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R2019-0048/1

March 12, 2019

Closing Date: Friday, March 29, 2019 at 6:00 p.m.

FROM: Vice President and Corporate Secretary

India - Program Towards Elimination of Tuberculosis

Program-for-Results

Program Appraisal Document

Attached is the Project Appraisal Document regarding a proposed loan to India for a Program Towards Elimination of Tuberculosis (R2019-0048), which is being processed on an absence-of-objection basis.

Distribution:
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Document of

The World Bank

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Report No: PAD3185

PROGRAM APPRAISAL DOCUMENT

ON A

PROPOSED LOAN

IN THE AMOUNT OF
US$400 MILLION

TO THE

REPUBLIC OF INDIA

FOR A

PROGRAM TOWARDS ELIMINATION OF TUBERCULOSIS

February 26, 2019

Health, Nutrition & Population Global Practice
South Asia Region

CURRENCY EQUIVALENTS

Exchange Rate Effective December 31, 2018

Currency Unit =	US$
INR 69.78 =	US$1

FISCAL YEAR
April 1 - March 31

Regional Vice President:	Hartwig Schafer
Practice Group Vice President:	Annette Dixon
Country Director:	Junaid Kamal Ahmad
Practice Manager:	Rekha Menon
Task Team Leader(s):	Ronald Upenyu Mutasa

ABBREVIATIONS AND ACRONYMS

ACSM	Advocacy, Communication and Social Mobilization
AIDS	Acquired Immuno-Deficiency Syndrome
AIC	Airborne Infection Control
BMGF	Bill and Melinda Gates Foundation
BMWM	Bio-Medical Waste Management
CA	Chartered Accountant
CAAA	Controller of Aid, Accounts, and Audit
CAG	Comptroller and Auditor General
CIEs	Central Level Internal Evaluations
CMSS	Central Medical Services Society
CPF	Country Partnership Framework
CPP	Central Procurement Portal
CTD	Central TB Division
CTF	Common Treatment Facility
CVC	Central Vigilance Commission
DALY	Disability-Adjusted Life Year
DBT	Direct Benefit Transfer
DDG	Deputy Director-General
DLI	Disbursement-Linked Indicator
DLR	Disbursement-Linked Result
DOHFW	Departments of Health and Family Welfare
DOTS	Directly Observed Treatment, Short-Course
DR-TB	Drug-Resistant TB
DST	Drug Susceptibility Test
EHS	Environmental Health & Safety
ESSA	Environmental and Social Systems Assessment
FM	Financial Management
FMR	Financial Monitoring Report
FPIC	Free and Prior Informed Consultation
FSA	Fiduciary System Assessment
GAC	Governance and Anti-Corruption
GDP	Gross Domestic Product
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GFR	General Financial Rules
GOI	Government of India
GPS	Global Positioning System
GST	Goods and Services Tax
HDI	Human Development Index
HCF	Health-Care Facilities
HIV	Human Immune-Deficiency Virus
IBRD	International Bank of Reconstruction and Development
ICT	Information and Communications Technology

IC	Infection Control
IDA	International Development Association
IEC	Information, Education, and Communication
IFSA	Integrated Fiduciary System Assessment
INR	Indian National Rupee
INT	Institutional Integrity
IRL	Intermediate Reference Laboratories
IRR	Internal Rate of Return
ISM	Implementation Support Mission
IT	Information Technology
IVA	Independent Verification Agency
JEET	Journey of Enhancing Targeted Interventions
JICA	Japan International Cooperation Agency
JMM	Joint Monitoring Mission
LTA	Long-Term Agreement
MDR-TB	Multidrug Resistant TB
MOHFW	Ministry of Health and Family Welfare
NCD	Noncommunicable Diseases
NGO	Non-Governmental Organization
NHM	National Health Mission
NPV	Net Present Value
NPY	Nikshay Poshan Yojana
NSP	National Strategic Plan
OPRC	Operational Procurement Review Committee
PAD	Project Appraisal Document
PAP	Program Action Plan
PDO	Program Development Objective
PFMS	Public Financial Management System
PforR	Program for Results
PIP	Program Implementation Plan
PP	Public Private
PPE	Private Provider Engagement
PPM	Public-Private Mix
PPSA	Private Provider Support Agency
PTETB	Program Towards Elimination of TB
RNTCP	Revised National TB Control Program
ROP	Record of Proceedings
SC	Scheduled Castes
ST	Scheduled Tribes
TA	Technical Assistance
TB	Tuberculosis
TSU	Technical Support Unit
WHO	World Health Organization
XDR-TB	Extensively Drug-Resistant TB

BASIC INFORMATION

Is this a regionally tagged project?	Financing Instrument
No	Program-for-Results Financing

Bank/IFC Collaboration	Does this operation have an IPF component?
No	No

Proposed Program Development Objective(s)

To improve the coverage and quality of TB control interventions in the private and public sector in targeted states of India

Organizations

Borrower:	Republic of India
Implementing Agency:	Ministry of Health and Family Welfare

COST & FINANCING

SUMMARY (USD Millions)

Government program Cost	8,300.00
Total Operation Cost	1,334.00
Total Program Cost	1,334.00
Total Financing	1,334.00
Financing Gap	0.00

Financing (USD Millions)

Counterpart Funding	**934.00**
Borrower	934.00
International Bank for Reconstruction and Development (IBRD)	**400.00**

Expected Disbursements (USD Millions)

Fiscal Year[1]	2019	2020	2021	2022	2023	2024
Absolute	40.00	70.00	80.00	80.00	70.00	60.00
Cumulative	40.00	110.00	190.00	270.00	340.00	400.00

INSTITUTIONAL DATA

Practice Area (Lead)

Health, Nutrition & Population

[1] Refers to World Bank fiscal year and figures provided are indicative.

Contributing Practice Areas

Climate Change and Disaster Screening

Yes

Private Capital Mobilized

No

Gender Tag

Does the program plan to undertake any of the following?

a. Analysis to identify Project-relevant gaps between males and females, especially in light of country gaps identified through SCD and CPF

Yes

b. Specific action(s) to address the gender gaps identified in (a) and/or to improve women or men's empowerment

Yes

c. Include Indicators in results framework to monitor outcomes from actions identified in (b)

Yes

SYSTEMATIC OPERATIONS RISK-RATING TOOL (SORT)

Risk Category	Rating
1. Political and Governance	Moderate
2. Macroeconomic	Low
3. Sector Strategies and Policies	Low
4. Technical Design of Project or Program	Substantial
5. Institutional Capacity for Implementation and Sustainability	Substantial
6. Fiduciary Fiduciary rating from IRT: Substantial as of 26-Nov-2018	Substantial
7. Environment and Social Environmental Risk rating from Specialist: Moderate as of 19-Nov-2018 Social Risk rating from Specialist: Moderate as of 19-Nov-2018	Moderate
8. Stakeholders	Moderate
9. Other	Low

10. Overall	Substantial

COMPLIANCE

Policy

Does the program depart from the CPF in content or in other significant respects?

[ ] Yes [✓] No

Does the program require any waivers of Bank policies?

[ ] Yes [✓] No

Safeguard Policies Triggered

Safeguard Policies	Yes	No
Projects on International Waterways OP/BP 7.50		✓
Projects in Disputed Areas OP/BP 7.60		✓

Legal Covenants

Sections and Description

Technical Support Unit (TSU): The Borrower shall establish and maintain a Technical Support Unit (TSU) under the Central TB Division (CTD) within 24 months of the Effective date; the unit shall be provided with competent, experienced, and qualified staff, in sufficient numbers and under terms of reference acceptable to the Bank, and be responsible for providing expert advice on strategic purchasing, private sector engagement, and direct benefit transfer management [Schedule 2, Section I (a)]

Sections and Description

State Technical Support Units (STSUs): The Borrower shall cause each of the Program States to establish, within 24 months of the Effective Date, and maintain throughout Program implementation, State Technical Support Units (STSUs), each of which shall be provided with competent, experienced, and qualified staff, in sufficient numbers and under terms of reference acceptable to the Bank [Schedule 2, Section I (b)] .

Sections and Description

Program Action Plan: The Borrower shall implement the Program Action Plan agreed with the Bank, in a manner and substance satisfactory to the Bank [Schedule 2, Section I (c)].

Sections and Description

Verification: The Borrower shall undertake a verification process, in accordance with the terms of reference agreed with the Bank, to certify the fulfillment of the Disbursement Linked Results (DLRs), and furnish to the Bank corresponding verification report(s), in form and substance agreed with the Bank [Schedule 2, Section III (B)].

Sections and Description

The Borrower shall cause each Program State to prepare and submit for approval to CTD annual Program implementation plans, which contain, inter alia, implementation arrangements, activities to be undertaken to achieve the DLIs and as per the Program Action Plan, financial and procurement arrangements at the state level and modalities of the performance-based mechanism under the Program [Schedule 2, Section I (B)].

Conditions

Not Applicable.

TASK TEAM

Bank Staff

Name	Role	Specialization	Unit
Ronald Upenyu Mutasa	Team Leader(ADM Responsible)	Public Health and TB Control	GHN06
Sreenivas Devarakonda	Procurement Specialist(ADM Responsible)	Procurement	GGOPZ
Tanya Gupta	Financial Management Specialist(ADM Responsible)	Financial Management	GGOIS
Sangeeta Kumari	Social Specialist(ADM Responsible)	Social Development	GSU06
Ajay Ram Dass	Team Member	Operations and Project Management	GHN19
Ambrish Shahi	Team Member	Direct Benefit Transfer	GSP06
Anupam Joshi	Environmental Specialist	Environment	GEN06
Di Dong	Team Member	Health Financing and TB	GHN05
Di Qiu	Team Member	Finance	CMD
Hiroshi Tsubota	Team Member	Finance	AFCW2
Jorge A. Coarasa	Team Member	Health Financing and TB Control	SACIN
Jose F. Molina	Team Member	Finance	FABBK
Maria E. Gracheva	Team Member	Project Operations	GHNGE
Martin M. Serrano	Counsel	Legal	LEGES
Raadhika Gupta	Counsel	Legal	LEGES
Sharlene Jehanbux Chichgar	Environmental Specialist	Environment	GEN06
Son Nam Nguyen	Team Member	Health Systems and PforR	GHN01
Suresh Kunhi Mohammed	Team Member	Public Health	GHN06
Tanusree Talukdar	Team Member	Operations and Project Management	SACIN
Victor Manuel Ordonez Conde	Team Member	Finance	WFACS

Extended Team

Name	Title	Organization	Location
Guy Stallworthy	Private Sector Consultant	BMGF	United States

Puneet Dewan	STC- Technical Adviser	World Bank	Seattle,United States
Ranjan B. Verma	Social Development Consultant	World Bank	India
Sameer Kumta	Senior Program Officer	BMGF	United States

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I. STRATEGIC CONTEXT

A. Country Context

1. India continues to be the world's fastest growing major economy. Growth has accelerated in the last two quarters to reach 8.2 percent in the first quarter of FY18/2019. This growth was supported by a revival in industrial activity, strong private consumption, and a rise in exports of goods and services. At the same time, the external situation has become less favorable. The current account balance has widened on the account of an increasing trade deficit (on the back of strong import demand and higher oil prices) from 0.7 percent of GDP in FY16/17 to 1.9 percent in FY17/18. Meanwhile, external headwinds—monetary policy 'normalization' in the US coupled with recent stress in some Emerging Market Economies—have triggered portfolio outflows from April 2018 onwards, putting additional pressure on the balance of payments. Going forward, growth is projected to reach 7.3 percent in FY18/19 and to firm up thereafter at around 7.5 percent, primarily on account of robust private and public consumption expenditure, a rise in exports of goods and services, and a gradual increase in investments. However, the current account deficit is also projected to remain elevated in FY18/19.

2. Since the 2000s, India has made remarkable progress in reducing absolute poverty. Between FY2011/12 and 2015, poverty declined from 21.6 percent to an estimated 13.4 percent at the international poverty line (2011 PPP US$1.90 per person per day), continuing the earlier trend of robust reduction in poverty. Aided by robust economic growth, more than 90 million people escaped extreme poverty and improved their living standards during this period. Despite this success, poverty remains widespread in India. In 2015, with the latest estimates, 176 million Indians were living in extreme poverty while 659 million, or half the population, were below the higher poverty line commonly used for lower middle-income countries (2011 PPP US$3.20 per person per day). Recent trends in the construction sector and rural wages, a major source of employment for the poorer households, suggest that the pace of poverty eradication may have slowed. India is still marked by disparities between urban and rural areas, as well as structural inequalities by gender, tribe, and caste. Addressing these inequalities will require increasing access, quality, and utilization of human development services, including health care.

B. Sectoral (or Multi-Sectoral) and Institutional Context

Health Outcomes and Health Financing

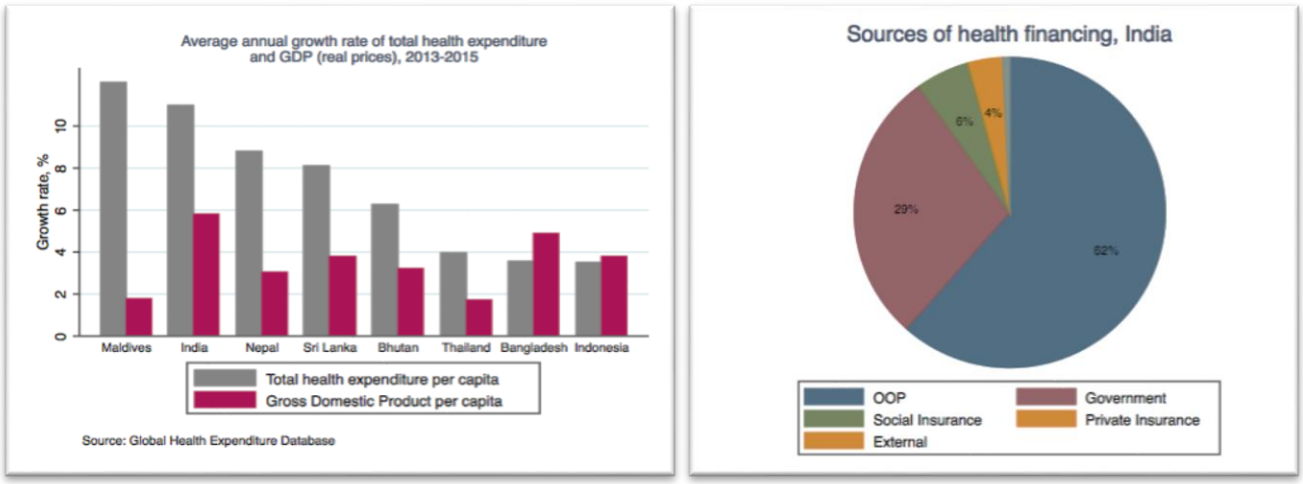
3. Despite substantial improvements in health outcomes since 1990, India still faces tremendous challenges in health care access, quality, and utilization. Between 1990 and 2016, infant mortality rates fell by half, deliveries in health facilities tripled, and maternal mortality ratios fell by more than 60 percent. However, overall progress in health remains slower than in countries of comparable income, and variations persist within and among states. Quality of care is a significant and complex challenge. India's demographic and epidemiological transition calls for an aggressive response to persisting communicable diseases and a burgeoning burden of non-communicable diseases (NCDs).

4. India's steadily increasing health expenditures are dominated by regressive out-of-pocket payments by households. Between 2013 and 2015, total health expenditures per capita grew by more than 10 percent per year–a higher rate than the country's GDP growth (Figure 1). Despite this rapid increase, India's health expenditures are relatively low at India Rupees (INR) 3,800 (US$56) per person, compared to US$233 per person in other lower middle-income countries[2]. In addition, there is a weak correlation between per capita health expenditures and outcomes across states. Despite increases in health expenditures through central level schemes, including tuberculosis (TB) control, the private sector continues to dominate the provision of health services in India. Out-of-pocket expenditures—accounting for 63 percent of India's total health expenditure—are driven by

[2] National Health Accounts (NHA) 2014-2015

outpatient care costs, diagnostics, and drugs, which disproportionately affect poor households[3].

Figure 1: Trends and Composition of Health Expenditures



TB control in India

5. TB is a prime example of a persisting communicable disease challenge for India. TB kills approximately 480,000 people every year in India. The country still contributes almost 25 percent of the global TB burden and this proportion has remained constant for more than 20 years. While the coverage of TB interventions by the public sector expanded rapidly from 1993 to 2012 under the Revised National TB Control Program (RNTCP), such coverage has plateaued, and TB treatment outcomes have stagnated over the past five years.

6. Drug-resistant TB (DR-TB) is a major public health threat to India and potentially to the world. TB is one of the world's top anti-microbial resistant pathogens, mostly due to poor management of TB patients. Resistance to first-line drugs is known as multi-drug-resistant TB (MDR-TB). Inappropriate management of MDR-TB can lead to a highly lethal form of TB called extensively drug-resistant TB (XDR-TB). Resistant forms of TB require more expensive drugs with higher levels of toxicity, case fatality, and treatment failure rates. Unfortunately, India has the world's highest burden of MDR-TB, with 37,000 cases or 24 percent of the world's total in 2016. India's health systems are ill-equipped to adequately respond to DR-TB, with DR-TB outcomes lagging global and regional trends. These resistant forms of TB threaten to erode India's health and development gains.

