** • Percentage/Number of pregnant women who know their HIV status : 1st yr 35%,2nd yr 70% & 3rd yr 70% • Percentage/Number of HIV positive pregnant women who received antiretroviral to reduce the risk of mother to child transmission1st yr 45%, 2nd yr 90% & 3rd yr90%. • This activity will additionally lead to improvised ICTC-ART linkages for general clients (90%)	With the Above Allocated amount the project will be expanded in to additional 193 districts in 10 States and 4 Union Territories.
Prong 4: Treatment, care & support to mothers living with HIV, their children Provide Care, support to mothers living with HIV and their children and families – by increasing community involvement in 212 districts in 22 states	▪ **Output:**positive pregnant women followed up after delivery ▪ **Outcome:** Percentage/Number of infants born to HIV positive women receiving a PCR test for HIV within 6 weeks of birth : 1st yr 45%,2nd yr 90% & 3rd yr 90%	With the Above Allocated amount the project will be expanded to additional districts in 10 States and 4 UT.
PR :SATHI		
Prong 3: Preventing vertical HIV transmission Engaging with Private sector • Number and % of pregnant women who know their HIV status (in private health sector)	• ***Output:*** 17, 68,576 pregnant women reached Year 1: ANC coverage 736,140 (2.8% of country's 26.4 million deliveries) Year2: ANC coverage 809,754 (3.1%) Year 3: ANC : 2, 22, 682 (0.8%)	**Additional output:** 4, 08,801 pregnant women reached Year 1: ANC coverage: 161,400 (0.6%) Year 2 ANC coverage: 194,040 (0.7%) Year 3 ANC :53,361 (0.2%)
Prong 4: Treatment, care & support to mothers living with HIV, their children Linking positive pregnantwomen in Private sector with PPTCT/ART and follow up of exposed children for EID ▪ Number and % of HIV-positive pregnant women who received antiretrovirals to reduce the risk of mother-to-child transmission (in private health sector) ▪ Nos. and % of infants born to HIV-positive women receiving a PCR test for HIV within 2	▪ ***Output:*** 4,471 HIV positive pregnant women started on lifelong ART Year 1: 1,325 (3.5% of national PPTCT burden of 38204) Year 2: 2,266 (5.9% of national PPTCT burden) Year 3: 880 (2.3% of national PPTCT burden)	▪ **Additional output:** 6659 Year 1: 2021 (5.3% of national PPTCT burden) Year 2: 3304 (8.6% of national PPTCT burden) Year 3: 1334 (3.5% of national PPTCT burden**)**

months of birth, (in private health sector)		
Module 4 :Health information system and M&E		
PR : NACO		
Routine reporting: Strengthening of ICT based patient monitoring systems and linking them to UID **Analysis, review and transparency:**periodic reviews and field visits, data analysis and dissemination **Surveys:** Operations Research and outcome and impact evaluation studies, Drug Resistance surveys, monitoring of adverse drug reactions (ADRs)	**Output :** • Integration of PLHIV database with UID • **Outcome :** Improved retention in care due to ICT based monitoring and tracking systems better management	• Roll out of ADR and TDR surveys at select sites • Nearly 300 ART centres will start reporting adverse drug reactions in 1st year 400 in 2nd year and 500 in 3rdyr of program
5. **Community system strengthening**		
PR :India HIV/AIDS Alliance		
Community-based monitoring for accountability Advocacy for social accountability Institutional capacity building, planning and leadership development	All 350 existing care and support centres will form Community Advisory Board (CAB) for monitoring the care and support activities and also to support the advocacy initiatives. **District Level Discrimination Response Team (DRT)** to reduce stigma and discrimination and activities to foster Greater Involvement of PLHA (GIPA) also will be part of Community System Strengthening **Capacity building of SLN and DLNs and Mentoring of PLHIV network organization**	With the establishment of 125 additional CSCs, key activities to strengthen the community system strengthening such as formation of Community Advisory Board and District Level Discrimination Response Team (DRT) will be established.
Module :Program management		
PR :NACO		
Technical and managerial support for national & sub-national level	▪ **Output**:Technical and managerial support to NACO and SACS in form of PO, TO and regional coordinators ▪ **Outcome** : strengthening program management unit at NACO & SACS	Not requested

Priority of proposed activities to be supported by above-allocation:

- Improved monitoring of treatment through scale up of viral load testing so that at least 80% of PLHIV on ART receive viral load testing in year

- Timely switch of ART by evidence through HIV Drug resistance survey and substitution through pharmacovigilance data
- Provision of third line ART for pt failing on 2nd line (around 3000 pts will be provided 3rd line over 3yrs)
- 125 Additional CSCs for strengthening treatment adherence, counselling and outreach including ICF through the 125 additional CSCs and integrated community and home based approach
- Improved PMTCT coverage in 193 priority districts of 10 states and 4 union territories (Plan India)
- Improved PMTCT coverage in private sector in 106 high load districts across 5 states and 3 Union Territories
- Human resource, training, supervision, technical assistance activities, and office cost of PR & SR
- Training of Health care providers at the ART Centres where Doctors, Nurse and other faculty members from the institution will be trained on Universal Work Precautions and training of private practitioners.
- Community System Strengthening through establishing CAB in 125 additional CSCs and capacity building, mentoring and organizational support for district and state level PLHIV networks

TB program

Impact

- Reduction in TB prevalence rate in India from 230 per 100,000 people (WHO estimated burden -2012) to 196 per 100,000 people by
- Reduction in TB incidence rate in India from 176 per 100,000 people (WHO estimated burden -2012) to 163 per 100,000 people by 2017
- Reduction in TB mortality rate in India from 22 per 100,000 people (WHO estimated burden -2012) to 18 per 100,000 people by 2017

Table 22: TB: Summary of interventions, expected outcomes and additional gains from above allocation amount

	Intervention	Expected Outputs/ Outcomes	Additional gain from above allocation amount
MODULE -1: TB Care and Prevention			
1.1	Case Detection and Diagnosis	▪ **Output:** approximately 3 million TB suspects will be examined. ▪ **Outcome:** an additional 10% increase in case notification.	• No of TB cases notified from urban slums & KPs and paediatric cases: 25000 • No of TB cases notified from private sector: 250000 Additional Geriatric and Diabetic TB suspects tested:280000
1.2	Treatment	▪ **Output:** Approximately 400,000 patients will be put on first line TB treatment in 9 states annually ▪ **135000 DRTB** cases to be treated with Second line drugs across the country ▪ **Outcome:** treatment success rate will be more than 85% in new smear positive TB cases.	
1.3	Prevention	▪ INH prophylaxis will be administered to paediatric	

		contacts of bacteriologically confirmed TB cases. 650,000 courses of INH will administer to paediatric contacts annually to prevent transmission of TB.	
1.4	Key Populations	▪ ***Output:*** 11,000 additional TB cases will be notified to the national program from tribal districts. The urban initiative will contribute significantly to overall case detection as mentioned in intervention 1.1. ▪ ***Outcome:*** Through these interventions the national program seeks to increase awareness and decrease incidence of TB and MDR TB among these key vulnerable populations.	▪ 12100 more TB cases to be detected in the tribal population ▪ At least 25000 TB cases will be identified from vulnerable and marginalized populations
1.5	Engaging all care providers	▪ ***Output:*** A total 2856 health facilities under CBCI CARD will be reporting as PHIs under the program. ▪ ***Outcome:*** These interventions will contribute significantly (350,000 towards case detection and treatment outcomes of the national program.	▪ Additional 150,000 TB cases will be notified to the programme ▪ No of qualified doctors sensitized on STCI and TB case notification: 5000 ▪ No of RHCPs & AYUSH sensitized/re-sensitized on TB: 23500 ▪ No of private labs sensitized on TB: 700
Module-2: MDR TB			
2.1	Case Detection and Diagnosis	▪ 30 additional C&DST laboratories will be upgraded. ▪ 30 negative pressure air handling units will be provided. ▪ 6 NRLs will be upgraded with gene sequencing. ▪ 200 additional CBNAATs will be deployed at different levels across the country. ▪ ***Output:***650000 DSTs will be performed, 1000 key lab staff will be trained in rapid diagnostics. ▪ ***Outcome:*** 135000 MDRTB will be detected and treated from all these interventions.	▪ 880000 MDR TB suspects will have access to diagnosis for early case detection
2.2	Treatment	▪ Second line drugs will be provided to 49800 MDR TB patients and 3000 XDR TB patients from this grant which is 50% of the total MDR and XDR of the country.	▪ 26800 out of 49800 MDR-TB Cases and 1800 out of XDR-TB cases to be treated with adequate supply of second line drugs