7. Many TB cases remain undiagnosed and/or inadequately treated. Despite increases in total new TB cases reported to the RNTCP (notified cases), India still accounts for approximately one third of the world's three million people with TB each year who are not diagnosed, treated, or officially registered by a national TB program. Most of these people are in their economic prime. In India, unnotified cases are either undiagnosed[4] or inadequately diagnosed and treated in the private sector. As such, delayed diagnosis and incomplete treatment are the greatest challenges to TB control in India—particularly among private providers, who are ill-equipped or unmotivated to sustain patients on prolonged, complex, and costly regimens.

8. TB is a disease of poverty. TB predominantly affects the poor and marginalized. It entrenches poverty through health and economic shocks to households least able to cope. A systematic review of studies in low- and middle-income countries shows that the total cost of TB ranges from 5 percent to 40 percent of a TB

[3] Gupta I, Chowdhury S, Prinja S, Trivedi M (2016) Out-of-Pocket Spending on Out-Patient Care in India: Assessment and Options Based on Results from a District Level Survey. PLoS ONE 11 (11): e0166775. doi:10.1371/journal. pone.0166775

[4] Undiagnosed TB represents a major public health failure given that an undiagnosed person with TB can infect 10-15 people. (Stop TB Partnership, 2015).

patient's annual household income. This share can even be higher than 200 percent for poorer households and patients with MDR-TB. A staggering 70 percent of patients in these countries took loans for TB treatment. India is no exception in this regard.

9. A combination of household and health system factors account for India's persistently high levels of TB. They include:

i. **Poor coordination in TB care:** The TB burden is exacerbated by fragmented health care provision through diverse providers, including an unregulated private sector accounting for more than half of TB cases treated in India. Convoluted patient pathways, especially in the private sector, prolong the times between onset of symptoms, diagnosis, and initiation of treatment[5].

ii. **Quality gaps:** Evidence points to quality gaps in TB diagnosis and treatment in both public and private sector, with varying levels of adherence to India Standards of TB Care[6]. A standardized patient study among providers in two cities found only: (i) 35 percent compliance with care standards; (ii) 31 percent of interactions with an order of microbiological testing; and (iii) 5 percent of cases with a prescription of anti-TB drugs.[7]

iii. **Delayed care-seeking and leakages in care cascade:** Many patients delay seeking care and do not adhere to treatment due to various behavioral and socio-economic factors. Transportation costs are a well-known barrier to TB care. High out-of-pocket costs related to TB treatment as discussed above also reduce treatment adherence. While under-nutrition is a major risk factors for TB, emerging evidence shows that it also contributes to unfavorable treatment outcomes.

iv. **Diagnostic laboratory network limitations:** In 2017, an external Diagnostic Laboratory Assessment revealed substantial deficiencies. To diagnose the estimated 2.8 million cases of TB and 150,000 cases of MDR-TB a year, laboratory capacity must be expanded by (i) further decentralizing molecular testing to Health Blocks; (ii) improving specimen referral and transport systems; (ii) engaging private providers and laboratories; (iii) deploying a centralized laboratory information system; and (iv) enhanced monitoring and evaluation, quality assurance and supportive supervision.

v. **Institutional capacity constraints at central and state levels:** There is a mismatch between the skills mix envisioned by the National Strategic Plan (NSP) 2017-25 and the current staffing situation of the RNCTP, including high vacancy rates in some high burden TB states. Key areas for further institutional strengthening include private sector contracting, Direct Benefit Transfer (DBT) for TB patients, information systems and performance-based management system between CTD and states.

10. Evidence suggests that strategic engagement with the private sector could be a game changer for TB control in India. Around 80 percent of people with TB make first contact with the health system through private providers[8]. In recognition of the roles of the private sector, the RNTCP has articulated guidelines and schemes for private sector engagement since 1999. However, most activities were only confined to pilots in Maharashtra and Gujarat states in the earlier years of the RNTCP. Several reviews of this period pointed to the lack of attention to private sector engagement. However, in 2012, the GOI: (i) approved the NSP 2012-17, which endorsed contracting Private Provider Interface Agencies to engage private providers; (ii) made TB a notifiable disease and passed a regulation to mandate TB notifications by private providers; and (iii) introduced the Nikshay information system on a large scale to enable TB case notifications by all providers. Following these policy actions, the GOI appointed dedicated Public Private Mix (PPM) Coordinators and worked with partners—

[5] Das et al., (2015). Use of Standardized Patients to Assess Quality of TB Care: A Polit Cross-Sectional Study. Lancet Infectious Diseases, November 2015.

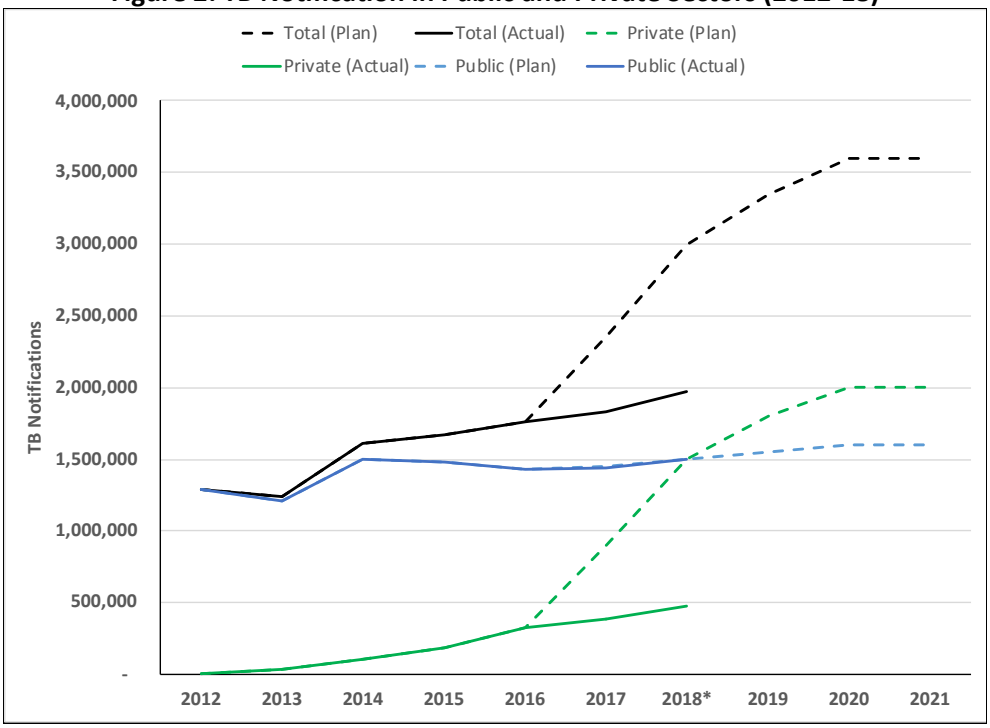
[6] Studies found low adherence to case specific checklists of TB care, inappropriate treatment and overuse of unnecessary treatment such as steroids and anti-biotics. See McDowell, A. Pai, M. 2016. "Treatment as diagnosis and diagnosis as treatment: empirical management of presumptive tuberculosis in India" IJTLD 20(4)

[7] World Health Partners (WHP), World Vision India, Lepra, Mamta, Alert, Karnataka Health Promotion Trust (KHPT) and Maharashtra Janvikas Kendra (MVK).

[8] Ministry of Health and Family Welfare, National Strategic Plan for Tuberculosis Elimination, 2017-25

USAID, the Global Fund to Fight AIDS, TB and Malaria (Global Fund), and the Bill and Melinda Gates Foundation (BMGF)—to test and roll out implementation models to engage the private sector in TB control. RNCTP data show that while public sector notifications have plateaued since 2012, recent efforts to engage private providers, while falling short of ambitious targets, have yielded promising results (Figure 2).

Figure 2: TB Notification in Public and Private Sectors (2012-18)



Source: Ministry of Health and Family Welfare

11. Determined to eliminate TB, India has launched a robust response with the National Strategic Plan (NSP) for Tuberculosis Elimination 2017-25. The GOI's NSP 2017-25 embraces evidence-based interventions, new technologies, bold innovations and major institutional reforms (please see section III below for further analysis), with the aim to achieve End TB goals by 2025, five years ahead of the global timeline of 2030. The comprehensive scope of NSP is matched by an impressive budget of US$8.3 billion. The transformative nature of India's NSP and the scale of its ambitions are thus unprecedented among countries with high burdens of TB. The GOI's actions speak louder than words – it already doubled the annual budget for TB within a span of one year, from US$252 million in FY2016 to US$525 million in FY2017. The Bank's proposed support builds on this bold vision and supports the NSP's out-of-the box innovations which are game changers in TB control. These include: (i) contracting of private provider interface agencies; (ii) expanding direct benefits transfer for patients; (iii) expansion of ICT services; and (iv) strengthening DR-TB services.

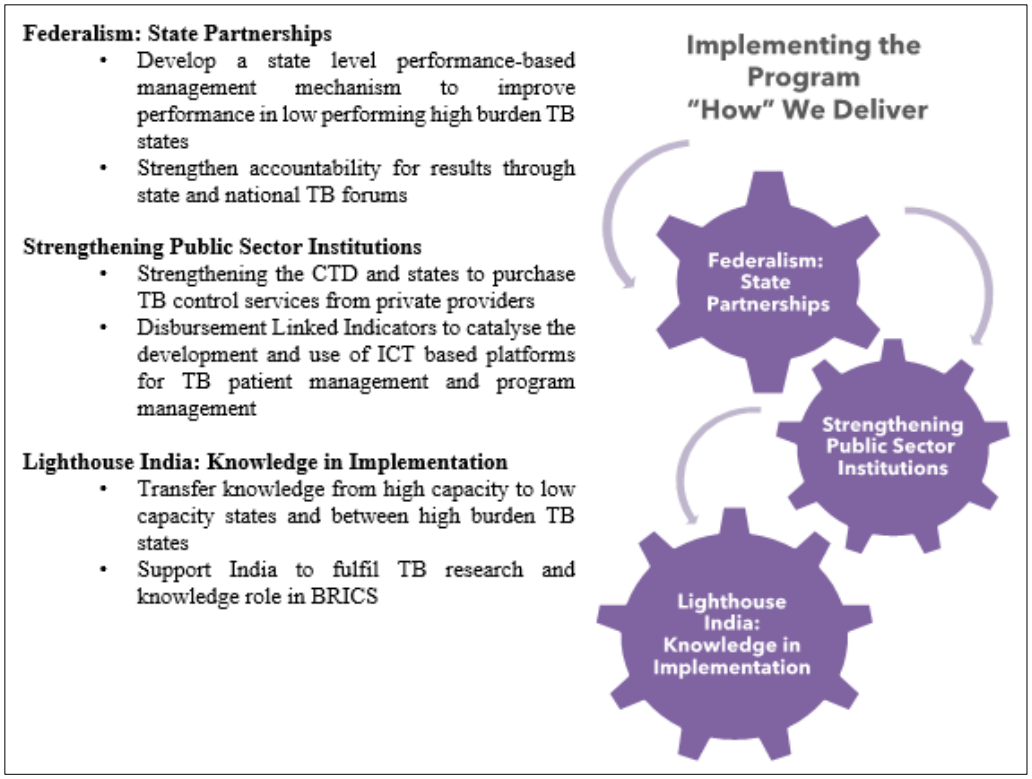
C. Relationship to the CPF and Rationale for Use of Instrument

12. The proposed operation builds on 20 years of successful partnership in TB control between the World Bank and the GOI. The Bank has a strong track record of supporting the GOI in TB control with three IDA projects since 1998. All of them were rated as Satisfactory for outcomes upon completion. The Bank's support has contributed to the scaling up of (i) Directly Observed Treatment, Short-Course (DOTS) to nationwide (1998-2006); (ii) services to poor and high-risk groups, including tribal households, HIV patients, and children; initiation of MDR-TB services (2006-2012); and (iii) universal access to diagnostics and quality TB care (2012-2017).

13. The proposed Program is consistent with the World Bank Group's Country Partnership Strategy FY18-

22; Report No. 126667-IN, July 25, 2018 discussed at the Board on September 20, 2018. By supporting India to tackle an infectious disease with substantial health and economic impacts as well as negative externalities, the Program directly aligns with the objectives of the CPF FY18-22 and contributes to Focus Area 3: Investing in Human Capital, one of the three "Whats" of the CPF. To achieve this objective, it will apply all of the four "Hows" of the CPF by: (i) leveraging the private sector through engaging private providers in TB control; (ii) strengthening public sector institutions; (iii) engaging a Federal India by working with both the CTD and states; and (iv) contributing to the "Lighthouse India" learning initiative by connecting practical know-how and innovations in TB elimination among states for the benefit of India and the wider world (Figure 3). The proposed Program will support government driven learning and will be coordinated with partners to systematically distill lessons from innovations at state and central levels.

Figure 3: PTETB Implementation and Links to the CPF



14. The proposed Program also contributes to the attainment of the Sustainable Development Goal 3 and the Health, Nutrition and Population Global Practice goal of ending preventable deaths and disability through Universal Health Coverage (UHC). The relationship between health and wealth is well-established, with better health resulting in enhanced cognitive development and increased human capital[9,10]. Besides affecting health, TB leads to income loss and forces people deeper into poverty. The Program will contribute to India's efforts to achieve UHC goals by promoting effective coverage of TB through the private and public sectors and patient support mechanisms.

15. The Program-for-Results (PforR) is the most suitable instrument for the operation. This is because the PforR: (i) allows the operation to be firmly anchored in the GOI's NSP for TB elimination ; (ii) focuses on results rather than inputs, which allows the flexibility to innovate and learn from different pathways for achieving the

[9] Mirvis D.M. and D.E. Bloom. 2008. Population health and economic development in the United States. *Journal of the American Medical Association*. 300(1): 93-95. Grantham-McGregor et al 2007.

[10] Grantham-McGregor, S., Cheung, Y. B., Cueto, S., Glewwe, P., Richter, L., Strupp, B., International Child Development Steering Group (2007). Developmental potential in the first 5 years for children in developing countries. *Lancet (London, England)*, *369*(9555), 60-70.

results, i.e. private sector engagement; (iii) uses country systems, with attention to system strengthening, which enhances development impact and sustainability; and (iv) is an instrument with which India already has had significant experience at both national and state levels.

II. PROGRAM DESCRIPTION

A. Government Program

16. The ambitious NSP 2017-25 constitutes the government program. The NSP lays out the GOI's strategic approaches and priority interventions to eliminate TB. The US$8.3 billion NSP 2017-25 is organized around four pillars (Figure 4), as follows:

Figure 4: Vision, Goal, and Strategic Pillars of India's National Strategic Plan for TB Control

VISION: TB-Free India with zero deaths, disease and poverty due to TB **GOAL:** To achieve a rapid decline in burden of TB, morbidity, and mortality, while working towards elimination of TB in India by 2025			
Detect • Improved diagnostics • Private provider engagement • Universal screening for drug-resistant TB • Systematic screening of high-risk populations	**Treat** • Reduced losses in cascade of care with support systems • Free anti-TB drugs for public and private TB cases • Enhanced TB regimens • Patient-friendly adherence monitoring • Elimination of catastrophic costs with social support	**Prevent** • Scale-up airborne infection control in high-risk settings • Expand treatment of latent TB infection in contacts and high-risk individuals • Address social determinants of TB among high-risk communities and families	**Build** • Restructure TB program • Build high-level political commitment

Source: Ministry of Health and Family Welfare

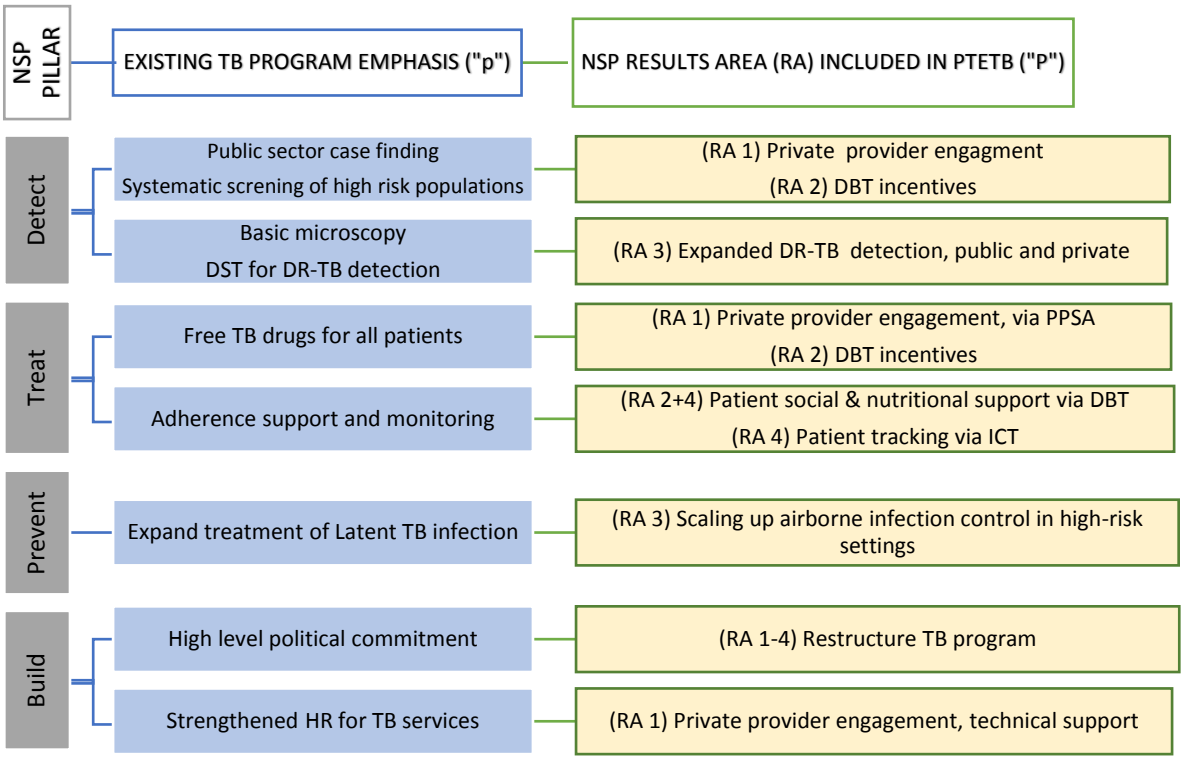
17. The NSP 2017-2025 is technically robust, comprehensive and bold: NSP rightly emphasizes early case-finding and effective treatment to interrupt transmission as key to TB control. It strives to better serve at least 1.5 million patients in the public system per year and, at the same time, to detect and improve the management of millions more in the private sector. To this end, NSP encompasses several new technologies, innovative implementation approaches and bold institutional reforms. First, the country adopts a more effective treatment regimen for drug-susceptible TB and shorter regimens for DR-TB in a bid to improve TB outcomes. Second, molecular testing will be further decentralized at the Health Block level. Third, based on the promising pilot results, the NSP will scale up engagement with private providers and provide them with incentives for TB notification and proper treatment. Fourth, notified TB patients will receive cash transfers, home visits, counseling and preventive interventions for treatment adherence. Fifth, Nikshay information system will be strengthened and other information technology will be leveraged to facilitate the scale up of such new interventions targeting both providers and patients. Finally, institutional strengthening will be prioritized in the NSP, with (i) improving staffing level and mix at all levels to match the focus and ambition of the NSP; and (ii) establishment of a TB control board to strengthen stewardship of resources and RNTCP oversight.

B. PforR Program Scope

18. The proposed Program Towards Elimination of TB (PTETB) is a well-defined subset of the government program. The PTETB was carved out of the NSP by: (i) result area; (ii) geographical area with the selection of priority states; and (iii) timeframe. Within the above-mentioned four NSP pillars (Figure 4), the Program focuses on four result areas: (i) scaling up private sector engagement; (ii) rolling out TB patient management and support interventions; (iii) strengthening diagnostics and management of DR-TB; and (iv) strengthening RNTCP institutional capacity and information systems. These results areas are inter-linked and mutually reinforcing.

The four result areas represent transformative changes required for service delivery to meet the ambitions and targets of the NSP. Figure 5 outlines the relationship between NSP and PTETB.

Figure 5: NSP vs. PTETB



Abbreviations: NSP=National Strategic Plan for TB Control 2017-2025. DST=Drug susceptibility testing. DR-TB=Drug resistant TB. DBT=direct benefits transfer. PPSA=Private provider support agency. ICT=Information and communication technology. HR=Human resources

19. Considering (i) the estimated TB burden and (ii) the gap between private notifications and estimated TB burden, the GOI selected nine states for the participation in the Program: Uttar Pradesh, Maharashtra, Bihar, Rajasthan, Madhya Pradesh, Karnataka, West Bengal, Assam, and Tamil Nadu. Together, these nine states account for:

- 60 percent of the public-sector notification in the country;
- 62 percent of the existing gap in private sector notification (based on NSP targets); and
- 70 percent of all private TB treatment nationwide (or 12 out of 19 million patient-months of anti-TB treatment distributed via private chemists)

20. Success in these nine states is critical for India to meet its NSP targets. The GOI's prioritization of these states will enable intensified implementation of high impact TB interventions at scale. In addition, these nine states will provide a platform for peer learning and for generating important lessons and evidence for the rest of the country. All the remaining 26 states and Union Territories will benefit from cross-cutting system interventions under the Program, mainly improvements to the Nikshay information system. In terms of timeframe, the Program is a time-slice of the NSP (i.e., five years out of seven remaining NSP years).

21. The total Program cost of US$1.334 billion accounts for 74 percent of total government expenditures on TB in the nine targeted states (including state-level expenditures and CTD expenditures relevant for activities in the nine states), or 16 percent of the US$8.3 billion in funding required by India's NSP 2017 to 2025 Program expenditures categories are detailed in Table 1. Excluded from the Program are expenditures related to major

civil works, high value procurement[11], procurement under the Global Drug Facility, hiring and maintenance of vehicles, and miscellaneous office operations. Expenditures on drug and material procurement will be at the CTD level, whereas other expenditures will be predominately at state level. The exact distribution may vary depending on the specific implementation arrangements in each state.

Table 1: Program Expenditure Requirements by Expenditure Categories

Category	Central-level Amount (US$ million)	State-level Amount (US$ million)	Total Amount (US$ million)	percent Total Amount
Supplies and Materials - Procurement of Anti TB Drugs, equipment, and laboratory materials	836	1	837	63 percent
Private sector support (PPM, NGO, PP support)	20	204	224	17 percent
Salaries and Benefits	13	120	133	10 percent
Honoraria	0	95	95	7 percent
Training	4	13	17	1 percent
Supervision and monitoring	3	12	15	1 percent
Patient support and transportation	0	13	13	1 percent
Total	860	474	1,334	100 percent

22. IBRD financing is US$400 million or 30 percent of the total Program cost estimate of US$1.334 billion. The GOI will finance the remaining 70 percent (Table 2).

Table 2: Program Financing

Source	Amount (US$ million)	percent of Total
IBRD	400	30
Government	934	70
Total Program Financing	1,334	100

23. The full GOI request for IBRD financing for the period 2019 to 2025 is US$500 million; the remaining US$100 million requested by GOI will be considered by the World Bank by March 2022.

24. As mentioned above, the Program will support four result areas which are inter-linked and mutually reinforcing. Below is a detailed description of these Results Areas.

25. **Result Area 1: Scaling-up Private Provider Engagement (US$176 Million):** The aim is to scale up private sector engagement to ensure timely diagnosis and notification and effective management of TB among patients in line with Standards of TB Care in India. The array of private providers in India relevant to TB control includes: Rural Health Practitioners[12], chemists and pharmacies, laboratories, qualified AYUSH providers, qualified allopathic Bachelor of Medicine General Practitioners, and specialists (such as pulmonologists). Until recently, the RNTCP's engagement with them has been sporadic and small-scale. The NSP envisages an initial doubling of the number of patients detected and treated, with most of the increase coming from engagement of such

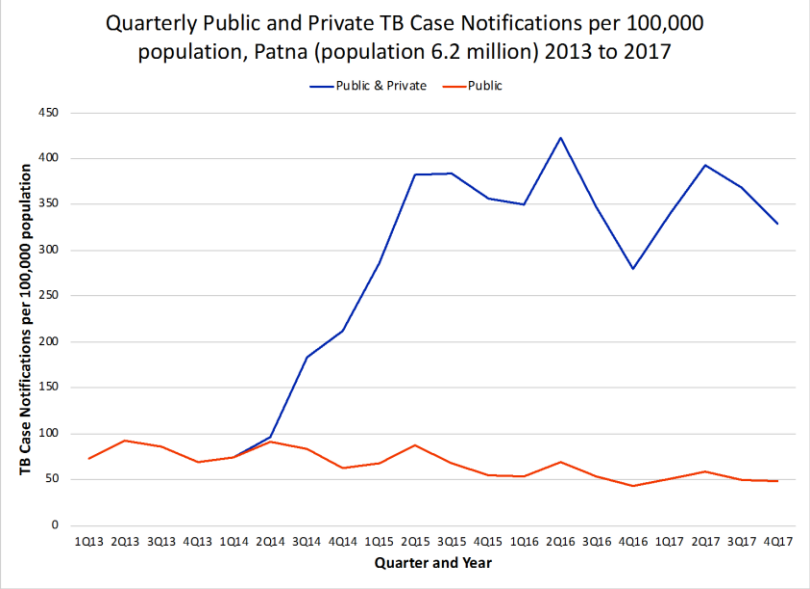
[11] This refers to contracts valued at or above Operational Procurement Review Committee (OPRC) thresholds (i.e., US$75 million for works; US$50 million for goods and non-consulting services; and US$20 million for consultant services).

[12] Also known as Rural Medical Practitioners, Less Than Fully Qualified Practitioners and quacks.

private healthcare providers. Approaches to engaging such a wide range of providers naturally differ: (i) high-volume specialists may merit assignment of dedicated staff to assist with TB patient notification and treatment support; (ii) doctors in solo practice are critical for decentralized case finding and management but require efficient engagement models given their large numbers; (iii) chemists and labs can provide specific TB services if their costs are covered; and (iv) informal providers can play a role in early referrals.

26. Strategic Rationale and Theory of Change: TB control efforts have been limited to public sector health services so far despite the fact that the majority of outpatient care is delivered by private providers. In urban areas, more than 80 percent of those ultimately diagnosed as TB cases start their health care journey with a private provider. However, it is well-documented that private providers often do not meet TB care standards. Delayed diagnosis, case mismanagement, inadequate patient counselling, high cost of care and negligible treatment adherence support all contribute to increases in drug resistance, TB recurrence, high mortality and catastrophic expenditures among private sector TB patients. Engaging the private sector for timely and accurate diagnosis, notification, and good patient management in line with the Standards of TB Care is a critical pathway for India's successful achievement of NSP objectives. Evidence from earlier pilots confirmed the efficacy of engaging with private providers. For example, in Patna, Bihar (a city with more than 6 million people and one of the sites of the Gates Foundation-supported program) private provider engagement increased total TB case notification more than four-fold between 2013 and 2017 (Figure 6). The treatment success rate among privately-notified patients was also increased to 74 percent (not shown).

Figure 6: Results from Private Sector TB Pilot

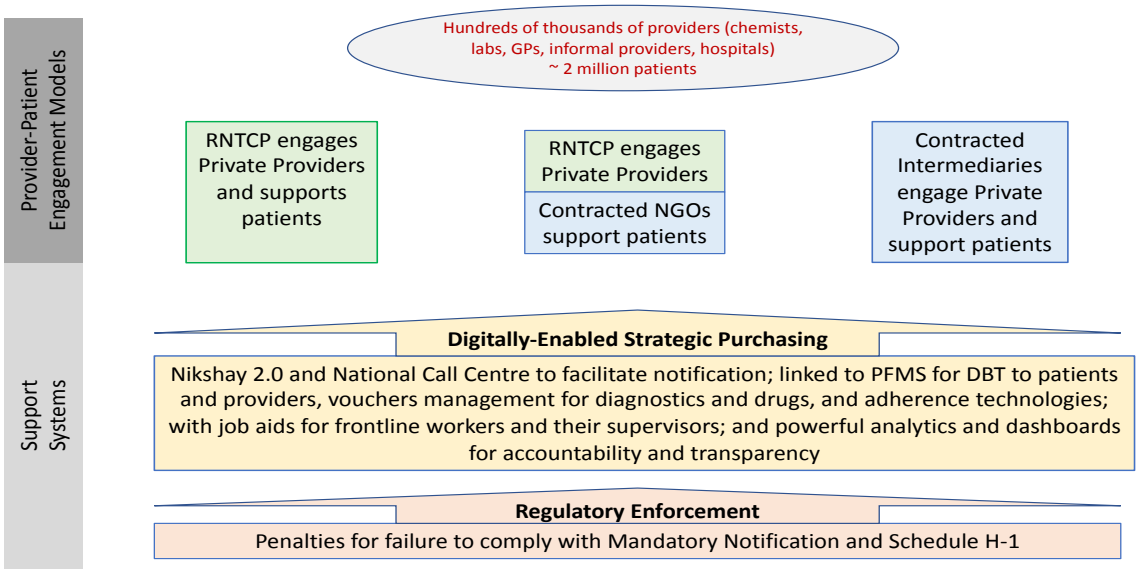


27. Built on years of pilots and more recent large-scale demonstrations, the GOI's new approach to scaling up private provider engagement is summarized in Figure 7[13]. Depending on the context, three different basic models will be used: (i) RNTCP field staff directly engaging private providers to elicit notifications and support patients; (ii) contracting of intermediary agencies to manage all aspects of private provider engagement and patient support; and (iii) a hybrid model in which RNTCP field staff engage the private providers and contract local NGOs for supportive functions, such as sputum transport or patient support. All models will be supported by Nikshay case-based information system which will enable large scale monitoring, strategic purchasing, direct electronic payments to patients and providers and new adherence support technologies. Digital systems for

[13] NSP will also support other approaches to engage private sector such as (i) use of health insurance schemes to scale-up private sector engagement; (ii) engaging private sector professional associations; and (iii) strengthening pre-service medical education related to TB. However, they are not priorities in the Program

recording and reporting will facilitate trust, accountability, and rapid-cycle performance management. The mix of incentives and engagement models will create an ecosystem for private sector engagement. The nine targeted states vary considerably in the strength of their TB programs, in their general public administration, and in their experience with contracting private providers. While all of them are expected to deploy all the strategic elements, the mix of engagement models will vary between states.

Figure 7: Pathways to scale in the current and planned approach to private provider engagement



28. However, each approach has its own strengths and weakness, which are summarized below (Table 3).

Table 3: Strengths and weaknesses in current pathways to scale for private provider engagement

Strategy	Details	Potential	Challenges
Direct RNTCP engagement	Deployment of several hundred contractual PPM Coordinators, in addition to thousands of other field staff	• Most comfortable approach for RNTCP • Demonstrated ability to increase notifications	Not yet able to ensure treatment adherence or quality of care
Contracting intermediaries	• Contract NGOs for support roles: sputum transport, lab technicians, adherence support • Issue more substantial contracts for end-to-end PPSA (here-to-fore donor-funded)	Demonstrated ability to increase case-finding and assure successful treatment outcomes	• Limited capacity for large-scale contracting • Few NGOs with skills and experience at scale
Digitally-enabled mass purchasing of private services	• User-friendly digital case-based registry • 99DOTS adherence monitoring • Call Centers to support notifications, treatment support • DBT/PFMS payments to patients, providers and treatment supporters • Potentially, vouchers for private diagnostics and drugs	• Efficiency at scale • Transparency • Data and analytics for management • Attractive to PPs because reliable, impersonal • Facilitates rapid testing and adoption of adaptations • Accountability for public funds	• Design and implementation of complex data systems

Strategy	Details	Potential	Challenges
Regulatory enforcement	• Mandatory notification decrees, with penalties for non-compliance • Drug Controller General enforcement of Schedule H1	Increases motivation for providers to notify	• Inconsistent enforcement

29. In light of the RNTCP's limited experience in engaging private providers, Technical Support Units (TSUs) will be established in the CTD and in each of the nine states to support strategic purchasing, private sector engagement, and DBT management under the Program. The CTD will set a minimum skills mix expected for a TSU and work with states to contract or develop such teams[14]. However, there will be flexibility in TSU configurations. For example, states with active Public Private Partnership Units will have the option to strengthen such units so that they can perform the TSU roles.

30. Four DLIs will be used to incentivize this results area. Prior result #1.0 will be about revision of national guidelines for engagement with private providers. DLI# 1.1 and DLI# 1.2 are related to results in TB notifications, management, and treatment outcomes by private providers. DLI# 1.3 will be about institutional strengthening to support private sector engagement. The GOI will provide incentives to private providers who notify TB patients.

31. **Result Area 2: Rolling out TB Patient Management and Support Interventions (US$60 Million):** TB control outcomes depend on whether TB patients seek care early and adhere to treatment. Thus, the GOI is rolling out TB patient support as one of its strategic interventions to eliminate TB.

32. Strategic Rationale and Theory of Change: Providing treatment enablers in the form of financial incentives and nutritional support can increase treatment adherence and treatment success rates. They are therefore recommended interventions under the WHO End TB Strategy. In this context, the GOI is rolling out a Direct Benefit Transfer (DBT) scheme to t to provide financial incentives to TB patients called Nikshay Poshan Yojana (NPY). The GOI will also support the incentives for private providers to notify TB and the incentive for tribal patients (Table 4).

Table 4: Direct Benefit Transfer Schemes for TB Patients and Providers

S.No.	Scheme Name	Amount to be paid	Scheme Description
1.	Nikshay – TB notification incentive for Private Sector Providers	INR 500 (US$7.23) upon notification and again upon treatment completion	Private providers are enrolled in the Nikshay data base and notify TB cases or manage and subsequently report to the RNTCP.
2.	Nikshay Poshan Yojana – Private and public-sector patients with drug susceptible TB (Nutritional Support)	INR 3000 (US$43.44)	Beneficiaries are TB patients under the RNTCP who are eligible for nutritional support in three installments of INR 1000 each.
3.	Nikshay – Tribal patients	INR 750 (US$10.86)	Beneficiaries are tribal TB patients treated under the RNTCP.

33. To implement NPY, RNTCP will use Nikshay, the web-based TB case monitoring system. This information system has already been deployed across India but still needs further strengthening to facilitate electronic

[14] The WHO, BMGF and the Global Fund will continue to provide technical support at CTD and state level while TSUs are being established.