		▪ 700 MDR TB counselors will be placed in the country at district level to counsel MDR TB patients which will result in low default and high treatment success rates. ▪ Domestic budgets will leverage some of the interventions such as trainings etc.	▪ 491 DR-TB counselors to be placed at district level for MDR-TB patients to address drop outs of follow up.
2.3	Prevention of MDR TB	▪ Air borne infection control measures will be taken in all DR TB centers across the country. ▪ 25 state teams will be constituted in States and Union territories to implement the AIC measures across health facilities across the country	

TB-HIV

India has two strong and mature public sector organizations to lead the effort in combating HIV and TB. Both programmes are working towards increased collaboration to integrate services for TB –HIV coinfected, and, more importantly, to ensure outcomes that protect the welfare of people who suffer from the two diseases. Details of the collaborative activities being undertaken to increase detection HIV-TB co-infected, provision of care and prevention of TB in PLHIV have been discussed in detail under section 1.3. Overall the investment under NFM will supplement the efforts of both programmes to achieve the following impact and outcomes:

Expected outcomes and impact:

- Reduction in TB TB/HIV mortality rate in India from 3.4 per 100,000 people (WHO estimated burden -2012) to 2.7 per 100,000 people by 2017
- Reduction in HIV- TB burden in the country
- Increase in detection of HIV-TB coinfected PLHIV by 10 % each year
- 95% of those diagnosed as HIV-TB coinfected initiated on ART

It may be noted that following activities are not budgeted under this module but will greatly enhance HIV-TB collaborations in terms of coverage, treatment outcomes and prevention

- Collocation of F-ICTC screening services at all DMC
- Single window services for HIV management and TB diagnosis and treatment
- Decentralisation and scale up of ART services *
- Early initiation of ART(at CD4 count < 500) to reduce risk of TB and its progression*
- Strengthening 4 symptom complex screening in all HIV settings*
- Strengthening joint programme management and supportive supervision*
- Strengthening Provider initiated HIV testing and counselling to all presumptive TB cases, TB patients and their contacts.
- Strengthening cross referrals
- Strengthening joint programme management

*Budgeted under other modules of NFM

The expected outputs/outcomes of the activities budgeted under HIV-TB module Intervention are given in Table 23 below.

Table 23 : TB-HIV -Summary of interventions, expected outcomes and additional gains from above allocation amount

Activities	**Expected Outputs/ Outcomes under Allocation funds**	**Additional gain from Above allocation amount**
Activities to be carried by HIV program		
NACO		
Strengthening monitoring and supportive supervision for HIV /TB activities by positioning treatment coordinator	***Output:*** Increased supportive mechanism for HIV – TB at facility level ***Outcome :*** *improved TB – HIV linkages*	Not requested
Implementation of Airborne Infection Controlin ART Centres.	***Output:*** all ART centers will have air borne infection control measures ***Outcome*** *: reduced incidence of TB among PLHIV*	Not requested
IHAA		
Strengthening and utilising community systems for HIV-TB ICF through symptom screening of PLHIV and their family members and supportive mechanism for TB-HIV linkages	**Output:** symptom screeningof PLHIV and their family members for TB and their **linkages for TB testing through a** dedicated TB/HIV outreach worker at all 350 CSCs. Out Come: At least 3% of HIV-positive patients who were screened for TB in HIV care or treatment settings. More than 42,000 PLHIVs registered in the CSCs would be referred for TB Testing.	The proposed grant will support the strengthening of the intensified TB case finding among PLHIV care settings including TIs, CSCs and DLN to additional 5750 PLHIVs
Linking key population to TB-HIV services	***Output:*** increased % of KP in TB and HIV detection, % of treatment of detected cases. ***Outcome*** % increase in HIV-TB co-infection detection and treatment	Reach to key populations such as IDUs, MSMs, TGs, FSWs with the Intensified TB Case finding through home based and community outreach will be increase. Hence increase in HIV and TB detection amongst such key populations will be ensured
Activities to be carried by TB program		
CTD		
Deployment of CBNAAT labs collocated/linked with ART centres for Active case finding amongst High HIV settings using appropriate new diagnostic tools	**Output:** All presumptive cases of TB amongst PLHIV to get CBNAAT testing done **Outcome:** Increased and prompt detection of TB in PLHIV leading to timely initiation of ATT and ART and minimizing linkage loss	Extending the activity in additional areas for Active case finding amongst High HIV settings using appropriate new diagnostic tools. No. of PLHIV offered CBNAAT: 250,000

		No. of additional CBNAAT machines access for PLHIV: 110
Provide counselling services to co-infected cases		Output: treatment adherence and successful completion Outcome : improvised treatment outcome
Introduction of INH preventive therapy to prevent TB among non – affected PLHIV	**Output:** 650000 PLHIV would receive IPT. **Outcome:** Prevention of TB in PLHIV	
Air borne infection control	**Output:**AIC practices to be implemented in and 92 DR-TB centers. Recording and reporting Health Care worker surveillance at all high risk settings **Outcome**: Reduced incidence of TB (MDR TB in particular) among PLHIV	
UNION & WVI		
Strengthening community level linkages between both programmes	**Output**:Establishmentof partnership with district level networks of PLHIV to engage them in TB control activities and subsequently improve detection of TB cases.	

HSS: Support has been requested under above allocation

Table 24 : HSS -Summary of interventions, expected outcomes

NACO	Activity	**Gains**
PSCM	Strengthening of SCM mechanisms and Infrastructure	**Output** :Infrastructure development for storage at SACS with facility for centralized cold chain monitoring for drugs and kits **Outcome** : better infrastructure at SACS for storage of drugs and other commodities
Health Workforce	Sensitization of HCP in general health system	**Output** : around 6,000 private practitioners and500,000healthcare providers will be sensitized in HIV and TB **Outcome:** reduction in stigma and discrimination. Improve referrals from the private sector, improved knowledge about HIV and TB care and diagnosis

3.4 This question is <u>not</u> applicable for Low Income Countries.

For TB and HIV, describe whether the focus of the funding request meets the Global Fund's Eligibility and Counterpart Financing Policy requirements as listed below:

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

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

India is a lower middle-income country and has provisions for 20% counterpart financing under the Global Funds Eligibility and Counterpart Financing policy requirements. Funding request focuses most of its budget (more than 70%) on underserved and most-at-risk populations and/or highest-impact interventions.

<u>HIV Program</u>

All activities proposed above, centres around patients living with HIV. This proposal aims at strengthening the efforts of government on high impact intervention towards universal access to ART for all PLHIV, reduction in morbidity & mortality associated with HIV, and movement towards the elimination of paediatric HIV. Most of the interventions in this proposal aim at improving access for prevention, care and treatment for key populations such as sex workers, MSM, TGs, Migrants, vulnerable groups, underserved populations in hard to reach areas, women (including pregnant women), children, TB coinfected individuals, across both high and increasing disease prevalence areas.

NACO: Scale up and decentralisation of ART centres, and Link ART centres from 1,300 to 2,100 is planned over a 2 year period, in districts particularly with rising prevalence. National AIDS Control Program in alignment with the National Strategy seeks to reach coverage of 1,253,004 PLHIV by providing them timely access to ART services by 2017. This will help to cover nearly 80% of the estimated PLHIV requiring ART and will be a giant leap in government's effort towards universal access to ART. Further to improve on morbidity and survival outcomes of PLHIV on ART, early detection of failure is enables timely switching to second line ART. Therefore, Viral Load scale up for patients on 1st line ART is planned to be scaled up in a phased manner. To maximise the impact, it is planned to prioritize viral load testing for patients who were initiated on ART prior to January 2007, HIV+ pregnant and breastfeeding women, patients with immunological failure, and all children < 5 years old. Laboratory systems strengthening with scale up POC CD4 facilities in low prevalence and hitherto underserved districts will benefit PLHIVs by leading to early initiation of ART and better monitoring of ART. These interventions will also provide impetus to interventions for HIV-TB by early diagnosis and treatment initiation. This investment will not only benefit PLHIVs, but also improve access of key populations to programme services.

HIV AIDS ALLIANCE: Scale up 125 Care and Support Centres in low prevalence states, and underserved areas with emerging pockets of new infections, and intensifiedTB case findingamong PLHIV with special focus on key populations. The focus will be on emerging pockets. Early linkages of PLHIV with focus on children, women and key populations to care and support, positive prevention, social and protection schemes is also planned within these activities.

SAATHI: The PPTCT program under NACP-IV targets 14,000,000 pregnant women to be tested for HIV. The private sector PPTCT intervention will be implemented across 11 states and two Union territories that are prioritized as per national PPTCT strategic plan. This geography contributes to 67% of the estimated national PPTCT burden and 89% of private sector PPTCT burden. A total of 1.76 million pregnant women (0.78 million/yr) will be tested for HIV and 4,471 HIV positive pregnant women will be identified and served during this project period

PLAN INDIA: During the project period a total of 36582305 pregnant women will be reached out and linked to PPTCT services. Around 10742077 will be adolescents and youth between age of 15 and 24 from high prevalence states and also states with rising prevalence like Gujarat and Odisha.