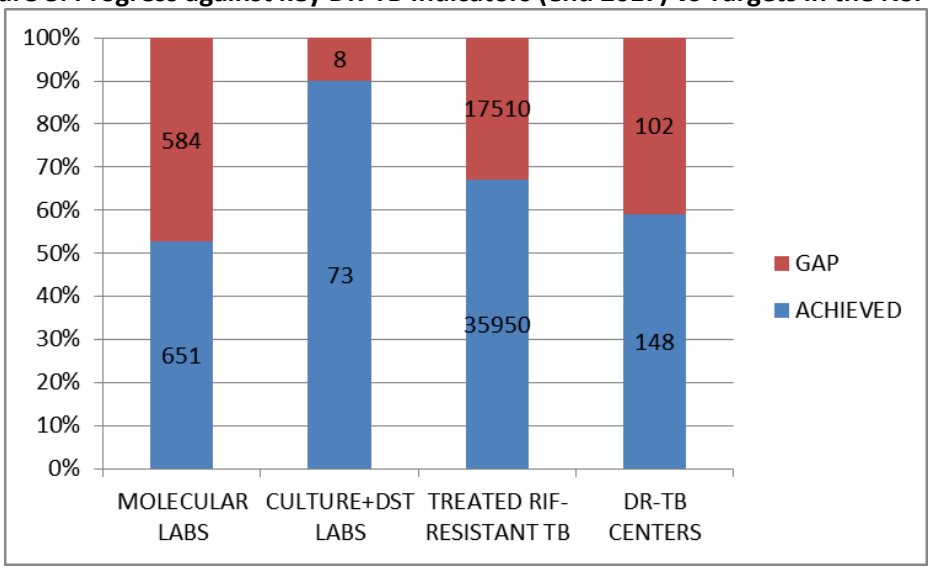
payments to beneficiaries, including integration with the GOI's Public Financial Management System (PFMS).

34. Three DLIs will be used to incentivize this results area. Prior result #2.0 will be about the development of information systems modules in Nikshay 2.0 to enable implementation of the DBT schemes. DLI#2.1 will be about rolling out digital payment and certification systems at district level for processing DBT payments to patients and private providers. DLI#2.2 will be about the proportion of patients receiving DBT through Nikshay.

35. <u>Result Area 3: Strengthening Detection, Treatment, and Monitoring of Drug-Resistant TB (US$70 Million):</u> The aim is to scale-up DR-TB interventions in India to aggressively respond to the complex and costly DR-TB challenge.

36. Strategic Rationale and Theory of Change: As mentioned above, India has the largest absolute burden of DR-TB in the world. While standard daily-dosed anti-TB drugs cost approximately US$50 per 6-month regimen, drug costs for rifampicin-resistant TB and variants are 30-60 times more expensive. A recently completed national anti-TB drug resistance survey found that roughly 25 percent of pulmonary TB patients in Indian public facilities have some forms of anti-TB drug resistance, and that 6 percent of all TB cases had MDR-TB. Progress against NSP 2017-25 targets on drug-resistant TB targets has lagged (Figure 8).

Figure 8: Progress against key DR-TB Indicators (end 2017) vs Targets in the NSP-TB



Source: Ministry of Health and Family Welfare

37. The proposed Program will address DR-TB control by tackling various bottlenecks simultaneously. First, the Program will support universal Drug Susceptibility Testing (DST), the gateway to additional testing and appropriate treatment. In the past, DST was prioritized for patients seeking care in the public sector, but not for those in the private sector. Developing robust sputum transportation to the growing number of public laboratories with molecular diagnostics capabilities for at least rifampicin susceptibility testing will be a key activity supported by the Program to facilitate DST. Second, the Program will track progress in detection of additional drug resistance and completion of treatment because poor treatment outcomes in DR-TB have been associated with fluoroquinolone resistance and poor adherence[15]. Third, an underappreciated component of DR-TB control involves improving airborne infection control in high-risk settings. The Program will support this important activity in DR-TB centers in the targeted states.

[15] Parmar MM, Sachdeva KS, Dewan PK, Rade K, Nair SA, Pant R, et al. (2018) Unacceptable treatment outcomes and associated factors among India's initial cohorts of multidrug-resistant tuberculosis (MDR-TB) patients under the revised national TB control programme (2007–2011): Evidence leading to policy enhancement. PLoS ONE 13(4): e0193903. https://doi.org/10.1371/journal.pone.0193903

38. Attention to DR-TB control has synergy with private provider engagement under the first Results Area. Private provider engagement has been shown to promote screening for DR-TB. The RNTCP's experiences in Mumbai and Patna are instructive. With private sector engagement, private providers in Mumbai could detect more than 3,500 or 30 percent, of MDR-TB cases citywide. Similarly, the Patna private provider engagement initiative detected nearly 800 MDR-TB cases—75 percent of the total in the district over the project period[16].

39. Under this Results Area, DLI#3.1 will incentivize rifampicin susceptibility testing for TB patients.

40. **Result Area 4: Strengthening RNTCP Institutional Capacity and Information Systems (US$93 Million):** The transformative nature of India's NSP and the scale of its ambition are unprecedented among countries with high burdens of TB. The Program will help the GOI build the institutional capacities required to succeed.

41. **Strategic Rationale and Theory of Change:** The RNTCP institutional capacity and information systems have been evolving with the expanding TB program. However, the staffing levels and skills mix are yet to match NSP goals at central and state levels, particularly in the nine states supported by the Program. The Program will therefore support the MOHFW to develop and implement a human resource plan to meet the needs of the NSP.

42. The transition to Nikshay 2.0 in September 2018 brought a paradigm shift to a comprehensive information system that tracks each patient through their entire TB episode. In addition to supporting TB patient management and adherence monitoring, it is also used for TB drug inventory management, DBT for providers and patients, and public finance management. Nikshay 2.0 is in the process of system stabilization and roll-out. However, there are still concerns about: (i) data quality (including authenticity and duplication of notified cases); (ii) use of data for decision making at all levels; (iii) private sector interface; and (iv) supply chain management features (including forecasting). The Program will support Nikshay 2.0 strengthening and data integrity. This includes development of modules for DBT schemes and private sector notification.

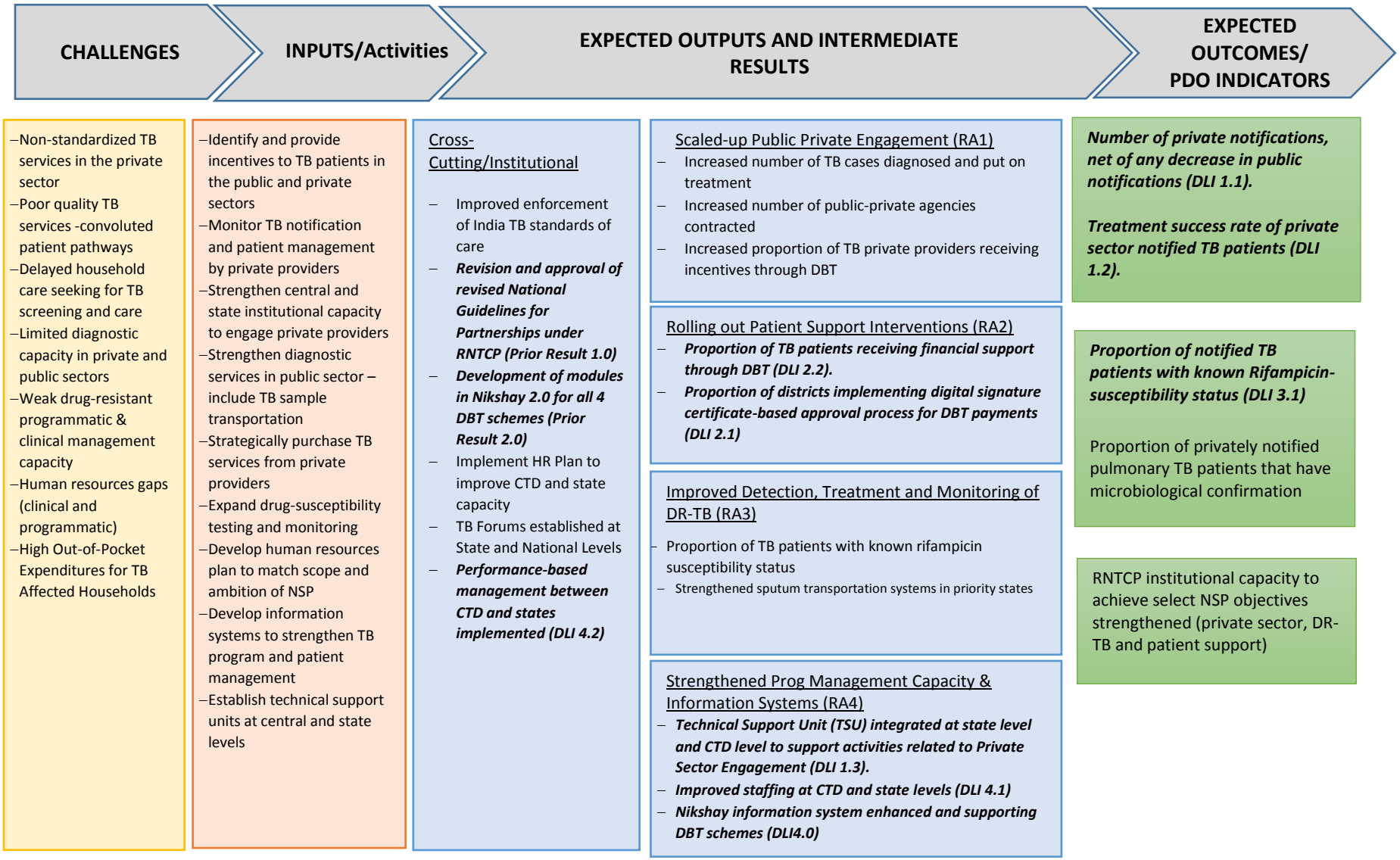
43. To hold state and districts accountable for results, the MOHFW will develop and roll out a performance-based management mechanism between the CTD and states (a.k.a. "state compact"), taking into account not only state performances but also their level of development and implementation capacity. A guideline will be developed in the first year of the Program to guide the implementation of this mechanism. It will include a performance-based management matrix or scorecard reflecting Program priorities, (notably private provider engagement, patient support, and data quality). Based on the state and district teams' performances as measured by the matrix/scorecard, the CTD will pay team-based incentives for state and district teams in the targeted states. The Program will also support annual State and National TB forums, which are venues for vertical integration of social accountability, civic engagement, stakeholder consultations, and peer learning at different levels. Both performance-based mechanism and TB Forums represent innovative approaches in the management and governance of RNTP.

44. **Three DLIs will be used to incentivize this results area.** The prior result #4.0 will be about a Nikshay mechanism for deduplication (of patients and providers) and reconciliation of different provider types. DLI#4.1 will be about human resource for health in TB. DLI#4.2 will be about the development and roll-out a performance-based management scheme between the central government and states. The amounts included under the DLI#4.2 only serve as incentives under the Program. These amounts will not match the exact amount of performance-based management incentives paid by CTD to states.

45. The Program's Theory of Change is illustrated below in Figure 9.

[16] Papinini et al. Effective service delivery for TB patients seeing care from the private sector in Patna. 2018. Publication pending; available on request.

Figure 9: Theory of Change



Text highlighted in ***BOLD and ITALICS*** denote the expected outputs and expected outcomes that are included in DLIs

C. Program Development Objective(s) (PDO) and PDO Level Results Indicators

46. The PDO is to improve the coverage and quality of TB control interventions in the private and public sector in targeted states of India.

47. Program Key Results Indicators

Coverage of TB interventions:

- The number of private notifications, net of any decrease in public notifications in targeted states (Annual)
- Proportion of TB patients receiving financial support via Nikshay Poshan Yojana in targeted states (Annual, by category of DBT scheme)
    - (i) Proportion of TB patients *notified by public providers* receiving 1st Nikshay Poshan Yojana payment in targeted states
    - (ii) Proportion of TB patients *notified by private providers* receiving 1st Nikshay Poshan Yojana payment in targeted states

Quality of TB interventions

- Treatment success rate of TB patients notified by private providers in targeted states (Annually, cohort of patients notified in prior calendar year)
- Proportion of notified TB patients tested for rifampicin susceptibility in targeted states

D. Disbursement Linked Indicators and Verification Protocols

48. To advance progress toward priority outcomes of the NSP 2017-25, the development of the Program DLIs (Table 5) followed these principles:

i. Maximizing the use of existing indicators in the government's NSP;
ii. Corresponding to priority areas of the NSP, especially major bottlenecks along the results chain and providing incentives for removing them;
iii. Stimulating performance at different levels of the RNTCP;
iv. Making full use of and strengthening the GOI's routine information system, Nikshsay; and
v. Balancing ambition ("stretch") and feasibility ("realism")

Table 5: Disbursement Linked Indicators

DLI	DLI Indicator	Scaling-up Private Provider Engagement	Rolling out TB Patient Management Support Interventions	Strengthening Detection, Treatment and Management Drug - Resistant TB	Strengthening RNTCP Institutional Capacity and Information Systems
1.1	Number of private notifications, net of any decrease in public notifications in targeted states (Annual)	✔		✔	
1.2	Treatment success rate of TB patients notified by private providers in targeted states	✔			
1.3	Establishment of Technical	✔			✔

DLI	DLI Indicator	Scaling-up Private Provider Engagement	Rolling out TB Patient Management Support Interventions	Strengthening Detection, Treatment and Management Drug - Resistant TB	Strengthening RNTCP Institutional Capacity and Information Systems
	Support Units (TSUs) in CTD and targeted states to support activities related to private sector, DBT, PFMS, and multi sectoral engagement as per agreed TOR				
2.1	Proportion of districts implementing Digital Signature Certificate (DSC) based approval process for DBT payment in targeted states		✔		
2.2	Proportion of TB patients receiving financial support via Nikshay Poshan Yojana in targeted states (Annual). DLI 2.2.1 Proportion of TB patients notified by public providers receiving 1st Nikshay Poshan Yojana payment in targeted states. DLI 2.2.2 Proportion of private sector notified TB patients receiving 1st Nikshay Poshan Yojana payment in targeted states.	✔	✔ ✔		
3.1	Proportion of notified TB patients tested for Rifampicin susceptibility in targeted states			✔	
4.1	Staffing capacity of the RNTCP strengthened: DLI 4.1.1: Development and approval of a multi-year RNTCP Human Resource Plan at CTD and state level to match the scale and ambition of the NSP. DLI 4.1.2: Reduction of the staffing gap identified by the Human Resource plan for CTD and the targeted states.				✔ ✔
4.2	Development and implementation of a				✔

DLI	DLI Indicator	Scaling-up Private Provider Engagement	Rolling out TB Patient Management Support Interventions	Strengthening Detection, Treatment and Management Drug - Resistant TB	Strengthening RNTCP Institutional Capacity and Information Systems
	performance-based management mechanism between the center and the targeted states.				

49. In addition to the above DLIs, the Program will support three prior results (see Table 6 below) that are critical reforms and outputs to form the foundation for Program implementation and success. Prior Results are expected to be achieved by the time the Program becomes effective. However, some of these results might be achieved within the first year of implementation.

Table 6: Prior Results

Prior Result	Prior Result Indicator	Private sector engagement	TB Patient Support	Drug - Resistant TB & surveillance	Program Management Capacity & Institutional Strengthening
1.0	Revision and approval of the National Guidelines for Partnerships under RNTCP	✔			
2.0	Development of Nikshay modules for all 4 DBT schemes (Nikshay Poshan Yojana, Tribal TB Patients, Private Providers and Treatment Supporters)	✔	✔		
4.0	Nikshay mechanisms developed for (i) deduplication (of patients and providers) and reconciliation of different provider types; and (ii) reconciliation of direct benefit transfer payments through Nikshay versus the public financial management portal for Nikshay Poshan Yojana.		✔		✔

50. The achievement of prior results and DLIs would trigger World Bank disbursements. The verification protocols for prior results and DLIs are detailed in Annex 3. There will be two Independent Verification Agencies (IVAs): one to verify DLIs related to IT systems development and functionality (given the special nature of IT systems, Ernst and Young has been selected to play this role) and one to verify programmatic DLIs (WHO has been selected to play this role). CTD will achieve recurrent DLIs by June 30th of each year. Verification of the DLIs will be undertaken subsequently by the IVAs.

Lessons Learned and Reflected in the Program Design

51. India's own experiences and lessons from elsewhere informed the Program design. Program design benefitted from lessons from RTNTP's various pilots, India HIV/AIDS Program; China TB Program's experiences

with incentives at different levels; and World Bank and other partners'[17] experiences in PforR, TB control, private provider engagement, and DBT. They include:

a. **Engaging private providers improves TB outcomes.** Pilots to engage private providers in India and elsewhere have demonstrated that it is possible to work effectively with private providers of all kinds to substantially increase case detection and treatment outcomes comparable with those in the public sector. However, engaging private sector should not be at the expense of public services. Relentless efforts are needed to ensure TB services in the public sector are continuously maintained and improved while private sector engagement is scaled up.

b. **Flexibility, innovation, and adaptation are critical to successfully engage private providers.** Perhaps this is the single most important lesson in engaging private providers for TB, both in India and elsewhere[18]. While there are common themes, there is no single operational model. Health markets differ significantly from one setting to another, and successful implementation requires adjustment of approaches over time. A potential solution lies in output-based contracting approaches that encourage flexibility for contractors to manage their inputs and tactics—if defined results and quality standards are met. Engagement of more than one implementing organization on the same terms can create healthy competition to drive performance. Also, it is important to respect private providers' need to attract and retain patients**.** Earlier approaches, in which private providers were simply instructed to refer presumptive TB patients to public providers, were unsuccessful

c. **The availability of timely, insightful, and well-communicated data has been critical.** Patient- and provider-specific data can be used to make rapid-cycle adjustments to program implementation and hold implementers accountable for results. Use of information technology greatly enhances engagement with private providers in notification, monitoring, and referrals.

d. **Constraints to strategic contracting in the RNTCP should not be underestimated.** Private sector engagement in TB control has been embraced by GOI leadership and reflected in policies and strategies. However, both capacity and buy-in for contracting by lower-level operational managers remains low. Continued dialogue, guidance, tools, and capacity building for strategic contracting are needed to facilitate private sector engagement at the frontline.

e. **Political commitment has been critical.** The Prime Minister's personal commitment to TB eradication has created unprecedented pressure to perform throughout the system and resulted in increases in RNTP resources. Continued commitment, advocacy, and resources will be required to realize this new and expanded vision.

f. **Use of evidence to inform interventions:** The success of India's HIV program is to a significant extent thanks to an evidence-based approach which enabled the government to: (i) focus on areas of greatest HIV burden; (ii) respond to different target groups and states with different HIV transmission dynamics differently; (iii) formulate strategic purchasing for HIV services; and (iv) mobilize best technical resources to address the country's HIV challenges. These lessons are important for the RNTCP.