Tuberculosis Program

RNTCP is committed to addressing the healthcare needs of vulnerable and marginalized populations. The proposal aims at strengthening the efforts of government for high impact interventions towards universal access to TB diagnosis and care, and reduction in morbidity and mortality, particularly among vulnerable groups. Most of the interventions proposed, aim at improving access for prevention, care and treatment in the socially marginalized and vulnerable groups such as urban slum populations, HIV-TB coinfected individuals, women, children, tribal populations, underserved populations in hard to reach areas, prisoners, and refugees across high and increasing disease prevalence areas. The commitment of RNTCP to key populations is clearly articulated in the Social Action Plan, including a Tribal Action Plan (Annexure 12) wherein special provisions have been made for patient support and retention of HR serving these key populations.This will entail sustaining the achievements of the program to date, finding unreached TB cases, treating all cases well, and responding to MDR-TB and TBHIV**.** The Tribal Action Plan emphasizes: (a) strengthening early reporting, (b) enhancing treatment outcomes, and (c) closer supervision of tribal areas. Specific measures include: increasing case detection and treatment success trends in targeted districts with higher proportions of the population who are from tribal groups, reducing default rates of female patients compared to male patients, promoting locally adapted information, education and communication (IEC) messages and patient education material, and operational research to assist in planning and implementation of RNTCP in tribal districts.

CTD as PR will strengthen its' work towards improving access to diagnosis and treatment in all socially and clinically vulnerable population. Interventions are discussed in detail in section 3.2

Tuberculosis Program: Union

The proposed project focuses all of its efforts on vulnerable and most-at-risk populations located in 60 cities across the country as well as vulnerable sub-populations in 285 districts. The focus within these target sites will be on vulnerable population groups such as slum clusters, notified and non-notifiedTribal populations, prison inmates, migrants and homeless, PLHIVs, children, and elderly contacts of TB patients. Enhanced case finding strategies proposed in this concept note, are known to be high-yielding interventions and have also been proven in the ongoing Axshya interventions.

Tuberculosis Program: WVI

World Vision India and its NGO-partners will primarily aim to help the country to reach missing TB and TB/HIV co-infected cases from KAP (Key Affected Population) through a comprehensive, community-centric and all-care-provider engagement approach. Under the New Funding Model the proposal aims to notify 60,000 TB cases to RNTCP from 100 priority cities and 28,000 selected villages within 70 targeted districts in 8 states of India. Besides, the project will facilitate INH-prophylaxis for 6,000 children-contacts, provide home-based counselling services to 1,000 MDR-TB patients and assist 36,000 TB patients to know their HIV status

SECTION 4: IMPLEMENTATION ARRANGEMENTS AND RISK ASSESSMENT

This section requests information regarding the proposed implementation arrangements for this funding request. Defining the implementation arrangements for the program including the nominated Principle Recipients (PRs) and other key implementers is essential to ensure the success of the programs and service delivery. For the single concept note for TB and HIV, the Country Coordinating Mechanism (CCM) can nominate one or more PRs, as appropriate given the country context**.**

4.1Overview of Implementation Arrangements

For TB and HIV (including HSS if relevant), 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 PRs).

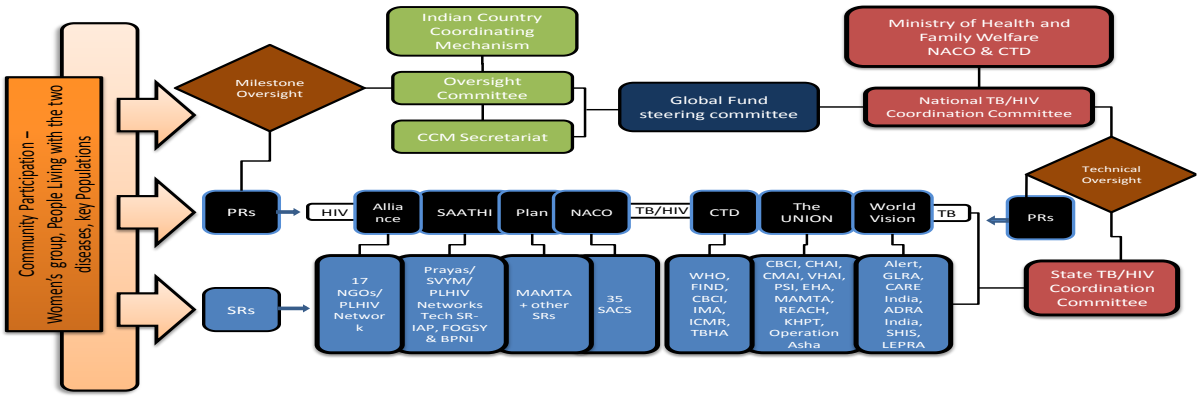
b. If more than one PR is nominated, how co-ordination will occur between PR(s) for the same disease and across the two diseases and cross-cutting HSS as relevant.

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

d. How coordination will occur between each nominated PR and its respective sub-recipient(s).

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

The India Country Coordinating Mechanism (ICCM) proposes Dual-Track Financing(DTF) implementation arrangements. In order to ensure high impact and high quality interventions at scale, across both HIV and TB diseases response system, the ICCM strongly believes in the need for DTF. The past experience of implementing DTF in the country has ensured better coverage of affected populations, ensuring sustainability of these efforts. India CCM is proposing **two Government PRs** (National AIDS Control Organization) and Central TB Division (CTD)) and **five Non-Government sector PRs** (Solidarity and Action Against The HIV Infection in India (SAATHII), PLAN India, India HIV/AIDS Alliance, The Union, and World Vision India) who have been selected through a transparent bid process. Being a proposal focused on strengthening the health system and improving access to treatment and care for communities, there is a large procurement component in the proposed investment, in particular, lifesaving drugs and strengthening laboratory facilities. The GoI PRs have the capacity and the footprint for such large volumes of procurements and extensive distribution channels across the country. In addition, the government is accountable to the public for quality and timely delivery of medical services and supplies. With respect to the funding allocation, the ratio between government PR and nongovernment PRs is 63:37 after accounting for the procurement and supply. Additionally, one of the Government PRs i.e. Central TB Division, has a sizeable portion of funds allocated to civil society sub-recipients. The coordination process under this Global Fund investment will be aligned to the existing coordination systems in the country. National TB/HIV Coordination Committee (NTCC), which is currently established and operational at national level, will continue to play a key role in facilitating coordination among the PRs. The State Coordination Committees will also look into the operations of proposed Global Fund-supported programmes. The role of these two committees at national and state level will be primarily for technical oversight and guidance. The National Technical Working Groups working under these two committees will play a key role in ensuring technical quality of the programmes being implemented. The National Framework for Joint HIV TB Collaborative Activities is in Annex 3. Besides the above, for better coordination within this proposed Global Fund investment, a national level NFM PR Coordination Body, which will directly report to the ICCM Oversight Committee, will be established. The details of the coordination mechanism are captured in the diagram below:



PR Coordination Committee will be the mechanism that will be represented by PRs, Representative sfrom the CCM Oversight Committee, National TB/HIV Coordinating Committee(NTCC), beneficiary groups (PLHIV networks) etc. This will be a platform for coordination, technical discussion, trouble shooting on any ground level coordination issues, as well as serve as alearning and sharing platform for the PRs. The oversight Committee of the CCM will be responsible for the oversight of milestones. The NTCC along with its Technical Working Group and State level Coordination Committee will provide technical oversight and quality assurance at both PR and SR level.

The National Coordination Committee (NCC) has been set up to manage the Global Fund-supported TB programmes. NCC will also include the NFM grant within its review processes and discuss progress during review meetings. The RNTCP also conducts Joint Monitoring Missions (JMM) at regular intervals of 3 years, which will also include all the Global Fund supported activities.
Plan India has identified one of the SRs (MAMTA), and others will be selected later through an objective and transparent selection process. Other PRs have selected their SRs based on their technical expertise and experience in managing health programmes and in particular HIV and TB. All SRs will be directly reporting to the PRs. State TB/HIV Coordination Committee will be brought in to provide technical support to the SRs. Management arrangements and coordination between respective PRs and SRs will be ensured through a comprehensive system for oversight (both technical and delivery-related) in keeping with the principles of supportive supervision. A system of Project Management Unit (PMU) will be established within each PR in order to manage the programme. The system will include contracts management, financial management and controls, regular assessments and reviews through M&E mechanisms, establishing procurement and supply chain management system, asset management system, technical support, capacity building etc. In addition to close monitoring of the programme through the PMU, a provision of technical support will be made available by creating a local panel of technical experts by each of the PRs to support the SRs in ensuring quality implementation of activities.

Efforts will be made to systematically assess capacities of the PRs and SRs as well as implementing specific or need-based technical assistance plans to address any capacity gaps identified. While managing and monitoring the SRs, community participation and community perspectives will be sought, to ensure results at the level of service provision and also to ensure quality activities are conducted by the SRs. The information generated through the MIS system will be used to provide feedback, reflect and learn, and make appropriate and timely programmatic course corrections. PRs will support SRs to establish appropriate internal programme management systems (through standard system guidelines) so as to deliver results,

and maintain quality while achieving rapid scale up and coverage, achieve execution excellence and ensure results which are linked to achievements of outcomes. Management arrangements will ensure performance is optimal across all SRs, and additional support will be provided to those SRs that require more technical support. The Global Fund rating system will be effectively used to determine the intensity and focus of support to each SR.

The system of PR-SR coordination will be clearly laid out in the Supportive Supervision guidelines that will be prepared by each of the PRs. This will include regular meetings, oversight of field visits, regular submission of reports by SRs and feedback by PRs etc. A robust Financial Management system will be put in place to ensure timely, transparent and accurate disbursement of funds to the SRs. Regular analysis of financial and programme information will be done, which will help to create an appropriate technical support plan and contract management decision-making guide. Community participation will also be ensured at all levels of coordination and decision making, and will representation of the PLHIV network and other key population groups such as sex workers, MSM, Transgender and Person Who Inject Drugs. Representatives of these groups will also be brought into the PR coordination mechanisms, state level coordination meetings and at the level of programme implementation. This will be included in the monitoring system and regularly measured to ensure commitment to participation of community members is given utmost priority at all levels of coordination.

4.2 Ensuring Implementation Efficiencies
Complete this question only if the CCM is overseeing other Global Fund grants.
From a program management perspective, describe how the funding requested links to any existing Global Fund grants, or other funding requests being submitted by the CCM at a different time.In particular, explain how this request complements (and does not duplicate) any human resources, training, monitoring and evaluation, and supervision activities.

The Global Fund's current portfolio of grants in India comprises 8 active HIV grants, 3active TB grants and 3 active malaria grants. The HIV programme in India is in its 4thphase of implementation and according to Global Fund's own preliminary calculation, the programme is "under resourced" by up to 33%.

For HIV, the current grants will end by the start date of this proposal in October 2015. Currently, RCC Round 4 support of the Global Fund is focused on care, support and treatment. With the increased need to scale up these activities and cover a larger number of people who require ART treatment, this NFM proposal seeks to raise the additional resources needed. Hence, there is no duplication (such as Counselling and Testing services PPTCT programme in India through RCC Round 2). This proposal also builds on past work. While the testing component will be implemented through DBS, the PPTCT outreach will be further strengthened through this project to enable access for a larger number of pregnant women to PPTCT services and ARV treatment. This project will supplement the existing staff of ICTCs, ART Centres, as well as support procurement of commodities such as testing kits and ARVS.

PPTCT staff will link PLHIV to CSCs in their districts, while CSC staff will follow up pregnant women in districts without PPTCT outreach. The Link Workers who were commissioned through Round 7 grant are trained in working on HIV matters and hence will be leveraged in linking the targeted interventions, key populations and vulnerable populations to services in rural areas. Earlier Global Fund grants where nurses and counsellors were trained will be leveraged to bring about this integration and provide the much-needed key population-friendly services particularly in the general health setting. Human resources, training resources, monitoring and evaluation tools, and supervision activities already part of the various components of the national program

at all levels, will not be duplicated, and existing mechanisms will be utilised leading to efficiencies.

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The TB control programme has well exemplified these implementation efficiencies earlier through consolidation of grants under Round, 2, 4, 6 into the Rolling Continuation Channel (RCC) and subsequently converged all existing grants into Single Stream funding TB (RCC + R9). The TB control programme proposes to achieve further efficiencies under NFM by continuing high-impact activities and proposing new activities that were hitherto not addressed through earlier grants or other resources. In addition to the above, the PRs will meet specifically around this issue and mapout further synergies and leveraging them. The PRs plan to develop a matrix around various GF rounds and how they address geography, priority groups, staffing, and facilities, then arrive at a roadmap for optimizing efforts and maximizing returns on GF rounds. This will be carried out during the negotiation of Project Axshya, supported by Global Fund, as it is being implemented in 374 Districts by The Union and World Vision India (WVI), demonstrating the importance of civil society participation in supporting RNTCP. The key assets of the project in the community are engagement of 30,000 Rural Health Care (RHC) and AYUSH Providers, 1,600 NGOs, 15,000 community volunteers, district TB Forums, community-based sputum collection and transportation for early diagnosis and treatment. There is an increased community ownership and functional systems establishment involving NGOs and government health facilities at community level. Under NFM, non-government PRs will optimize their sources built over past project activities. The newer activities will aim to integrate with existing available resources to enhance the performance of systems built in the past to have higher returns.

4.3 Minimum Standards for Principal Recipient (PR) and Program Delivery			
For both TB and HIV complete thetablebelow for each nominated PR. For more information on Minimum Standards refer to the Concept Note Instructions.			
PR 1 Name	Department of Economic Affairs Implementing Agency: Central TB Division	**Sector**	**TB**
Does this PR currently manage a Global Fund grant(s) for this disease component or a stand-alone cross-cutting HSS grant(s)?		☑Yes ☐No	
Minimum Standards		**CCM assessment**	
1. The Principal Recipient demonstrates effective management structures and planning		The Central Tuberculosis Division (CTD) of the Ministry of Health and Family Welfare (MOHFW), led by the Deputy Director General (TB), manages the Revised National Tuberculosis Control Programme (RNTCP) at the central level. The Deputy Director General (TB) reports to the Director General of Health Services. A Joint Secretary (Public Health) is responsible for the programme, reporting to the Additional Secretary andDirector of the National Health Mission (formerly the National Rural Health Mission), who in turn reports to the Secretary of Health and Family Welfare. CTD is organized in three divisions, each under the responsibility of an Additional Deputy Director General:	

	(i) Programme Management, Research, Donor Coordination, and coordination with the National Health Mission (ii) Supervision, Monitoring and Evaluation, Epidemiology and Human Resource Development; Advocacy & Communication; Partnerships (iii) Procurement and Supply Management; Finance, Contractual Manpower management. CTD focuses on policy development, technical oversight, monitoring and evaluation and capacity building. It also has responsibility for national-level planning and budgeting, financial management of funds utilized at the central level and transferred to the states for RNTCP activities, central procurement of anti-TB drugs, and coordination with external partners and other government departments. Several committees and research institutes provide technical guidance to CTD. CTD has a remarkable track record of successfully implementing global fund grants and consistent good ratings since 2002 in various rounds of global fund mechanisms, which is a testimony to the excellent managerial capacity of the organization.
2. The Principal Recipient has the capacity and systems for effective management and oversight of Sub-Recipients (and relevant Sub-Sub-Recipients)	The PR has demonstrated effective management and oversight of the SR partners since 2002. SR management plan is also attached.
3. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud	Over a decade of experience in implementation of Global Fund Grants has enriched the programme with valuable lessons, experiences and best practices. Over the years, actions on lessons learned have led to strengthening of internal control systems to detect early warning signs of misuse or fraud. The current financial management systems are robust and periodic external and internal audits further provide a good means of financial guidance and oversight.
4. The financial management system of the Principal Recipient is effective and accurate	The administrative and financial management structures of RNTCP are part of the National Health Mission. MOHFW and each state and union territory have entered into a memorandum of understanding for implementation of the National Health Mission, including RNTCP. At the state level, the State TB Officer in the State TB Cell is part of the National Health Mission State Programme Management Unit, reporting to the Director of Health Services and the Director of the National Health Mission in the state. The State TB officer with the support of a team oversees district-level programme implementation, reviews staff training, undertakes minor procurement, prepares technical and financial reports, ensures quality control, and monitors programme indicators. In bigger states of the country, a State TB Training and Demonstration Centre supports the State TB Cell, encompassing three units: (i) training unit, (ii) supervision and monitoring unit and (iii) Intermediate Reference Laboratory (IRL), supporting the RNTCPs quality assurance system for the sputum smear microscopy network in the state. The PR follows high standards in financial management at different levels. It ensures that Global Fund conditions are fulfilled. The PR conducts regular periodic reviews of financial management systems of SRs and undertakes field visits to ensure that project goals are attained