III. PROGRAM IMPLEMENTATION

A. Institutional and Implementation Arrangements

52. The MOHFW is the implementer of the proposed Program and the CTD provides stewardship for Program implementation. At the central level, the MOHFW's CTD is the primary responsible agency for policy

[17] Partner experiences includes Global Fund's ongoing JEET Program and Bill and Melinda Gates Foundation's Universal Access to TB Care Pilots in Mumbai, Patna and Meshana.

[18] WHO (2018) Engaging private health care providers in TB care and prevention: a landscape analysis.

development, technical oversight, quality assurance, monitoring and evaluation, and capacity-building for the RNTCP. RNTCP services and systems are highly-standardized, and anti-TB medicines are procured centrally by MOHFW to ensure quality and uniformity of treatment.

53. Table 7 summarizes the TB Program governance structure under the CTD:

Table 7: Governance and Leadership Structure of the TB Program

Level	Administrative Head	Technical Head	General Health System
Central	Secretary – Health and Family Welfare, Additional Secretary (Health), Joint Secretary in charge of TB	Deputy Director General-TB	
State	Principal Secretary- Health and Family Welfare and Mission Director- NHM	State TB Officer	Director- Health Services
District	District Collector/Deputy Commissioner	District TB Officer	District Health Officer/Chief Medical Officer/Civil Surgeon

54. The Deputy Director General (TB) of MOHFW is the technical head of the TB program. Administratively, a Joint Secretary is responsible for the program, reporting to the Additional Secretary (Health). The Additional Secretary (Health) in turn reports to the Secretary of Health and Family Welfare. Several committees and research institutes provide technical guidance to the CTD.

55. At the state level, RNTCP administrative and financial management structures are merged with those of the NHM. The MOHFW and each state and union territory have entered a memorandum of understanding for implementation of the NHM, which includes the RNTCP. The State TB Officer in the State TB Cell is part of the NHM State Program Management Unit, reporting to the Director of Health Services and the Director of the NHM in the state. The State TB officer—with team support—oversees district level program implementation, reviews staff training, undertakes minor procurement, prepares technical and financial reports, ensures quality control, and monitors program indicators.

56. At the district or municipal level in large cities, the District Health Officer/Chief Medical Officer or an equivalent functionary in the district is responsible for all medical and public health activities, including TB control. The District TB Officer at the District TB Center manages the RNTCP and coordinates with other programs and departments. The District TB Officer is assisted by a Medical Officer and supervisors of TB/HIV coordination, PPM, and advocacy, communication and social mobilization (ACSM), as well as other staff. The RNTCP now has service delivery and administrative structures in 632 districts in 35 states and union territories

57. At the sub-district level, the TB Unit manages day-to-day RNTCP services. Planned alignment of TB Units with the block-level administrative structures of the NHM (Block Program Management Units) will mean that the responsibilities of the Block Medical Officer will include the RNTCP (along with other health programs and services), with a Medical Officer (TB Control) or Program Officer focusing on TB services, and a Senior Treatment Supervisor and Senior TB Laboratory Supervisor providing support. There are currently 2,700 TB Units, for average coverage of one TB Unit per 500,000 population. With 5,900 sub-district administrative units in the country, such an alignment will more than double the number of TB Units. Each TB Unit will then serve 200,000 population—100,000 in tribal, desert, remote and hilly regions. The subsequent increase in Senior Treatment Supervisors will enhance the supervisory and management capacity, notably to handle MDR-TB services and expanded public-private engagement.

58. Central Government-State Relationship: The RNTCP is a centrally driven program. Historically, TB implementation has been conceptualized and designed at the central level using a 'one size fits all' approach with rigid control of inputs. This is not optimal for a diverse country as well as an epidemic that has wide geographic variations in terms of levels, patterns and trends and driving factors. Within this context, the RNTCP will greatly benefit from state and district level innovations driven by local context and TB epidemic dynamics. The main instrument for Program planning is the Program Implementation Plan (PIP), which will be developed and approved annually at state and central levels. As discussed above, a performance-based management mechanism will also be developed to stimulate the performance of state and district teams. The performance matrix that is being developed by CTD includes measures to assess the extent to which states execute PIP.

59. Institutional Strengthening: As discussed above, the Program will support the strengthening of existing RNTP structures as well as putting in place new arrangements (e.g. TSUs, State and National TB Forums) to enhance program planning, evaluation, and reporting capacity at various levels. The CTD will further strengthen implementation of annual State and National TB Forums, which provide an opportunity to: (i) review implementation progress; (ii) distill key lessons and resolutions at different levels; (iii) amplify citizen voice and social accountability in TB control; and (iv) provide a platform for multi-sectoral engagement.

Scaling Up Private Provider Engagement

60. To date, the CTD has not directly engaged intermediaries, other than by coordinating with donor-funded projects. Under the Program, CTD will conduct strategic purchasing of Private Provider Support Agencies, private drugs and diagnostics from distributors, and lab services from large laboratory networks that operate across multiple states. While implementation models will vary from place to place, there will be a significant increase in the contracting of intermediaries, either for specific functions such as sputum transportation or adherence support, or for the full end-to-end model that has been demonstrated so successfully in Patna and Mumbai.

61. All levels of the RNTCP have important roles to play in private provider engagement (PPE). The CTD will (i) develop National Partnership Guidelines for PEE (a prior result) to guide the PPE implementation. And (ii) convene the National Technical Working Group on PPE to advise the Program and provide technical support in PPE. As discussed, TSUs will be established in both the CTD and targeted states to support the design and management of such contracts, which will then be executed through the state NHMs. The Program will build on the technical support being provided to states under Global Fund and BMGF supported pilots. The Global Fund program will provide interim capacity building support in some of the states in years 1 and 2.

Partnership to support the Program

62. Collaboration with other development partners will be maximized to effectively support the GOI in Program implementation. In addition to financing independent verification of the Program, the BMGF will provide technical assistance in PPE and DBT. WHO will provide specialized technical support to the Program as well as serve as the IVA for programmatic DLIs. The Program will benefit from the experience of private sector pilots supported by the BMGF and Global Fund. In addition, United States government agencies (i.e., USAID and the CDC) are also financing DR-TB innovations and use of technology to strengthen patient adherence to treatment. The World Bank team will thus work closely with all relevant development partners under the Program.

B. Results Monitoring and Evaluation

63. The CTD has more than twenty years of experience implementing World Bank supported operations,

including one DLI-based TB project with satisfactory outcomes. The CTD will report on DLI achievement and provide evidence to the World Bank in line with the agreed verification protocol. The CTD will commission the WHO and Ernst and Young to undertake independent verification of results as per protocols accepted by the World Bank.

64. Since 2012, the RNTCP has developed and continuously improved Nikshay - a robust information system based on individual patient records for (i) notification and monitoring of TB patients and (ii) routine program monitoring. Under the NSP 2017-25, the CTD is taking the system to the next level as Nikshay 2.0 to accommodate new activities in private sector engagement, DR-TB, and patient support. Data quality and use of data for decision making will be critical for successful implementation of the NSP 2017-25. To complement HIMIS data, the Program will commission surveys as well as independent verification of data. Low-cost, just-in time and practical implementation research will be carried out under the Program to inform decision making and contribute to the "Lighthouse India" initiatives.

C. Disbursement Arrangements

65. Guiding principles for disbursement under the Program:

a. The GOT will pre-finance Program expenditures using its own budget[19].
b. The CTD will prepare technical reports to document the achievement of DLIs. The technical reports will be verified by IVAs (WHO and Ernst and Young) as per terms of reference agreed with the World Bank. The CTD will then communicate the achievement of DLIs and corresponding DLI values to the World Bank along with the supporting documents. For time-bound DLIs, achievement of the DLIs must happen before the deadlines specified in the DLI matrix.
c. For a non-scalable DLIs, the World Bank will disburse the DLI value only upon full achievement of its targets. For a scalable DLI, the World Bank will disburse against the level of DLI achievement as per the DLI formula.
d. The World Bank will issue an official letter to the CTD endorsing the achievement of the DLIs and disbursement values.
e. The CTD will submit the disbursement claim of the DLI values to the Controller of Aid, Accounts, and Audit (CAAA) in the GOI.
f. The CAAA will submit the disbursement claim to the World Bank, and the funds will be disbursed by the World Bank to the GOI under IBRD loan terms. The GOI will release funds to the CTD as per agreed financing norms between the Ministry of Finance and the MOHFW.

66. In the last year of the Program (2024), the CTD will coordinate with the World Bank and reconcile the audited Program expenditures (incurred under identified budget lines) with the DLI amounts disbursed by the World Bank. Any shortfall in the Program expenditure in relation to the DLI disbursement will be adjusted by the World Bank from the final DLI claim.

D. Capacity Building

67. Human Resource for RNTP: As discussed earlier, RNTCP capacity has been evolving over time and become much stronger at higher levels. However, the staffing levels and skills mix are yet to match the NSP ambitions. The Program will support this critical area, with a DLI to incentivize the development and implementation of the staffing plan. Capacity building for new areas (PPE, DBT) will be prioritized under the Program.

[19] A forecast of disbursements will be developed at the time of Program effectiveness to inform GOI budgeting and planning processes.

68. Implementation capacity building: As Program implementation requires additional capacity and skills at the CTD, states and districts levels, the GOI will develop a detailed multi-year capacity building plan. The CTD and states will execute capacity building activities annually according to the plan with the technical support of the Bank and key partners.

69. Learning and Adaptation Mechanisms: The Program will support learning at various levels of implementation. The Program will support central and state level TB fora which will provide platforms within and across states for multi-stakeholder technical and implementation reviews, documentation of best practices and showcasing of innovations related to the results areas of the Program. TSUs at central and state levels will pay a pivotal role in operationalizing TB fora. In line with this, TSUs will support State TB Offices to develop and execute systematic learning and knowledge dissemination plans. At the national level, the Bank and other partners will support the CTD to commission operations research and evaluations of the DBT schemes, private sector engagement and DR-TB. The operations research will inform policy and programmatic decisions of the RNTCP. This includes mid-course adjustments to Program interventions. Learning under the Program will contribute to the broader "Lighthouse India" learning initiative by connecting practical know-how and innovations among the Indian states and between the GOI and high-burden TB countries. In addition to the above, the Program will leverage quarterly technical review meetings convened by WHO for states and CTD officials to identify and resolve implementation bottlenecks across various areas of the NSP.

IV. ASSESSMENT SUMMARY

A. Technical (including Program economic evaluation)

70. The fundamental approach of the Program is to target private provider engagement and patient support in parallel with strengthening public sector TB services. There is no alternate pathway to TB control in India that does not involve PPE and patient support. Even future diagnostic tools and treatment regimens will need such systems to reach poor patients with subsidized services. India's PPE approach under the Program is technically sound because it has been demonstrated to be cost-effective at scale by the GOI evaluation of the pilots which covered 5 percent of India's population. Experience elsewhere (including those from the China's TB program) points to the same direction.

71. Toward this end, there are several game changers in the Program design. These include: (i) contracting of private provider interface agencies; (ii) expanding direct benefits transfer for patients; (iii) expansion of ICT services; and (iv) strengthening DR-TB services. First, a key mechanism to augment PPE capacity is through contracting interface (or intermediate) agencies by the TSUs. Second, DBT is crucial to incentivize patients for treatment adherence. Third, Nikshay and the call center system are force multipliers, enabling a limited number of public sector staff and contracted partners to efficiently support hundreds of thousands of private providers. Fourth, DR-TB is a special market failure that requires public provision, and public provision of DR-TB testing and treatment is a useful lever for private engagement. The large numbers of DR-TB cases detected when private providers are engaged require expansion of service delivery infrastructure. The program includes activities and incentives to address each of these expected challenges.

72. The selection of the nine states for the Program is strategically justified by (i) the burden of TB, (ii) the dominant nature of private health provision, and (iii) current gap in private sector notifications in such states. In aggregate, the nine states represent 12 of 19 million patient months of anti-TB treatment distributed via private chemists, or 70 percent of all private TB treatment nationwide. Remaining states will still benefit from

Program support for cross-cutting system strengthening such as Nikshay, but success in these nine states will contribute substantively towards national achievement of NSP 2017-25 goals.

73. Adequate institutional arrangements and governance structures are in place for Program implementation. There is strong emphasis on capacity development in new thematic areas such as private provider engagement and DBT. TSUs will be established to strengthen the implementation capacity of states and CTD to scale up private sector engagement. Mechanisms for central and state implementers to collaborate with each other, as well as to coordinate with other country stakeholders and external development partners, are well-established and will be further enhanced under the Program. The MOHFW has moderate to high technical and management capacity to undertake Program activities. This will be augmented by technical support by other development partners, including the World Bank.

Program Expenditure Framework

74. The comprehensive NSP 2017-25 is costed at US$8.3 billion. Over the past four years, the GOI's central level budget for TB increased at an average nominal rate of 31 percent annually (26 percent in real terms, net of inflation). In 2018 alone, it increased by 70 percent. As per NSP, further nominal increase is expected at around 12 percent during the Program. Given India's high GDP growth rate (between 6.4 percent-8.2 percent in the past 5 years, and a projection of 7.8 percent in 2019) and the GOI's high commitment to TB, funding sustainability and predictability is not a major risk to the Program. However, to meet DLI targets on private sector engagement and DBT, budget and expenditures in related categories (i.e., private sector support, honorarium, patient support and transportation) would need to grow more rapidly than (i) historical rates and (ii) other expenditure categories during Program implementation.

75. The expenditure needs projection used actual FY2017-18 expenditures by budget line in the CTD and nine targeted states as the baseline, assuming the annual expenditure growths for each budget line to be proportional to the yearly targets of relevant DLIs.

76. Budget outturn in the past three years shows reasonably well-functioning budget allocation and execution, ranging from 87 percent to 150 percent. For FY18, utilization is 150 percent of the original budget due to increased donor commitments, leading to a substantial increase in the Externally Aided Component.

Program Economic Evaluation

77. A detailed economic analysis demonstrated the Program's positive development impact. Within the Program period of 2019-2024, if all DLI targets are met, the Program will at least prevent 308,350 deaths and save 591,286 DALYs. When long-term benefits are considered, the Program will gain over 4.16 million DALYs over a 20-year period (Table 8). Assuming the monetary value of 1 DALY equaling per capita GDP of India, the benefits of the Program is around US$5.45 billion. Cost per DALY averted through the Program is US$274. Applying India's GDP per capita as the threshold for cost-effectiveness as recommended by the WHO, the Program is highly cost-effective. The Program's estimated Net Present Value (NPV) is largely positive (US$3.79 billion), with an estimated Internal Rate of Return (IRR) around 54 percent, and benefit-to-cost ratio of 5.58. In sensitivity analysis with different GDP growth rates and inflation, the Program still has reasonably good returns.

Table 8: Estimated Program Health Benefit

Result areas	Health benefits	2019-20	2020-21	2021-22	2022-23	2023-24	Total (2019-24)	Total (2025-38)
Private Sector Engagement in TB Control	Estimated deaths averted	10,131	25,971	47,571	70,380	96,531	250,582	
	Estimated DALYs gained	9,827	33,968	76,366	121,984	201,219	443,365	2,829,468
MDR-TB	Estimated deaths averted	7,604	12,272	14,204	12,382	11,306	57,768	
	Estimated DALYs gained	7,376	18,701	31,104	41,132	49,607	147,921	736,175
Total	Estimated deaths averted	17,735	38,242	61,774	82,762	107,836	308,350	
	Estimated DALYs gained	17,203	52,670	107,470	163,117	250,827	591,286	3,565,643

78. In addition to the direct health benefits, the Program is likely to bring additional economic benefits. First, the economic loss to TB in 2016 was around 1 percent of India's GDP. By reducing the future TB disease burden, the program will bring future economic return. Second, more than half of TB costs are due to income loss, and the Program will improve economic productivity of TB patients. Third, as TB disproportionally affects the poor; the Program is pro-poor and will contribute to poverty reduction in India.

79. The Program's rationale for public investment is strong. According to the Copenhagen Consensus, engaging private sector for TB management has higher return to investment (179.4 to 1) than most public health interventions (including nutrition, hygiene and cervical cancer screening interventions) and many non-health public interventions (such as e-marketing for farmers and supporting startup incubators)[20]. While 70 percent of TB patients seek care in the private sector, TB detection, case notification, service quality, and treatment success in the private sector are far behind the public sector, partly due to the lack of incentive and support for the private providers to provide quality TB services. By strategically investing public resources in private sector (performance-based incentives and support to private providers), as well as in government capacity to manage private sector (private contracting, surveillance, and management), this Program is investing in areas with high returns for the GOI.