	and guidelines are adhered to. The accounts of each district health society and state dedicated officials specializing in financial management manage the health society. They are also subject to annual audits. The Comptroller and Auditor General of India conduct an audit at national level.
5. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products	There are 6 General Medical Stores Depots, (GMSD) which act as National warehouses. The State drug stores are regional warehouses under the programme. CTD has developed standardized storage guidelines based on which the State Drug Stores and District Drug Stores have been upgraded. CTD has developed Standard Operating Procedure Manuals for State and District Drug Stores. The trainings are being conducted by CTD at the State level for the SDS and District level staff managing drug logistics. Recently, Guidelines for Storage of 2nd Line Anti-TB Drugs for RNTCP have also been finalized and disseminated to the states and districts for further implementation. This Guideline reflects the space requirements, specification for the drug store, shelves,racks and storage arrangements, stacking arrangements, control of humidity and temperature, packing instructions and the systems to be adopted for adequate security. These guidelines are also available at RNTCPs website www.tbcindia.org.
6. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment / program disruptions	A dedicated supply management agency is in place under the program for more than a decade reporting to a senior level officer. The stock and supply positions up to the peripheral level are monitored regularly through an established management information system. In addition, the programme has a mechanism to continually monitor supplies and initiate prompt corrective actions. The personnel handling supplies and distributions chain at national, state, district and peripheral levels are trained and equipped to handle exigencies. A provision of buffer stocks ensures that there are no disruptions on account of supplies of health products. There are also dedicated warehouses at national, state and district levels for storage of health products with financial provisions to ensure timely transportation.
7. Data-collection capacity and tools are in place to monitor program performance	RNTCP has a well-developed Monitoring and Evaluation strategy (document attached). The programme performance is routinely monitored through a multipronged approach of (1) Quarterly reporting from all Tuberculosis Units (TUs) to national level through EPI info. This is being diligently analyzed and states are provided feedback for improving performance. (2) The new real-time web-based software NIKSHAY is in an advanced stage and all TUs are simultaneously reporting in this mechanism. NIKSHAY also has provision to report notification from the private sector, laboratories, and other facilities. Over time this will also enable the programme to follow individual patients for enhanced public health outcomes.
8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately	A fully functional routine reporting system is already in place. Each peripheral health institute (PHI) submits a monthly report to TU. TU consolidates monthly reports of all PHIs reporting to it and transmits a report every quarter to the district. The district further transmits quarterly reports to state and national level. The state consolidates all district quarterly reports and shares the same at national level. All this data is being routinely validated for its accuracy and CTD also

		provides quarterly feedback to states on their program performance.	
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain		The Procurement, Supply and Logistics Unit in the Central TB Division (CTD) fulfills the procurement and supply chain management functions at the central level. The unit is under the supervision of an Additional Deputy Director General. The inbuilt safeguards of product quality through a mechanism of formulations of technical specifications by an expert committee, floatation of bids to vendors who fulfill mandatory qualification criteria to comply with quality, the pre-dispatch inspection of products, and a certificate of quality assurance from an authorized laboratory ensures that products meet the specified quality criteria. Further, to ensure that products meet the quality parameters during their use at decentralized level during their shelf life, random quality testing of drugs from the field through a certified quality assurance laboratory is an additional safeguard under the programme.	
PR 2 Name	The Union	**Sector**	**TB**
Does this PR currently manage a Global Fund grant(s) for this disease component or a stand-alone cross-cutting HSS grant(s)?		☑Yes ☐No	
Minimum Standards		**CCM assessment**	
1. The Principal Recipient demonstrates effective management structures and planning		The Union has established a Project Management Unit (PMU) with adequate technical, financial and administrative capacity. The PMU is managing the current grant coordinating with 8 Sub-recipient partners working in 300 districts across 21 states. The PMU ensures adequate planning and timely implementation of project activities which is demonstrated by the continued achievement of 'A' rating	
2. The Principal Recipient has the capacity and systems for effective management and oversight of Sub-Recipients (and relevant Sub-Sub-Recipients)		The PR has demonstrated effective management and oversight of the SR partners working in 300 districts over the last 4 years.	
3. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud		The Union has a robust internal control mechanism to prevent and detect misuse or fraud at various levels. This is ensured through benchmarks for the PR and SRs, and is detailed in the technical, financial and operational guidelines, and checked during regular monitoring of project activities.	
4. The financial management system of the Principal Recipient is effective and accurate		The PR follows high standards in financial management at different levels. It ensures that Global Fund conditions are fulfilled at all levels. PR conducts periodic reviews of financial management systems of SRs and undertakes regular field visits to ensure that project goals are attained and guidelines are adhered to.	

5. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products		Not applicable, as The Union will not be procuring any drugs or consumables under the grant.	
6. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment / program disruptions		There is no distribution/transportation of drugs and consumables planned in the grant. However the project will transport sputum specimens to the microscopy centres for which adequate transportation mechanisms have been established under the existing grant. These will be further strengthened for improving efficiency.	
7. Data-collection capacity and tools are in place to monitor program performance		The PR has developed an in-house web-based tool to monitor programme performance at all levels in real time. Project staff have been oriented on these tools and have been provided guidelines. PR and SRs are experienced in Strategic Information (SI) management.	
8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately		Project activities are being reported to PMU by SRs on a quarterly basis. The performance of the project is reviewed with project managers of SRs on a quarterly basis apart from routine field visits by the PMU.	
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain		PR and SRs have the capacity to ensure that project activities are implemented in a quality manner.	
PR Name 3	World Vision India	**Sector**	**TB**
Does this PR currently manage a Global Fund grant(s) for this disease component or a stand-alone cross-cutting HSS grant(s)?		☑Yes ☐No	
Minimum Standards		**CCM assessment**	
1. The Principal Recipient demonstrates effective management		The PR has a PMU (Project Management Unit) led by a Project Director who is further assisted by one Technical Advisor, one Finance Manager and one M&E Manager to provide the overall administrative, managerial and technical directions to the project along with its regular review, monitoring and	

structures and planning	supervision. Besides, the PMU has three additional Finance Officers and two M&E Officers to conduct programmatic and financial monitoring of sub-recipients. The PMU is further assisted and guided on an ad hoc basis by WVI's National Office located in Chennai. PMU functions as per a specific plan that each PMU member has to develop in consultation with the Project Director and as per the requirements of the SR-partners.
2. The Principal Recipient has the capacity and systems for effective management and oversight of Sub-Recipients (and relevant Sub-Sub-Recipients)	The PR has developed the following systems for effective management and oversight of the SRs: • Planned field-visits by PMU members for direct supervision and monitoring of project activities and data verification, providing feedback to SRs and recommendations for betterment with regular follow up. • On-the-job and on-site training of the SR/SSR partners for on-the-spot rectifying of emerging issues • Review of quarterly reports and other reports (both programmatic and financial) submitted by the SRs, giving feedback and follow-up • Rolled out Standard-Operating-Procedures (SoPs) for standardization in project implementation, monitoring and financial management across all SRs • Conducting central level SR-review meetings • Quarterly review of the project's capacity building of SR partners on various aspects of the project, updating newer developments in TB control and care, and under-taking administrative actions when required and streamlining discrepancies.
3. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud	The internal control system developed by the PR to prevent and detect misuse or fraud is comprised of the following activities: (i) Cross-checking of vouchers, bills and related financial documents with programmatic plans and activities; any mismatch found is clarified immediately from the respective SR/SSR (ii) Stringent data verification in the field which compulsorily includes verification at the beneficiary level to know the extent of benefit provided by the project to them (iii) Administrative actions directly against SR-level project staff and SSRs in case of any financial irregularities detected (iv) SoPs as mentioned earlier guides the PR to detect financial mismatch with the already implemented activities by SR/SSRs in the field as implementation of every activity under the project is monitoring by following the guidelines adopted in the SoPs. The SoPs have been developed to ensure standardized (v) Implementation of the activities across the project.
4. The financial management system of the Principal Recipient is effective and accurate	The project has developed the following financial management system: (i) FPMS software for de-centralized data recording (ii) Monitoring visits by the PMU finance team for data verification and validation (iii) SoP finance is utilized for cross-checking if policy and procedures are being followed by the SRs/SSRs (iv) Analysis of quarterly financial reports
5. Central warehousing and regional	Not applicable as the PR doesn't deal with health products of any kind in the project.

warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products	
6. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment / program disruptions	Not applicable as the PR doesn't deal with health products of any kind in the project.
7. Data-collection capacity and tools are in place to monitor program performance	The following system has been built in the project for data collection and monitoring project performance: Baseline database: All the districts (currently 74) have 5 district-level registers kept under the custody of the respective District-Coordinators of the SRs. These registers document detailed accounts of project-level information, utilizing standardized templates provided by the PR. These registers constitute the baseline database of the project. Similar registers are maintained by Project Managers of the SRs to record the state-level activities. These registers are regularly checked by the PMU members on field-visit for accuracy, verification and updating
8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately	Reporting system: Reports are developed compiling the data captured in the registers in the standardized reporting formats supplied by the PR. Following is the flow of reporting of the project: SSR (Sub-Sub Recipient) to DC (District Coordinator) on monthly basis ↓ DC to Project Manager of the SR on quarterly basis ↓ Project Manager to PMU on quarterly basis Strict timeliness is maintained across the project to ensure timely reporting. Clarification is asked for delayed reporting and documented. Progress reports along with project action plans are shared with RNTCP program managers like DTOs and STOs on a quarterly basis. PMU also shares progress reports with CTD in the same fashion. The project is also reviewed by RNTCP through the Central Internal Evaluation of RNTCP and National Coordination Committee of the TB-grant PRs. Feedback systems: Feedbacks are routinely provided under the following situations: • After any field visit • Review of the reports • Review of records • Meetings with SRs/SSRs • Interaction with community in the field

		• Meetings with RNTCP-staff Recommendations given in the feedbacks are followed up on a regular basis.	
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain		Not applicable as the PR does not deal with health products of any kind in the project.	
PR 4 Name	Department of EconomicAffairs Implementing Agency: National AIDSControlOrganization (NACO)	**Sector**	**HIV/AIDS**
Does this PR currently manage a Global Fund grant(s) for this disease component or a stand-alone cross-cutting HSS grant(s)?		☑Yes ☐No	
Minimum Standards		**CCM assessment**	
1. The Principal Recipient demonstrates effective management structures and planning		National AIDS Control Programme, Ministry of Health and Family Welfare, Government of India provides leadership to HIV/AIDS control in India through 35 State AIDS Control Societies (SACS) which will be the main sub recipient. Secretary to the Government of India heads the National AIDS Control Programme. For administrative and non-technical divisions, officers of the rank of Additional Secretary, Joint Secretary, Director Finance, one Deputy Secretary and a number of Under Secretaries, who are officers with several years of managerial/administrative experience, are deputed. In addition, there are Deputy Director Generals, Assistant Director Generals and Joint Director (IEC) for technical divisions. Further, experts from relevant fields support NACP managerially and technically. NACP's remarkable track record of successfully implementing global fund grants from five rounds is a testimony to the excellent techno-managerial capacity of the organization.	
2. The Principal Recipient has the capacity and systems for effective management and oversight of Sub-Recipients (and relevant Sub-Sub-Recipients)		SR management plan is attached	

3. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud	Being in the third year of implementation of this grant and programme, several lessons have been learnt and mid-course corrections made. The current financial management systems are robust and periodic external and internal audits further provide a good means of financial guidance and oversight.
4. The financial management system of the Principal Recipient is effective and accurate	Under NACP, expenditure is incurred at national, state (SACS) and field levels (at government health facilities where ART Centres and SACs are located). The spending at the national level is aimed at central procurement of goods and services and is appropriately captured in the national budget of the Ministry of Health and Family Welfare. Release of funds to states is also captured there. NACP is implementing self-devised Computerized Project Financial Management System (CPFMS) to capture project accounts. Receipt of central funds by states is captured on CPFMS as well as releases to field units (government hospitals and health care delivery points) for expenditure in the field. Detailed line items of each activity are available on CPFMS for capturing expenditures under each component.
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	NACP does not maintain any Central Warehousing. The supplies centrally procured are directly supplied to the Consignees i.e. State AIDS Control Societies (SACS). At the state level, the SACS maintain warehouses complying with good storage practices to ensure adequate condition, integrity and security of health products. Designated Store Officers are appointed in each SACS for ensuring maintenance, supervision, monitoring and efficient supply chain management systems. The Standard Operating Procedures (SOPs) for storage, distribution, monitoring and reporting are prescribed as part of the Operational Guidelines.
6. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment / program disruptions	The supplies of commodities are delivered at stores of SACS and are then further distributed to service facilities, based on their consumption patterns in such a manner that the facilities should have at least 3 months stock in hand at any point of time. The facilities send reports of availability of commodities to SACS on a monthly basis. The SACS Officers in turn compile these reports and send it to NACP. The state officers with the support of Regional / District officers monitor the stock position of commodities to ensure that there is no stock out/expiry. The Logistics Coordinators and Assistant Logistics Coordinator at NACP monitor the stock position at SACS level as well as facilities to ensure that there is no stock out /expiry. The short expiry drugs/kits are transferred from one place to another based on consumption and future needs.
7. Data-collection capacity and tools are in place to monitor program performance	The Central monitoring and Information system has been used so far as the mechanism to report on key activities by the states. Since 2010, an improved system called Strategic Information and Management System has been designed and is being implemented in a phased manner. This has been a challenge given the geographical diversity and the health system status of the country. However, the programme has managed to scale up significantly and will further strengthen M&E systems to ensure correct, consistent and complete data.
8. A functional routine reporting system with reasonable coverage is	As explained above, significant scaling up under the programme has managed to further strengthen the M&E systems to ensure availability of accurate, consistent and complete data sets.

in place to report program performance timely and accurately			
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain		The PR is comprehensively responsible for ensuring that the products being purchased under the Global Fund financing agreement meet requirements under the GFATM's 'Quality Assurance Policy'.	
PR 5 Name	Plan India	**Sector**	**HIV/TB**
Does this PR currently manage a Global Fund grant(s) for this disease component or a stand-alone cross-cutting HSS grant(s)?		☑Yes ☐No	
Minimum Standards		**CCM assessment**	
1. The Principal Recipient demonstrates effective management structures and planning		A Country Management Team (CMT) under the leadership of the Executive Director manages the operations of Plan India. The members CMT are Directors in charge of Programs, Strategy, Administration, Finance, Grant management and Human Resources. Plan India has team of Technical Advisors including Health, Early Childhood Care Development (ECCD), Child Protection, Household and Economic Security (HES), Water and Sanitation Advisor (WASH) as well as a number of mid-level management staff for areas of field operation, research, administration, financial management, logistics, and ICT. The Country team is also composed of internal auditors. Eleven decentralized state offices headed by State Managers handle Plan India's field operations. These state Managers are responsible for day-to-day program implementation through the grass root level NGO partners. The Plan India has an annual program planning cycle and a 5-year strategic planning cycle. The annual plan cycle is a part of the 5-year program cycle. The annual program cycle is developed in consultation with the SR's, key stakeholders and the beneficiaries and then approved at the appropriate authority level and signed out in the form of Program Outlines.	
2. The Principal Recipient has the capacity and systems for effective management and oversight of Sub-Recipients (and relevant Sub-Sub-Recipients)		The Operational model of Plan India is based on the concept of decentralized functioning where the field level implementation is pitched in by the field level NGO partners also called as SRs. The systems and procedures for monitoring and reporting have been developed by keeping in mind this model of working with SRs and SSRs. The authority levels have also been devolved in a similar manner and complete automated systems have been placed at strategic locations to capture data on implementation to generate reports and activate an online monitoring system called PPM (Program and Project Model).	
3. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud		Plan India employs Internal Auditors to assure the transparency and conformity of day-to-day operations. Additional auditors may be employed if there is a demand generated by a large volume of grants. Furthermore, an internal audit team is conducted by the global associates of	

	Plan India at the level of Plan's International Headquarters with staff at each Regional Office. The team visits Plan India every 12 months to verify adherence to organizational policies and procedures in all records, programs and transactions. An international audit firm, contracted through competitive tender, audits the operations of Plan India annually. Additional external audits are commissioned for individual grants as specified in the grant agreement. Plan India assures in its agreements with implementing partners that these organizations meet the same stringent audit standards.
4. The financial management system of the Principal Recipient is effective and accurate	A team of 18 regular staff members, headed by the Director – Finance and Operation, manages plan India's finance department. The finance staff are based both at the Country Office and state office while the SR's have their own Finance staff. All financial transactions are recorded daily in the General Ledger (GL) accounting software. The system allows all departments to automatically generate real-time reports and analyses that can act as a basis for planning, budgeting and for producing financial reports by project and by department. GL has various levels of access to ensure sufficient segregation of tasks: recording, control, consolidation and reporting. An accounts assistant on the basis of approved supporting documents that are posted in the system after verification by the GL Accountant and the Accounts Manager makes all accounting entries. The financial accounting system of Plan India has a long history of competent management of grants by a number of international donor agencies. A number of grants involved the signing of sub-recipient agreements. In these cases, Plan India provides sub recipients with start-up workshops and intensive coaching and mentoring to ensure efficient grant disbursements and to manage identified financial risks. For the financial management of large grants, Plan India establishes separate finance and accounting teams reporting to the Director-Finance and Operations. This approach has been successfully implemented by Plan Country Offices in many countries for the financial administration of Global Fund grants. To ensure good quality and timeliness of financial deliverables, Plan India has at its disposal the relevant instruments, tools and software. These combined with sound expertise, account for excellent credentials for a rigorous management of finances and more specifically, of cash flow. The cash flow monitoring goes beyond the level of Plan India as each program/project has a cash flow schedule that is equally tracked at the level of Global and regional level. And in the framework of the donor's requirement, Plan India is flexible in adopting its systems and procedures for a particular program to ensure timely disbursement of funds to local grantees and beneficiaries as necessary, purchase of materials, equipment and supplies, recruitment of project staff and timely implementation of all activities.
5. Central warehousing and regional warehouse have capacity, and are	Not applicable as the PR doesn't deal with health products of any kind in the project.