80. The World Bank's added value in this Program will center around its experience in implementation support and research in TB control, as well as its expertise in results-based approaches, private sector engagement and DBT in general. Given its global footprint, the World Bank can also facilitate the sharing of (i) relevant lessons from elsewhere with India and (ii) best practices generated from this Program's innovative approaches with global health and social protection communities.

B. Fiduciary

Fiduciary Assessment

81. The PforR Program will rely on country systems for financial management, procurement, and Governance

[20] Indian states are testing a new way of setting development priorities. https://www.economist.com/asia/2018/06/14/indian-states-are-testing-a-new-way-of-setting-development-priorities?fsrc=rsspercent7Casi&mc_cid=edcb4313d9&mc_eid=beb0742f0e.

and Anti-Corruption (GAC) at various implementing levels. The country systems have their own inherent strengths and weaknesses which are detailed in the full Integrated Fiduciary Systems Assessment (IFSA)[21] disclosed as a separate document. The conclusion of the IFSA is that the Program's fiduciary systems at the various levels of implementation provide reasonable assurance that the financing proceeds will be used for intended purposes with due attention to the principles of economy, efficiency, effectiveness, transparency, and accountability. During the IFSA, certain areas of improvement have been identified, and recommendations made as part of the PAP and risk mitigation matrix.

Program Fiduciary Systems

82. The RNTCP has implementation structures embedded within the NHM responsible for programmatic and fiduciary management in the nine states. Funds are routed from the center to the State Treasuries and then onward to the implementing agencies' respective Bank accounts. The planning process is lengthy, and the budget release are often delayed until mid-year, and there are concerns over delays in fund releases from the Treasury to the NHM; and some states have also reported the need for regular follow-up for release of the state share to the Centrally Sponsored Scheme (CSS). However, resources are not a constraint for Program implementation due to opening balances available with the implementing agencies, and the provision to avail temporary loans from NHM funds.

83. The books of accounts are maintained at the central, state, and district levels with varying levels of automation. In three of the nine states, such books are also maintained at the sub-district level. PFMS is used sporadically across the states to track the utilization of funds and to make DBT payments (linked to Nikshay). Building on ongoing CTD reforms, PFMS implementation will therefore be scaled up and mainstreamed for Program expenditure reporting. This will require hands-on training of staff at different levels.

84. The internal control framework at national and state levels are embodied in the Budget Manual, Financial Rules, and Treasury Code, as well as in the Store Purchase and Works Manuals and other related employee rules. To improve Program fiduciary monitoring and oversight, the CTD Financial Management cell will hold periodic review meetings with Financial Management officials from the state and district TB cells every six months.

85. The Central Medical Services Society (CMSS), under administrative control of the MOHFW, will carry out major Program procurements (i.e., drugs and equipment) using the NIC e-procurement system. The CTD procurement cell carries out some procurements of services, e.g. selected media and laboratory services. Such procurements by CMSS and CTD are carried out in accordance with the GOI's 2017 General Financial Rules (GFR).

86. Annual requirements for TB drugs and diagnostics will be assessed (based on last year's consumption, remaining stocks, expected deliveries against ongoing contracts and other relevant factors) and consolidated for economy of scale by the CTD. The indents including relevant technical specifications and consignee list with consignee wise quantity requirements will be send by the CTD to the CMSS for procurement. The bid notices and bidding documents are published on the CMSS website and Central Procurement Portal (CPP), both of which offer free access. An abridged advertisement is published in the newspapers for information of the bidding community. The time allowed for preparation of bids is three weeks. In the future, the bidding documents under the Program will contain a clause requiring compliance with Bank's Guidelines on Preventing and Combating

[21] IFSA was conducted at the national level for the CTD and CMSS; and in sample seven out of the nine selected states. Procurement assessment was limited to CMSS and CTD as 90percent of program procurement is expected to be done by CMSS & CTD. The procurement at states are minimal.

Fraud and Corruption (July 2015) and the eligibility clause.

87. The evaluation of technical bids is done by Technical Evaluation Committee (TEC) consisting of CMSS officers, a TB Program Officer, and one external expert, usually from a hospital. TEC examines the availability of bid security and other documents, conducts technical evaluation, and verifies the qualification criteria. The TEC report is approved by the CMSS sub-committee consisting of the DG&CEO (Chairman), OSD, Internal Finance Department (IFD) of Ministry, Director (EPW) of Ministry and Director of Program Division (RNTCP). After approval by the sub-committee, financial bids are opened only from technically responsive bidders. A summary statement of the financial bids is prepared and uploaded on the portal. The commercial evaluation is done by a committee called Price Bid Evaluation Committee (PBEC) who committee determine the reasonableness of prices and prepares a Bid Evaluation Report (Commercial) and submits it to the same CMSS sub-committee. This committee recommends the bids to the CMSS governing body for approval. The Governing Body of CMSS consists of 16 members with AS&DG as the Chairman. The quorum is any five members. Once the Governing Body accords approval, long term agreements (LTAs) are signed. The time from opening of bids to the signing of LTA takes between three and eight months. There have been notable improvements in the procurement lead time over the past 10 months.

88. To maintain uninterrupted supplies, the CMSS finalizes LTA with a minimum of two suppliers, for the tendered product (e.g. drug) with 70 percent of the orders given to the lowest bidder (a.k.a L1 bidder) and the balance of 30 percent to the next lowest bidder who agrees to match the price of the L1 bidder. Accordingly, L1 and matched bidder shall pay a security deposit at the rate of 5 percent of the total value of the goods. Subsequently, the CMSS issues Purchase Orders against the LTAs. The consignee list along with the quantities for each warehouse are mentioned in the Purchase Order.

89. Upon arrival of drugs from the suppliers at CMSS warehouses, the inspection and quality testing of medicines starts. Quality testing is done through empaneled laboratories meeting the qualification criteria. Empanelment was undertaken through an advertised tendering process in the past. However, during the current fiscal year, this system has not been followed and only government laboratories have been empaneled. Delays by government laboratories in submitting test reports have been documented. This is a problem which needs to be addressed and monitored during implementation.

90. Medicines are quarantined until the clearance by the Quality Control Department based on the laboratory reports. The 20 CMSS warehouses have the responsibility of delivering medicines and medical supplies to the respective state warehouses and Government Medical Stores Depots (GMSD), using the "e-Aushadhi" information system. The state warehouses and GMSDS further distributes the medicines to the respective health centers, TUs, PHI and end users. The inventory control system needs to be further strengthened.

91. Supply chain management of drugs from the CMSS warehouse to the state's warehouses, GMSDS, TUs and PHI is monitored by CTD through the Nikshay information system. The CTD also carries out random testing of the drugs across the country through third party agencies and accredited testing laboratories.

92. Currently any procurement complaint is received and addressed by the same staff who handle procurement, which is a conflict of interest. Under the Program, an electronic complaint handling portal (as part of Grievance Redressal System) will be developed by December 30, 2019 which will be handled by an independent team for all complains related to CMSS purchases. This will include monitoring and publishing information on complaints received, percentage of complaints addressed, and time taken to resolve complaints.

93. The CMSS is a lean organization with limited staff carrying out multiple tasks. Delays in evaluation of bids,

requirement of multi-stage approvals which might delay the finalization of procurement decisions, delays in obtaining test reports from nominated laboratories, substandard quality of drugs, and stock out of drugs are key risks to the program. These risks are addressed as part of the PAP. It is also recommended that the CMSS provide periodic reports on advance, utilization and available balances to CTD quarterly to improve accounting, reporting, and transparency.

94. The State Health Societies statutory audit is done by private Chartered Accountants in a timely manner. Every state has an Audit Committee that meets two to three times a year to discuss the audit plan, findings, and compliance. A private Chartered Accountant (CAG empaneled) is appointed to conduct an annual audit, the report of which is endorsed by the CAG. Additionally, the expenditures incurred at the central level by CTD will be audited by the CAG. All nine states' TB Program audit reports (issued by CA firms), CMSS entity audit reports (issued by CAG) and central level expenditure audit report (issued by CAG) will be submitted within nine months of closing each financial year. The external audit scope will include: (i) reviewing contracts to ensure that contracts are not awarded to sanctioned firms; (ii) assessing their effectiveness and internal control; (iii) ensuring no High Value Contracts over the OPRC under the program without approval.

95. The Program is not expected to require large contracts valued at or above Operational Procurement Review Committee (OPRC) thresholds (i.e., US$75 million for works, US$50 million for goods and non-consulting services, and US$20 million for consultant services).

Governance and accountability systems

96. CTD and CMSS operations fall under purview of the Central Vigilance Commission (CVC), Comptroller and Auditor General (CAG), as well as the Right to Information Act of Government of India. Although GAC implementation on the ground varies from state to state, overall existing systems provide a good foundation for improving program transparency and accountability. In general, the line department oversight is fulfilled by a Chief Vigilance Officer, and Vigilance Committees are also established at district levels with varying degrees of effectiveness. The GOI is fully committed to ensuring that the Program is not affected by fraud and corruption and has agreed that it will also be governed by the "Guidelines on Preventing and Combating Fraud and Corruption (July 2015)[22]." The CTD, the GOI, and CMSS have agreed to report to the Bank any credible and material allegations of fraud and/or corruption related to the Program as part of the overall program reporting requirements. The Bank will inform the recipient and the CTD about any allegations that it receives. The Bank's right to investigate allegations regarding the Program's activities and expenditures, and the related access to required persons, information, and documents will be observed in accordance with the standard arrangements for this purpose between the GOI and the Institutional Integrity (INT) unit of the Bank.

97. Risks and Mitigation Measures: Based on the assessment and identification of risks, overall fiduciary risk rating is considered **Substantial** and mitigation actions have been agreed to and detailed in the PAP (Annex 3).

98. In addition to the above-mentioned risks mitigated through actions documented in the PAP, fiduciary performance will be monitored during Program implementation, through the following indicators:

a. Funds transferred in a timely manner (measured in days);
b. Timely preparation of annual financial statements within three months from end of FY;
c. PFMS rolled out across states;

[22]Available at https://policies.worldbank.org/sites/ppf3/PPFDocuments/Forms/DispPage.aspx?docid=3682&ver=current

d. Periodic Financial Reporting submitted by CMSS;
e. Timely submission of audit reports within six months from end of FY;
f. Average length of procurement Processes (including contracts awarded within initial bid validity);
g. Time taken for supply of drugs to reach the CMSS warehouse from suppliers;
h. Time taken for quality testing of drugs; and
i. Percentage of procurement complaints addressed

99. The above indicators will be monitored every six months by CTD and reports will be shared with the Bank.

C. Environmental and Social

100. The Environmental and Social Systems Assessment (ESSA) was carried out in line with World Bank policies and procedures for PforR financing for the identified Program. The ESSA provides a comprehensive review of relevant environmental and social management systems and procedures in India pertaining to detection and treatment of TB care[23]. The ESSA also identifies the extent to which the country systems are consistent with the World Bank's PforR Policy and Directive, and recommends necessary actions to address potential gaps, as well as opportunities to enhance performance during program implementation. The Program's overall environmental and social risk rating is **Moderate** and can be effectively mitigated within the existing environmental and social management systems. All risks/effects analyzed, and mitigation suggested by ESSA are applicable to both public and private sectors.

101. The ESSA relied primarily on a desk review of relevant documents and was complemented by field visits to health care facilities, DR-TB and antiretroviral treatment centers, Common Bio-Medical Waste Treatment Facilities (CBMWTFs), IRLs, and private laboratories. Consultations, interviews, and discussions were also held with key program stakeholders, experts, government officials, and community groups[24].

102. Environmental Benefits: the Program is likely to introduce positive environmental, health, and safety provisions for healthcare and lab workers in high-risk settings (DR-TB Centres, ART Facilities and TB Containment Labs) by (i) reducing the risk of contracting TB and other infectious diseases, (ii) providing training in personal protective equipment for health workers, and (iii) strengthening the servicing and decommissioning of key lab safety equipment. At the same time, the Program will strengthen environmental systems for better management of medical waste, infection control, and accident management at facility level. Under Results Area 3, the PTETB will also have a dedicated focus on implementation of airborne infection control (AIC) measures as an integral component of Environment Health and Safety.

103. Environmental Impacts and Risks include: (i) infection control associated with TB services, including safe handling of clinical and infectious waste, sputum, sharps (slides) generated from diagnosis and treatment services; (ii) high risk settings requiring high adherence to AIC measures and use of personal protective equipment to ensure health workers' health and safety, patient and public safety; (iii) adequate disposal of all waste streams including bio-medical waste, solid wastes (e-waste, plastics and pharmaceuticals), and liquid waste (chemical reagents, effluents) streams so that there is no contamination to soil and water bodies

[23] The ESSA was disclosed both in-country on MoH&FW website (December 14, 2018) and World Bank external website (December 17, 2018).
[24] These included CTD officials in charge of environmental and social aspects, state TB officers, development partners during the program preparation in Delhi, Lucknow, Mumbai, Pune, Hyderabad, Udaipur, and NGOs and academia currently engaged in the RNTCP

associated with their disposal; (iv) ensuring that all key lab safety equipment would need to be serviced and kept in good working condition; and (v) preventing risks to public and worker exposure to infectious diseases through improved management of airborne infection control and medical waste handling practices. These risks are well defined, site-specific and easily mitigated. However, with inadequate attention and poor management, these issues can pose greater risk to worker and public health and safety.

104. While the Program will not include large scale construction, there may be minor renovations works required for upgradation of diagnostic facilities and implementation of AIC measures in existing HCF premises. Environmental impacts by such small works are envisaged to be moderate and temporary or site-specific and can be mitigated within the current systems for environmental management. There are no anticipated adverse impacts to natural habitats, physical cultural property, natural resources.

105. Consultations and information disclosure: In addition to meetings with RNTP stakeholders as discussed above, a free and prior informed consultation with tribal communities was carried out in tribal blocks of Pune and Udaipur districts belonging to Schedule-V areas under the constitution of India. Following preparation of the draft ESSA, a national level multi-stakeholder consultation workshop was conducted in Delhi on November 28, 2018. Participants concurred with the ESSA findings and mitigation measures. In addition, participants had the following suggestions to strengthen environmental and social performance under the Program:

i. States require flexibility for planning and implementing Tribal Strategy. The State incentive grants can be utilized for showcasing innovations in this area.
ii. To operationalize TB forums at State and district level, and support State TB cells, it would be useful to engage a professional agency/institution.
iii. Creation of specialized unit in NTI Bangalore that can cater to servicing and maintenance of key lab equipment's (bio-safety cabinets, Air Handling units, and centrifuge). This would cater to the 64 IRLs in India.
iv. Hiring of State officers/experts to supervise, monitor and strengthen Bio-Medical Waste Management (BMWM) and AIC.
v. Hiring of State social experts to supervise and monitor the implementation of social safeguards activities, including citizen engagement, ACSM, gender, tribal health issues.
vi. Mainstreaming AIC capacity and responsibilities to plan and implement with IC officers of medical colleges and district IC committees so that technical capacity and knowledge remains institutionalized.
vii. Creation of easy to understand guidance handbook for environment health and safety management for STOs and DTOs to include key aspects of BMWM, IC and AIC.
viii. Developing abbreviated guidelines for planning and retrofitting DR-TB centers to conform with national guidelines on AIC, IC, and BMWM. This includes guidance on consumables (protective gear, chemicals, vendors, suppliers).
ix. Bio-medical engineers at the district level posted under NHM can be utilized to provide support for RNTCP lab network at the DMC and TU level.

Table 9: Applicability of the ESSA Core Principles

Core Principle 1: *Environmental and social management procedures and processes promote environmental and social sustainability in the program design, avoid, minimize, or mitigate against adverse impact, and promote informed decision-making -* ***Applicable***

Summary Findings: To better manage Program's environmental effects, mitigation measures include, among others: (i) strengthening environment health and safety monitoring capacity in CTD and states on bio-medical waste management and airborne infection control; (ii) developing accreditation criteria for C&DST labs to include enhanced EHS and biosafety criteria; (iii) update biomedical waste trainings to include management of all wastes including e-waste and hazardous wastes; (iv) ensuring emergency response mechanisms such as fire detection, and accident reporting and response mechanisms to be functional at all HCFs and Labs; (v) strengthening AIC and general infection control capacity at facility level; (vi) developing guidance for State and District TB officers on EHS as part of national guidelines/ regulations. Screening for all environmental risks and impacts will be conducted by the healthcare facility in charge, with guidance from DTO.
Core Principle 2: *Avoid, minimize, or mitigate the program's adverse impacts on natural habitats and physical cultural resources* ***–Not applicable***
Core Principle 3: *Protect public and worker safety against the potential risks -* ***Applicable***
Summary Findings: TB diagnosis and treatment exposes healthcare and lab workers to risks associated with exposure to TB, hazardous materials, infections, as well biosafety, and would require mitigations These include, among others: (i) improving occupational health and safety practices at healthcare facilities through infrastructure design, AIC, infection control, protocols for addressing accidental spills; (ii) providing protective clothing and personal safety equipment, as required; (iii) ensuring safe storage, segregation, transport and disposal of biomedical and hazardous wastes; (iv) implementing good practices with regards to cleanliness, hygiene and general waste management; (v) ensuring worker and public health and safety focusing on emergency response and fire safety; (vi) conducting maintenance of critical lab safety equipment; (vii) training for workers in sputum collection transport on biosafety and use of spill kits and (viii) having qualified biomedical engineers and technical staff available to service, maintain and conduct safety testing on critical lab equipment in the IRLs.
Core Principle 4: *Land acquisition and resettlement - avoids or minimizes displacement, and affected people -* ***Not Applicable***
Summary Findings: There is no land acquisition or resettlement, as Program's civil works is limited to minor renovations within the existing footprint of the facilities. Screening will be conducted in facilities where any repair, renovation and/or expansion is proposed under the Program by the facility- in-charge with guidance from DTO. The resettlement to be avoided includes involuntary displacement of people who are illegally occupying areas within the grounds of the health facilities.
Core Principle 5: *Due consideration to cultural appropriateness of, and equitable access to, program benefits giving special attention to rights and interests of Indigenous People and vulnerable groups-* ***Applicable***
Summary Findings: In recent years, some of the tribal areas have been reporting a high incidence of not only drug sensitive but also drug resistant TB cases. The NSP 2017-25 also recognizes limited progress in a special action plan for tribal populations. Improving access and coverage requires not only screening and treatment activities but also adopting culturally appropriate ACSM and communication approaches. The Program provides for special incentives in the tribal and difficult to reach areas for transportation to patients and sputum sample transportation to enhance access.
Core Principle 6: Avoid exacerbating social conflict - ***Not Applicable***
Summary Findings: While there are some areas affected by social conflicts in the 9 targeted states, including left wing extremist (LWE) issues, the Program interventions do not exacerbate any social conflicts. It will strike to improve the overall health of the population and reach vulnerable pockets with TB interventions. Exclusion of any groups in terms of caste, religion, and/ or geography by the Program is not expected.

106. Considering the nature of the Program, OP 7.50 International Waterways or OP 7.60 Disputed Territories are not applicable.

Assessment of Environment Systems

107. The provisions of the existing environmental legal and regulatory framework are adequate but require enabling institutional and technical capacity for compliance. While the provisions of the Biomedical Waste

Management & Handling Rules (as amended on March 2018), Infection Management and Environment Policy Framework (IMPS) are being implemented, provisions of other relevant environmental acts such as hazardous, solid, plastic and e-waste rules applicable to RNTCP require additional capacity building efforts. Currently BMW, IC, AIC is being managed by different committes and technical specialists; and coordination needs to be strengthened at both facility level and state levels. Efforts are also required to improve the monitoring of the management of different kinds of wastes, including liquid waste and effluents from labs and TB treatment facilities. National and RNTCP Program guidelines are adequate for addressing the following risks (i) patient and worker safety, (ii) biosafety, (iii) air borne infection control, (iv) packaging and transport of infectious sputum samples and (v) surveillance and screening of TB workers. However, there is scope for strengthening the existing RNTCP technical and operational guidelines to include EHS aspects and ensure full coverage of activities under the NSP, through careful planning, capacity building and institutional coordination to achieve sustainable outcomes.

108. Capacity to manage environment health and safety has been instilled into the RNTCP institutional framework at the national level but requires more dedicated support at state and district levels to strengthen implementation of EHS activities. Although there are comprehensive national guidelines covering institutional, administrative and infrastructure needs, AIC implementation has been limited to a few pilot centers, and each health facility is responsible for how they implement the guidelines, with different capacity resulting in varied practice. AIC is critical to ensuring worker safety in high risk settings. The program results framework supports preparation of AIC action plans in DR-TB Centres.

109. The ESSA recommended measures to strengthen environment health and safety performance through the programme implementation plan, this includes: (i) hiring of environmental experts in the targeted states as part of the RNTCP HR plan; (ii) strengthening accreditation criteria for private sector C&DST labs to include EHS and biosafety criteria consistent with national regulations; (iii) preparing and implementing health and biosafety advisory for workers involved in sputum collection and transport; (iv) updating of BMW trainings to include most relevant rules and regulations, e-waste and hazardous wastes, liquid waste and implementing a training program for all RNTCP staff; (v) building capacity and technical expertise (biomedical engineers) for maintenance and safety testing of critical lab equipment such as biosafety cabinets, centrifuge and air handling units and (vi) strengthening of AIC capacity at the state and facility level along with better institutional coordination with the public works department that usually undertakes the construction work. The ESSA leads to one PAP action for environment to develop SOPs/ protocols for servicing and decommissioning of key lab safety equipment to ensure health and safety of lab workers.

110. Assessment of social systems: As discussed above, the Program does not involve any land acquisition, resettlement, or any major construction. It will only support minor renovation within the existing footprint of the facilities. Screening will be conducted by the health care facility in-charge with guidance from DTO to rule out any adverse social impact by any civil works. Both health facility in charges as well as DTOs will be training by the social safeguard officer at the State TB Cell. The legislative framework to ensure social sustainability and the interest of marginalized and vulnerable populations, including SC and ST populations, is already aligned with World Bank's safeguard policies. The targeted states account for 51.5 million tribal population (49 percent of the India' tribal population) and have both scheduled V and Scheduled VI areas as defined under the Constitution of India with special legislative and judicial provision including customary rights in scheduled-VI areas. The NSP 2017-25 also recognizes that there has been limited progress in special action plans for tribal populations while some of them have been reporting a high incidence of not only drug sensitive but also DR-TB cases. It is therefore important to strengthen the TB control activities in these difficult areas. To extend the incentives designed for tribal populations and for tribal areas, the CTD shall follow the designated tribal areas (tribal districts and blocks and scheduled areas) as per Ministry of Tribal Affairs, as well as strengthen data

collection and monitoring of the tribal population transport reimbursement and other incentives. The key social risk emerges from capacity gaps to deal with tribal issues, ACSM, and the program's gender responsiveness. The risks identified will be mitigated by: (i) updating /preparing and implementing a coherent social and behavior change communication (SBCC) strategy and action plane; (b) strengthening data collection and monitoring of tribal population transport reimbursements and annual CTD report to capture coverage and trends in DBT for tribal populations, (c) developing and adopting a framework for TB among women which will include specific programmatic interventions (such as outreach strategies to enable early reporting) towards addressing socio-cultural barriers; and (d) updating 'Partnership guidelines,' 'Technical and Operational Guidelines for TB Control in India' and monitoring mechanisms and tools such as CIE and State Level Internal Evaluation (SIE) to include specific interventions such as outreach in tribal and hilly areas, ACSM (with revised financial norms), gender responsiveness and SBCC. The Program has moderate social risk rating.

111. Gender: Women and girls make up nearly one million of the estimated 2.8 million TB cases in India each year; TB is the fifth leading cause of death among women in the country, accounting for nearly 5 percent of fatalities in women aged 30–69. Although more men are affected by TB, women experience the disease differently and suffer from more stigma. The rapid assessment of gender and TB in India reveals the differential aspects of TB among women. This includes women delaying seeking care for TB because of a high household work burden; low awareness, mobility, poor access to resources, and limited decision-making power. In addition, women face stigma when seeking care in the public sector and disproportionately seek care in the private sector. These factors considerably influence TB case detection and adherence to treatment. A gender framework for TB to address socio-cultural barriers to TB care for both women and men will be developed and adopted in year 2 of the Program and is an agreed action in the PAP. In addition, the scaling up of private provider engagement for timely diagnosis and effective management of TB patients will include outreach to women. An intermediate result indicator to track the treatment success rate of female TB patients notified by private providers in targeted states has been included in the results framework.

112. Citizen Engagement: The CTD will enhance citizen engagement in the TB response. This includes creating/strengthening TB forums at district, state and national levels to (i) review implementation progress; (ii) distill key lessons and resolutions at different levels; (iii) amplify citizen voice and social accountability in TB control; and (iv) provide a platform for multi-sectoral engagement. The scope of community engagement will include: (i) providing patient support services through community participation - including awareness creation and stigma reduction, screening for TB and TB-related morbidity, referring for diagnosis of TB and related diseases, providing treatment adherence support, linking social support to patients, and helping address equity and non-discrimination issues; and (ii) informing and empowering communities as well as institutionalizing accountability platform by creating feedback mechanisms on TB services at all levels using community monitoring tools. The scope of community engagement is much wider than the current terms of reference developed for the state and district TB forums. The key Program action is to strengthen the community empowerment and accountability mechanism.

113. Grievance Redress Mechanism: The RNTCP National Call Centre "Nikshay Sampark" is a major grievance redress mechanism for the Program. It answers queries on services available and grievances related to various aspects of Program implementation. All grievances registered by Call Centre Executives is escalated to the Centre In-charge and Team Lead for further processing, using a standardized format from the official email of Nikshay Sampark (nikshay.sampark@rntcp.org). All emails from the team lead (or nodal point) will be marked to the respective District TB Officer (DTO) and State TB Officer (STO) where the patient/caller is residing or currently/registered. The prime responsibility of resolution of grievances is with the DTO. All grievances are supposed to be acted upon within 7 days of reporting and should be resolved maximum within 1 month. Once the response has been received from STO/ DTO, the call center then contacts the patient/ person on the

response and record whether the grievance has been resolved and whether the patient/ person is satisfied with the response. A separate list of all grievances is shared with the CTD on weekly basis along with updated (final) resolution status. The RNTCP will have a proper Grievance Redressal Policy, which should be like a Standard Operating Procedure with defined escalation matrix.

114. Communities and individuals who believe that they are adversely affected as a result of a Bank supported PforR operation, as defined by the applicable policy and procedures, may submit complaints to the existing program grievance redress mechanism or the WB's Grievance Redress Service (GRS). The GRS ensures that complaints received are promptly reviewed in order to address pertinent concerns. Affected communities and individuals may submit their complaint to the WB's independent Inspection Panel which determines whether harm occurred, or could occur, as a result of WB non-compliance with its policies and procedures. Complaints may be submitted at any time after concerns have been brought directly to the World Bank's attention, and Bank Management has been given an opportunity to respond. For information on how to submit complaints to the World Bank's corporate Grievance Redress Service (GRS), please visit *http://www.worldbank.org/GRS*. For information on how to submit complaints to the World Bank Inspection Panel, please visit *www.inspectionpanel.org*.

The ESSA concludes that the program has a moderate environmental and social risk.

115. The key environmental risks also emerge from: (i) lack of dedicated capacity at state level to plan and monitor BMW, IC and AIC activities; (ii) a shortage of dedicated biomedical engineers to support lab safety; (iii) inadequate management of infection control associated with TB related diagnostic and treatment services; and (iv) inadequate management of the incremental increases in biomedical and other wastes generated through Program supported activities. There are no high impact activities associated with the PforR boundaries such construction of large buildings, central bio-medical waste treatment facilities, and effluent treatment plants (these activities are not eligible for including under the Program).

116. The key social risk emerges from capacity gaps to deal with tribal issues, ACSM, communication, and the Program being gender responsive. Engagement with private sector requires revisiting the strategies for ACSM, SBCC and other emerging needs. In addition, the Program not having adequate and dedicated human resources for addressing social risks at national and state level presents additional challenges. The Program activities do not anticipate any land acquisition and/or resettlement.

D. Risk Assessment

117. Based on the integrated risk assessment, the **overall risk of the Program** is considered **Substantial.**

118. Technical design risk is Substantial. As discussed above, The NSP 2017-25 is robust and prioritizes high impact interventions. Government financing for TB control has been increasing significantly and there is continued commitment at the highest levels of the GOI. In this context, the Program supports the GOI to scale-up newest interventions of the NSP 2017-25. These interventions (private sector engagement and patient support through DBT) are built on successful pilots in India as well as the global evidence. However, GOI has limited experience in directly engaging the private sector for TB control. There are significant inherent risks to engage the private sector at the scale envisaged by the Program. The main risk being the GOI's lack of strategic purchasing capacity at state and national levels. Such interventions are therefore high-risk, high-reward activities which can be game changers for India to achieve NSP 2017-25 goals. Risk mitigation measures identified which include setting up of TSUs at national and state levels are robust and the team will systematically review the risks, undertake process evaluations to identify implementation bottlenecks and

introduce mid-course corrections as needed.

119. Environmental and social risk is Moderate. The MOHFW is familiar with World Bank safeguard policies, and no major environmental or social risks or impacts are envisaged due to the absence of major civil works and the overall positive social impacts of the Program. There are no high impact activities in Program boundaries such as construction of large buildings, bio-medical waste treatment facilities, and effluent treatment plants. The key environmental risks emerge from: (i) lack of dedicated capacity at state level to plan and monitor BMW, IC and AIC activities; (ii) shortages of laboratory staff and dedicated biomedical engineers to monitor laboratory safety; (iii) management of infection control associated with TB related diagnostic and treatment services; and (iv) management of the increased biomedical and other waste generated through the Program supported activities. These risks are managed utilizing country systems for environment health and safety management, supported by capacity strengthening activities recommended as part of the ESSA.

120. Stakeholder risk is Moderate, owing mainly to the relatively non-controversial nature of the Program objectives and design and the robust collaboration in TB control between the MOHFW and development partners, including the private sector and civil society. The MOHFW recently established a National Technical Advisory Group on private sector engagement for TB control that will actively provide advice and support to strengthen the MOHFW's engagement with the private sector during the implementation of the Program.

121. Institutional Capacity for Implementation and Sustainability Risks is Substantial. Although the CTD team has considerable experience implementing a Bank-supported project, the CTD has limited technical capacity to manage the implementation of some novel interventions proposed under the Program—specifically, the envisaged rapid scale-up of the private sector engagement and the DBT. The CTD will need rapid scale-up of staff capacity in these technical areas to guarantee high quality implementation at scale. r Capacity building activities for key CTD and state level stakeholders will be continued during implementation phase. The MOHFW will develop a human resource plan and implement it as part of the PAP monitored under the Program.

122. Fiduciary risk is Substantial. Main risks include: (i) inadequate staff at the CMSS; (ii) delays in bid evaluation; (iii) absence of a unified accounting system; and (iv) weak financial management monitoring at the CTD level. Risk mitigation measures have been identified and included in the Results Framework and the Program Action Plan.

123. In addition, the Program was screened for climate and disaster risks. The following hazards are applicable to the geographic areas covered under the Program: extreme temperature, extreme precipitation and flooding, drought, sea level rise, and storm surge. The impact of these hazards in the short to medium term is assessed as "moderate". The use of updated sputum transportation systems which help minimize the need for patients to travel large distances to seek care. Transport incentives will be provided by the GOI under a separate initiative to vulnerable populations to connect them to TB centers and this will be an important resilience measure if these areas are impacted by climate/disaster events. The minor renovations supported by the Program will support climate-friendly technologies such as use of renewable energy and energy saving appliances. In implementing these measures, improvements will be made to ensure that healthcare infrastructure is climate smart. This means introducing low-carbon technologies and increasing the resilience of health facilities to impacts of climate change. Climate and disaster related information will be used in decisions around allocation of TB resources and supply chains (supply of drugs, equipment etc.) so that there is no impact on service delivery.

ANNEX 1. RESULTS FRAMEWORK MATRIX

Program Development Objective (PDO): To improve the coverage and quality of Tuberculosis control interventions in the private and public sector in targeted states of India.