aligned with good storage practices to ensure adequate condition, integrity and security of health products	
6. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment / program disruptions	Not applicable as the PR doesn't deal with health products of any kind in the project.
7. Data-collection capacity and tools are in place to monitor program performance	Plan India utilizes an established system of grants administration and monitoring, which guarantees a sound and rigorous tracking of project outputs and expenditures. Plan India implements a monitoring and evaluation system known as Program Accountability and Learning System (PALS) under the direction of monitoring and evaluation officers at the Country Office and in each of its Program Unit offices. PALS use a participatory approach to assure the accountability of programs to both the beneficiaries and to the financial donors. Monitoring focuses on the quality of services provided and on the changes in the lives of children and communities achieved. One of the PALS tools is the software-based Program and Projects Module (PPM) that concurrently monitors programs and finances to generate reports relating outputs to expenditures, planned versus actual implementation and reasons for variances. Mid-term and final evaluations of Plan India's programs and strategies are an integral part of the regular program cycle. In addition, evaluations of grant-funded programs and projects are implemented according to the grant contribution agreement. Most of the operational research conducted by Plan India over the last years has been in the context of regional Plan research projects on adolescent sexuality and reproductive health, violence against children, birth registration and other global thematic areas of Plan's work.Plan India has invested extensively in its ICT infrastructure. The Country Office and three regional hubs managing 11 Program Unit offices are fully networked with 24-hour internet access. Each office has a domain and a security server. Full-time ICT user support is available at each office. Some of Plan's corporate information systems, as for instance the General Ledger accounting system, are web based so that they can be accessed at all times by all Plan Departments worldwide. Security of all data is maintained through user access rights and passwords.
8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately	The Project reporting in Plan India is done on key activities and milestones. Standard monitoring information that all projects must collect includes: • Project implementation progress. • Budget versus actual.

	• Output delivery. • Output location. 'Project implementation progress' report focuses on the quality of the project's processes and outputs viewed from the perspectives of different stakeholders. The report highlights the project's adherence to Plan's values and its contribution to PU Programme Objectives. The project progress log (a project diary) provides an opportunity to record this information in the Plan India's in built software called as Program and Projects Module (PPM) management information system. A project completion report (PCR) is prepared by the Plan project point person in consultation with the stakeholders involved, at the end of each assignment. The report highlights strengths and weaknesses of the project process and results (including its contribution to PU Programme Objectives) and identifies any lessons learned and recommendations for future work doing similar projects or following similar approaches. The report also details planned vs. actual (budget, output, location, community/partner contribution) and provides an explanation for significant variances. A key input to the PCR is information recorded in the project progress log. The periodicity of the report is donor dependent and a report scheduler is prepared at the beginning of the grant and a reminder system is set to inform the implementing staff of the due date of the reports.
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain	Plan India has a Procurement Policy to guide the procurement of goods and services. Processes for bids and tenders are clearly outlined based on their value. Finance and Admin division jointly along with the Purchase Committee (PC) that has members from different departments, provide oversight for the policy. The Quality Assurance Team, with a team of Internal Auditors is responsible for verification. Each year, the PC is reconstituted and the members are trained in the procedures and systems involved in the procurement of assets and services within the organization. For large grants, Plan India recruits the appropriate number of procurement and logistics specialists as members of the grant management team. The procurement experience of Plan as a Global Fund Principal Recipient can also be mobilized to support procurement under a potential Global Fund contract in India.

PR 6 Name	SAATHII	**Sector**	**HIV/AIDS**
Does this PR currently manage a Global Fund grant(s) for this disease component or a stand-alone cross-cutting HSS grant(s)?		☑Yes ☐No (but has been SR for two GFATM grants)	
Minimum Standards		**CCM assessment**	
1. The Principal Recipient demonstrates effective management structures and planning		A Board of Trustees (Boot), Management Committee (MC) at organizational level and Local Management Committee (LMC) at office level governs SAATHII. The Boot is comprised of experts from the field of HIV/AIDS, corporate governance, human rights, education and development. The MC which is comprised of the president, two country directors and three associate directors is responsible for implementing policy decisions taken by the Boot. MC is also responsible for overall	

	coordination of programs, administration and finances of the organization. Towards this, MC conducts monthly programmatic and administrative reviews and addresses grievances put forward by employees and volunteers. At the beginning of every financial year, the Management Committee (MC) undertakes an annual administrative, financial and programme planning exercise in consultation with the Trustees, and relevant Consultants, Advisors and Employees across all city offices. The plan identifies major expenses anticipated in relation to administration, programmatic and in-house capacity building activities. This information is used for preparing a tentative budget as part of the annual plan of the organization. As a result of long-term staff retention and involvement, SAATHII has the second generation of leaders in place. There is considerable range in individual skills among the various tiers of staff in the organization. The skills and experience of the staff can be classified as: technical expertise and experience in gender, sexuality, reproductive health, HIV/AIDS and STI prevention, care, support and treatment, managerial and directorial skills, procurement and finance control, monitoring and evaluation, and research and documentation. SAATHII's organization systems and governance practices are documented in its comprehensive systems audits for pre-grant for two Global Fund grants, two evaluations by NACO, and program specific audits conducted by such consultancies as KPMG and PWC. Project management and planning have helped SAATHII grow its staff strength from 17 to 111, portfolio of grants from 4 to 54, offices from 2 to 9, and grant award amounts from USD 11, 933 to USD 1.31 million the last 12 years.
2. The Principal Recipient has the capacity and systems for effective management and oversight of Sub-Recipients (and relevant Sub-Sub-Recipients)	SAATHII's partner profile has grown over the past 12 years to encompass over 75 as of date. These include NGOs, community based organizations and networks of PLHIV, private sector healthcare providers, in addition to non-funding relationships with professional medical associations and government departments. Almost 100% of SAATHII's project deliverables are partnership-driven and partner agency dependent. Of direct relevance to the proposed project, SAATHII works with four state partners in private sector PPTCT, and more than 1,000 private hospitals who provided counselling and treatment to pregnant women and report data to the National AIDS Control Programme and to SAATHII. Thus, a core competency is partner management, which includes partner capacity building, criteria for partner selection, partnership renewal, and visibility actions that are in line with government protocols. Existing Project Management and MIS systems provide templates for developing systems and tools for the proposed project. Key Management Systems consist of processes, SOPs, Guidelines, templates, check-lists and tools that enable the adherence, timeliness, data collection, reporting and flagging of program activities, partners, organizations and situations, including anticipating and responding to adverse events. Besides providing an ability to comply with all mandated and agreed reports and documentation, Management Systems provide an ability to forecast and manage resources, budget and people processes.Key instruments used for effective management and oversight of partner organizations (sub-recipients) include: (i)

	Checklists, periodic, comprehensive and in-depth reviews are used to ensure timeliness, quality assurance, compliance with goals and milestones, early warnings on issues and deviations from plan (ii) Besides routine monitoring and process evaluation, mentorship, experience-sharing and review forums are integral parts of SAATHII's management approach. During these, development and revision of shared vision and goal for upcoming years are reviewed and modified as needed, and sharing of learning conducted to enable achievement towards the shared goals, (iii) Partner-specific (sub-recipient) quarterly financial audits (internal) and annual statutory audits are part of the financial management. In addition comprehensive project-specific systems and process-wide audits are conducted periodically as part of the M&E.
3. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud	Internal control systems include a system of multiple signatories on cheques and other instruments, interim audits and statutory annual audits, procurement systems designed to ensure objectivity, rigorous approval systems for payments, centralized banking operations. The same standards apply to grantees. Given the nature of SAATHII's work, several of its projects require collaborations or partnerships with civil society organizations (CSOs) of varying nature. These collaborations involve provision of micro- to large sub-grants to these CSOs, which include both Non-governmental Organizations (NGOs) and Community-based Organizations (CBOs). Financial management of partners is carried out as per the statutory requirements of the country and in accordance with SAATHII's financial policy and Sub-granting management procedures. SAATHII ensures that sub-grant funds are released as per agreement terms and conditions. Funds are released on submission of detailed forecasts (with explanations), periodic financial reports, related accounting documents, and progress report of the program. The release of second installment is based on satisfactory performance at the first quarter. The systems set forth in the financial and accounting policy and the partner capacity build on the same, the periodic financial reports, periodic partner visits and evidence verification is geared towards preventing or detecting misuse of fraud.
4. The financial management system of the Principal Recipient is effective and accurate	SAATHII has a cash-based accounting system that correctly and promptly records all transactions and balances making clear reference to the budget and workplan of the grant agreement. Account payee cheques pay all the payments above INR 5000. More than one individual signs banking instruments. A separate set of books of accounts is maintained for each project and a centralized banking and funder management system is in place. All payment vouchers and receipts are recorded within one week of the transaction and standard vouchering process is followed. Monthly Bank reconciliation statement is generated and approved by the authority and included in reporting to funders. SAATHII adopted internal auditing systems from the financial year 2008-09. The internal auditing committee is comprised of selected finance staff with defined scope of auditing and carries out the internal auditing. Regular financial reviews are held at branch offices and at central office. The Finance Head (FH) of each office conducts accounts and financial review, including

	program-finance variance analysis, once in a month before sending MIS. This includes verification of vouchers, supporting documents, Trial Balances and ledger. Details of these procedures are available in the financial and accounting policies document of SAATHII. Financial systems and controls have been scrutinized and have passed pre-grant and program audits by external consultants and auditors of acting on behalf of Government of India, bilateral and private foundation donors.
5. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and security of health products	Not applicable as the PR doesn't deal with health products of any kind in the project.
6. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment / program disruptions	Not applicable as the PR doesn't deal with health products of any kind in the project.
7. Data-collection capacity and tools are in place to monitor program performance	SAATHII has experience managing multi-state, multiyear, multi-partner projects. Each project has its Monitoring and Evaluation (M&E) framework that spells out indicators, means of verification and validation processes. In case of projects where SAATHII is the PR, we develop the M&E framework. For instance, SAATHII has developed a comprehensive MIS system in its private sector PPTCT program which collects data under various indicators and used for analysis and reporting. The data of the PPTCT program are shared with the government within the given government format. In other cases (such as the GFATM projects of which we serve as SR), we follow the framework and tools developed by the PR. These systems assist in systematic tracking of project course, and enable evidence-based correction. SAATHII has specific, time-bound analysis of key indicators to assess the progress made along a desired pathway within any given time frame. Project MIS systems are developed for the current projects and the Key Management Systems consist of processes, SOPs, Guidelines, templates, check-lists and tools that enable the adherence, timeliness, data collection, reporting and flagging of program activities.
8. A functional routine reporting system with reasonable coverage is in place to report	SAATHII has a systematic review and reporting mechanism for all its projects. Monthly reports are generated and shared within a specific timeframe. Quarterly narrative reports, Quarterly quantitative reports and financial reports are generated at the end of each quarter and the reports are shared with the donors and significant stakeholders. The project

program performance timely and accurately	admin team follows up on the timely submission of these reports. SAATHII also reports in time to state and national government
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain	Not applicable as the PR doesn't deal with health products of any kind in the project.

PR 7 Name	India HIV/AIDS Alliance	**Sector**	
Does this PR currently manage a Global Fund grant(s) for this disease component or a stand-alone cross-cutting HSS grant(s)?		☑Yes ☐No	

Minimum Standards	**CCM assessment**
1. The Principal Recipient demonstrates effective management structures and planning	PR has built an efficient team having demonstrated managerial skill to operate effectively from M&E, Program and Finance point of view. Senior Management Team of the organization efficiently guides the team.
2. The Principal Recipient has the capacity and systems for effective management and oversight of Sub-Recipients (and relevant Sub-Sub-Recipients)	PR through regular monitoring visits at SRs and SSRs has established sound systems of oversight for management and operations of SRs and SSRs. Detailed analysis of quarterly reports, received from SRs, provide an important tool for strong control over the operations at SR and SSR level on regular basis.
3. The internal control system of the Principal Recipient is effective to prevent and detect misuse or fraud	PR has established a strong internal control system, in compliance with accounting standards and generally accepted accounting principles in India. Regular monitoring visits by finance team at SR/SSR level, coupled with periodic review by external professional accounting firm leads to prevention and early detection for misuse or fraud at SR level. This has been validated when the OIG carried out its review in 2012.
4. The financial management system of the Principal Recipient is effective and accurate	PR has established strong financial controls and management at the organization, which is regularly monitored and updated by professional finance team and reviewed by external professional accounting firm at regular intervals.
5. Central warehousing and regional warehouse have capacity, and are aligned with good storage practices to ensure adequate condition, integrity and	Not applicable as the PR doesn't deal with health products of any kind in the project.

security of health products	
6. The distribution systems and transportation arrangements are efficient to ensure continued and secured supply of health products to end users to avoid treatment / program disruptions	Not applicable as the PR doesn't deal with health products of any kind in the project.
7. Data-collection capacity and tools are in place to monitor program performance	Through systematic flow of data in a pre-designed reporting template from SR to PR, its analysis, interaction with SR/SSR personnel, coupled with data validation visits by PR provides efficient monitoring of program performance. The PR is also now implementing a dashboard to monitor the grant performance since early 2014.
8. A functional routine reporting system with reasonable coverage is in place to report program performance timely and accurately	Yes, there is a routine quarterly reporting system in place from SR to PR with regard to M&E, Program and Finance
9. Implementers have capacity to comply with quality requirements and to monitor product quality throughout the in-country supply chain	Not applicable as the PR doesn't deal with health products of any kind in the project.

4.4 Current or Anticipated Risks to Program Delivery and PR(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, PR(s) and key implementers' capacity, past and current performance issues.

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

The portfolio analysis prepared by the GF India Country Team identifies four major risks:

- Insufficient programmatic data quality that can influence public health decisions;
- Weaknesses in financial reporting and audit compliance that have resulted in disbursement disallowances and other financial losses to the grant programs;
- Inadequate quality assurance of pharmaceuticals and diagnostic products that potentially contribute towards drug resistance and poor treatment outcomes; and
- Governance and capacity issues characterized by conflicts of interest and restricted information flow.

While the CCM and the PRs take cognizance of the above findings India is NOT in full agreement with the above findings and analysis. Given below are responses to these issues:

- Insufficient Programme Data: Both the HIV and TB Programmes in India have extensive Programme data – which includes one of world's largest HIV surveillance, extensive MIS data and studies / research.

- The data emerging from these are regularly used in strategizing and financial allocations. As in any programme data, there is scope for improvement and we have identified

The following areas:

- Inclusion of Private sector data
- Review and further simplification of programme data, based on usage and a multi-level Information Needs Analysis.
- Cloud based solutions and dashboard, which make information real time, thereby enhancing data for decision-making.
- A National Programme Management Unit has been established at CTD for technical and financial support to the grant's programme and has initiated the process of addressing financial gaps and issues with review of records and audit compliance. NACO already has program management team comprising of Program officers & technical officers to look into the issues pertaining to grant implementation and reporting.
- Quality Assurance (QA) of Anti-TB Drugs has been accorded special importance by RNTCP and measures are taken at the time of procurement and also Post Procurement to maintain quality of Anti-TB Drugs. A comprehensive Quality Assurance Scheme (QAS) has been developed and implemented for RNTCP drug supplies at various levels. Procurement for the World Bank funded States is done through ICB by Procurement Agency of Ministry of Health and Family Welfare. For this procurement, WHO-GMP Certification is required, Joint Inspection for verification of WHO-GMP Certificates by a team under DCG (I) is ensured and pre-dispatch inspection of all batches is done. For GFATM funded states, procurement is done through Green Light Committee (GLC) and Global Drug Facility (GDF) of Stop TB Partnership from the "WHO Pre-Qualified suppliers" only. Post procurement QA is done by conducting random sampling of drugs and testing them in the contracted laboratory. The contracted laboratory sends the reports on drug tests to the sender, with a copy to CTD, within 15 days of receipt of the drug samples.

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.

☒	Table1: Financial Gap Analysis and Counterpart Financing Table
☒	Table2: Programmatic Gap Table(s)
☒	Table3: Modular Template
☒	Table4: List of Abbreviations and Attachments

☒	CCM Eligibility Requirements
☒	CCM Endorsement of Concept Note