Indicators	NSP		DLI	Unit	Baseline	Annual Target Values					Frequency	Data Source/ Methodology	Responsibility for Data Collection
						YR1	YR2	YR3	YR4	YR5			
PDO Level Results Indicators													
PDO Indicator 1- DLI 1.1: Number of private notifications, net of any decrease in public notifications in targeted states (Annual)	■		■	Number	263,549	400,000	480,000	576,000	691,200	800,000	Annual	NIKSHAY	CTD
PDO Indicator 2- DLI 2.2: Proportion of TB patients receiving financial support via Nikshay Poshan Yojana in targeted states (Annual, by category of DBT scheme)	■		■										
PDO Indicator 2.1- DLI 2.2.1: Proportion of TB patients *notified by public providers* receiving 1st Nikshay Poshan Yojana payment in targeted states (Annual)				percent	11 percent	30 percent	40 percent	50 percent	60 percent	70 percent	Annual	NIKSHAY	CTD
PDO Indicator 2.2- DLI 2.2.2: Proportion of TB patients *notified by private providers* receiving 1st Nikshay Poshan Yojana payment in targeted states (Annual)				percent	0	10 percent	20 percent	30 percent	50 percent	60 percent	Annual	NIKSHAY	CTD
PDO Indicator 3- DLI 3.1: Proportion of notified TB patients tested for Rifampicin susceptibility in targeted states (Annual)	■		■	percent	29 percent	35 percent	45 percent	50 percent	55 percent	60 percent	Annual	NIKSHAY	CTD

PDO Indicator 4-DLI 1.2: Treatment success rate of TB patients notified by private providers in targeted states (Annual, patients notified in prior calendar year)	■		■	percent	9 percent	20 percent	35 percent	50 percent	60 percent	70 percent	Annual	NIKSHAY	CTD
Intermediate Results Area 1: Scaling Up Private Provider Engagement													
Intermediate Results Indicator 1: Proportion of privately notified Pulmonary TB patients that have microbiological confirmation in targeted states		■		percent	0 percent	10 percent	20 percent	30 percent	40 percent	45 percent	Annual	NIKSHAY	CTD
Intermediate Results Indicator 2-DLI 1.3: Establishment of Technical Support Units (TSUs) in CTD and targeted states to support activities related to private sector, DBT, PFMS, and multi sectoral engagement as per agreed TOR			■	Text	No TSUs	Mechanism to contract TSUs developed and approved by the MOH&FW	10 TSUs established at CTD and state levels by MOH&FW	N/A	N/A	N/A		CTD administrative data	CTD
Intermediate Results Indicator 3: Proportion of Blocks with molecular diagnostic services operational in targeted states				percent	15 percent (681/4461)	18 percent	21 percent	24 percent	27 percent	30 percent	Cumulative	CTD administrative data	CTD
Intermediate Results Indicator 4: GOI annual expenditure on strategic purchasing under NGO/Private Provider budget head in targeted states (INR per year)				Amount (INR)	197 Million	208 Million	286 Million	420 Million	548 Million	760 Million	Annual	RNTCP expenditure data	CTD
Intermediate Results Area 2: Rolling-out TB Patient Management and Support Interventions													
Intermediate Results Indicator 5: Percentage of beneficiaries out of total notified TB Patients seeded in Nikshay within 3 months of notification.				percent	68 percent	70 percent	72 percent	75 percent	80 percent	85 percent	Annual	NIKSHAY	CTD

a) Aadhaar b) Verified bank account				percent	33 percent	40 percent	45 percent	50 percent	60 percent	70 percent	Annual	NIKSHAY	CTD
Intermediate Results Indicator 6: Gender responsive framework for RNTCP developed by CTD & approved by MOH&FW				Text	N/A	Framework developed & approved by MOH&FW	N/A	N/A	N/A	N/A		CTD administrative data	CTD
Intermediate results Indicator 7 Proportion of TB patients notified by private providers for whom at least one DBT incentive payment was made to their private providers. (Reported data for TB patients disaggregated by gender)				percent	0	15 percent	25 percent	35 percent	50 percent	60 percent	Annual	NIKSHAY	CTD
Intermediate Results Indicator 8: Proportion of beneficiaries receiving financial support (2nd payments of Nikshay Poshan Yojana) through DBT in targeted states				percent	0	24 percent	32 percent	40 percent	48 percent	56 percent	Annual	NIKSHAY	CTD
Intermediate Result Indicator 9: Treatment success rate of female TB patients notified in targeted states in the private sector.				percent	0 percent	15 percent	30 percent	40 percent	50 percent	60 percent	Annual	NIKSHAY	CTD
Intermediate Results Area 3: Strengthening Detection, Treatment and Monitoring of Drug-Resistant TB													
Intermediate Results Indicator 10: Proportion of DRTB centers in the targeted states with the action plan for AIC	■			percent	34 percent	40 percent	45 percent	50 percent	60 percent	70 percent	Annual	CTD administrative data	CTD
Intermediate Results Indicator 11: Proportion of notified rifampicin-resistant TB cases with second-line drug-susceptibility testing results documented within 3 months of DR-TB treatment initiation				percent	32 percent	40 percent	50 percent	55 percent	60 percent	65 percent	Annual	Lab Register	CTD

Intermediate Results Indicator 12: Treatment success rate among MDR/RR-TB patients (treatment cohort)	■			percent	46 percent	48 percent	52 percent	55 percent	60 percent	65 percent	Annual	NIKSHAY	CTD
Intermediate Results Area 4: Strengthening RNTCP Institutional Capacity and Information Systems													
Intermediate Results Indicator 13: Annual surveillance system analysis published; including data quality by district, annual state/CTD surveillance system evaluation, and estimates for potential under-notification and duplication				Text	N/A	Annual analysis published	Annual analysis published	Annual analysis published	Annual analysis published	Annual analysis published	Annual	Analysis Reports	CTD
Intermediate Results Indicator 14: Number of targeted states replacing paper TB registers with e-TB Nikshay adopted real-time monitoring of notification and quality of care in at least 50 percent of districts				Number	0	3	5	8	8	8	Cumulative	CTD administrative data	CTD
Intermediate Results Indicator 15-DLI 4.2: Development and implementation of a performance-based management mechanism between the center and the targeted states			■	Text	N/A	Mechanism developed and approved	Implementation in 5 States	Implementation in 8 States	Implementation in 8 States	Implementation in 8 States	Cumulative	CTD administrative data	CTD
Intermediate Results Indicator 16: Number of targeted states adopted and transitioned from paper-based to electronic SOE generated from PFMS				Number	0	2	6	8	9	9	Cumulative	CTD administrative data	CTD
Intermediate Results Indicator 17: Number of Annual TB Forum at state and national level conducted to: (i) promote citizen engagement; (ii) foster learning within and between states; and (iii) to provide a multisectoral platform for TB control				Number	0	3	5	8	8	8	Annual	CTD administrative data	CTD

Addendum: Definitions of Selected Intermediate Results

Results Framework Indicator	Numerator	Denominator	Notes
Intermediate Results Indicator 1: Proportion of privately notified pulmonary TB patients that have microbiological confirmation in targeted states	Number of privately-notified pulmonary TB patients in reporting cohort with test result (molecular or bacteriological) confirming TB.	Number of privately-notified pulmonary TB patients	IGRA or TST results do not count
Intermediate Results Indicator 3: Proportion of Blocks with molecular diagnostic services operational in targeted states	Number of health blocks with RNTCP CBNAAT operational in house at end of calendar year.	Number of health blocks	Metric for decentralization of molecular diagnostics. Transport schemes to send specimens to another block for molecular testing do not count.
Intermediate Results Indicator 5: Percentage of beneficiaries out of total notified TB Patients with seeded in Nikshay within 3 months of notification. - **Aadhaar and** - **Verified bank account**	Number of patients with Aaadhar entry date/Bank Account verification date within 3 months of treatment initiation	Number of notified TB patients	Date of Aadhar entry and date of bank account verification in Nikshay will be used for analysis
Intermediate Results Indicator 8: Proportion of beneficiaries receiving financial support (2nd payments of Nikshay Poshan Yojana) through DBT in targeted states	Number of TB patients notified in the first 6 months of each calendar year with 2 documented payments of NPY by the end of the same reporting year in the targeted states.	Number of TB patients notified in the first 6 months of the calendar year in the targeted states	Cohort is limited to TB patients notified in the first 6 months of each calendar year because payments require time to be made and recorded. In addition to total number, data should be stratified by public and private notifications.
Intermediate Result Indicator 9: Treatment success rate of female TB patients notified in targeted states in the private sector.	Female TB patients notified by private providers in the targeted states whose treatment is successful (annual).	All women notified by private providers in the targeted states (annual).	Baseline is zero because the limited available data is not fully disaggregated. The target for women is lower given the low baseline. However, the Program seeks to reduce the treatment success rate between men and women.
Intermediate Results Indicator 10: Proportion of DRTB centers in the targeted states with the budgeted action plan for AIC	Number of DRTB centers with budgeted action plan for AIC	Number of DRTB centers in the targeted states	This includes nodal and district DR-TB centers
Intermediate Results Indicator 11: Proportion of notified rifampicin-resistant TB cases with second-line drug-susceptibility testing results documented within 3 months of DR-TB treatment initiation	Number of notified DR-TB patients (with at least rifampicin resistance) in the first 6 months of each calendar year, who have result for at least fluoroquinolone resistance, documented within 3 months of DR-TB treatment initiation.	Number of notified DR-TB patients (with at least rifampicin resistance) in the first 6 months of the calendar year.	Cohort is limited to DR-TB patients notified in first 6 months of each calendar year, given the time lag of DST, and the need to collect data for the indicator by the end of the calendar year.

ANNEX 2. Disbursement Linked Indicators, Disbursement Arrangements and Verification Protocols

Disbursement Linked Indicators	DLI Baseline	Disbursement-Linked Results				
		Results to be Achieved by FY2019/20 (Year 1)	Results to be Achieved in FY2020/21 (Year 2)	Results to be Achieved in FY2021/22 (Year 3)	Results to be Achieved in FY2022/23 (Year 4)	Results to be Achieved in FY2023/24 (Year 5)
1.0 Revision and approval of National Guidelines for partnerships under RNTCP (Prior Result)	National Guidelines for partnership 2014 in existence	CTD has revised and adopted National Guidelines for partnerships under RNTCP≠				
Allocated Amounts		USD 16,000,000				
1.1 Number of private notifications, net of any decrease in public notifications in Program States (Annual)	263,549 (2017)	400,000	480,000	576,000	691,200	800,000
Allocated Amounts		USD 130 per additional patient notified by private sector net of any decrease in public notifications compared to the previous calendar year	USD 130 per additional patient notified by private sector net of any decrease in public notifications compared to the previous calendar year	USD 130 per additional patient notified by private sector net of any decrease in public notifications compared to the previous calendar year	USD 130 per additional patient notified by private sector net of any decrease in public notifications compared to the previous calendar year	USD 130 per additional patient notified by private sector net of any decrease in public notifications compared to the previous calendar year
1.2 Treatment success rate of TB patients notified by private providers in Program States (Annual, cohort of patients notified in prior calendar year)	9 percent (2017)	20 percent	35 percent	50 percent	60 percent	70 percent

Disbursement Linked Indicators	DLI Baseline	Disbursement-Linked Results				
		Results to be Achieved by FY2019/20 (Year 1)	Results to be Achieved in FY2020/21 (Year 2)	Results to be Achieved in FY2021/22 (Year 3)	Results to be Achieved in FY2022/23 (Year 4)	Results to be Achieved in FY2023/24 (Year 5)
Allocated Amounts		USD 114,754 per every 0.1 percentage point increase from the previous calendar year	USD 114,754 per every 0.1 percentage point increase from the previous calendar year	USD 114,754 per every 0.1 percentage point increase from the previous calendar year	USD 114,754 per every 0.1 percentage point increase from the previous calendar year	USD 114,754 per every 0.1 percentage point increase from the previous calendar year
1.3 Establishment of a TSU in CTD and STSUs in Program States to support activities related to private sector, direct benefit transfer, public financial management system, and multi-sectorial engagement as per agreed terms of reference	No TSU/STSU in place	MOHFW has developed and approved the mechanism to contract TSU and STSUs±	1 TSU established at CTD and 9 STSUs at state level by MOHFW			
Allocated Amounts		USD 5,000,000	USD 1,500,000 for each TSU/STSU established			
2.0 Development of Nikshay modules for all four direct benefit transfer schemes (Nikshay Poshan Yojana, Tribal TB Patients Scheme, Private Providers Scheme and Treatment Supporters Scheme) (Prior Result)	Only Nikshay Poshan Yojana existing in Nikshay (Sept 2018)	Modules for all four schemes (Nikshay Poshan Yojana, Tribal TB Patients Scheme, Private Providers Scheme and Treatment Supporters Scheme) functional in Nikshay. Modules include payment processing				

Disbursement Linked Indicators	DLI Baseline	Disbursement-Linked Results				
		Results to be Achieved by FY2019/20 (Year 1)	Results to be Achieved in FY2020/21 (Year 2)	Results to be Achieved in FY2021/22 (Year 3)	Results to be Achieved in FY2022/23 (Year 4)	Results to be Achieved in FY2023/24 (Year 5)
		and confirmation of payment.				
Allocated Amounts		USD 2,500,000 for each module				
2.1 Proportion of districts implementing digital signature certificate-based approval process for direct benefit transfer payment in Program States	0 percent	20 percent	40 percent	60 percent	80 percent	
Allocated Amounts		USD 62,500 per every 1 percentage point increase from the previous calendar year	USD 62,500 per every 1 percentage point increase from the previous calendar year	USD 62,500 per every 1 percentage point increase from the previous calendar year	USD 62,500 per every 1 percentage point increase from the previous calendar year	
2.2.1 Proportion of TB patients notified by public providers receiving the 1st Nikshay Poshan Yojana payment in Program States (Annual)	11 percent (Aug 2018)	30 percent	40 percent	50 percent	60 percent	70 percent
Allocated Amounts		USD 389,831 per every 1 percentage point increase from the previous calendar year	USD 389,831 per every 1 percentage point increase from the previous calendar year	USD 389,831 per every 1 percentage point increase from the previous calendar year	USD 389,831 per every 1 percentage point increase from the previous calendar year	USD 389,831 per every 1 percentage point increase from the previous calendar year
2.2.2 Proportion of TB patients notified by private providers	0 percent	10 percent	20 percent	30 percent	50 percent	60 percent

Disbursement Linked Indicators	DLI Baseline	Disbursement-Linked Results				
		Results to be Achieved by FY2019/20 (Year 1)	Results to be Achieved in FY2020/21 (Year 2)	Results to be Achieved in FY2021/22 (Year 3)	Results to be Achieved in FY2022/23 (Year 4)	Results to be Achieved in FY2023/24 (Year 5)
receiving the 1st Nikshay Poshan Yojana payment in Program States (Annual)						
Allocated Amounts		USD 366,667 per every 1 percentage point increase from the previous calendar year	USD 366,667 per every 1 percentage point increase from the previous calendar year	USD 366,667 per every 1 percentage point increase from the previous calendar year	USD 366,667 per every 1 percentage point increase from the previous calendar year	USD 366,667 per every 1 percentage point increase from the previous calendar year
3.1 Proportion of notified TB patients tested for rifampicin susceptibility in Program States (Annual)	30 percent	35 percent	45 percent	50 percent	55 percent	60 percent
Allocated Amounts		USD 233,333 per every 0.1 percentage point increase from the previous calendar year	USD 233,333 per every 0.1 percentage point increase from the previous calendar year	USD 233,333 per every 0.1 percentage point increase from the previous calendar year	USD 233,333 per every 0.1 percentage point increase from the previous calendar year	USD 233,333 per every 0.1 percentage point increase from the previous calendar year
4.0 Nikshay mechanisms developed for (i) deduplication (of patients and providers) and reconciliation of different provider types; and (ii) reconciliation of direct benefit transfer payments through Nikshay versus the public financial	Only manual mechanism for deduplication of patients and providers in existence	(i) CTD has developed Nikshay features and manuals for deduplication; and (ii) CTD has run the first system-wide round of patient deduplication to ensure that all TB notifications represent distinct episodes for each patient as unique≠				

Disbursement Linked Indicators	DLI Baseline	Disbursement-Linked Results				
		Results to be Achieved by FY2019/20 (Year 1)	Results to be Achieved in FY2020/21 (Year 2)	Results to be Achieved in FY2021/22 (Year 3)	Results to be Achieved in FY2022/23 (Year 4)	Results to be Achieved in FY2023/24 (Year 5)
management portal for Nikshay Poshan Yojana (Prior Result)						
Allocated Amounts		USD 14,000,000				
4.1.1 Development and approval of a multi-year RNTCP Human Resource Plan at CTD and state levels covering the Program States	No human resource plan in existence	MOHFW has developed and adopted RNTCP Human Resources Plan±				
Allocated Amounts		USD 10,000,000				
4.1.2 Reduction of the staffing gap identified by the RNTCP Human Resource Plan for CTD and the Program States	0 percent		25 percent	50 percent	60 percent	70 percent
Allocated Amounts			USD 571,429 per every 1 percentage point reduction from the previous calendar year, up to a maximum of USD 19,600,000	USD 571,429 per every 1 percentage point reduction from the previous calendar year, up to a maximum of USD 19,600,000	USD 571,429 per every 1 percentage point increase from the previous calendar year	USD 571,429 per every 1 percentage point increase from the previous calendar year
4.2 Development and implementation of a performance-based management mechanism between the CTD and the Program States	No performance-based mechanism in existence	CTD has developed and approved a performance-based mechanism±	Five (5) Program States have implemented the performance-based mechanism in year 2	Eight (8) Program States have implemented the performance-based mechanism in year 3	Eight (8) Program States have implemented the performance-based mechanism in year 4	Eight (8) Program States have implemented the performance-based mechanism in year 5

DISBURSEMENT LINKED INDICATORS	DLI BASELINE	DISBURSEMENT-LINKED RESULTS				
		RESULTS TO BE ACHIEVED BY FY2019/20 (YEAR 1)	RESULTS TO BE ACHIEVED IN FY2020/21 (YEAR 2)	RESULTS TO BE ACHIEVED IN FY2021/22 (YEAR 3)	RESULTS TO BE ACHIEVED IN FY2022/23 (YEAR 4)	RESULTS TO BE ACHIEVED IN FY2023/24 (YEAR 5)
Allocated Amounts		USD 9,000,000	USD 689,655 for each Program State in which the mechanism is implemented	USD 689,655 for each Program State in which the mechanism is implemented	USD 689,655 for each Program State in which the mechanism is implemented	USD 689,655 for each Program State in which the mechanism is implemented

≠ These DLRs must be met not later than three (3) months after the Effective Date.

± These DLRs must be met not later than nine (9) months after the Effective Date.

Verification Protocol Table: Disbursement Linked Indicators

	DLI	Definition/Description of achievement	Protocol to evaluate achievement of the DLI and data/result verification		
			Data source/agency	Verification entity	Procedure
Scaling Up Private Provider Engagement					
1.0	Revision and approval of National Guidelines for Partnerships under RNTCP	Final documents and MOH&FW circular or other proof of formal adoption submitted to IVA. Guidelines to include output-based contracting of intermediary organizations.	RNTCP	WHO	Draft guidelines will be shared with World Bank for comments before finalization. IVA will review final documents and confirm achievement.
1.1	Number of private notifications, net of any decrease in public notifications in targeted states (Annual)	Increase in the number of new TB case notifications of all types by private healthcare providers during each calendar year relative to the previous year, minus any reduction in the number of new TB case notifications of all types by public providers relative to the previous year (targeted states).	RNTCP from Nikshay	WHO	IVA will (i) review NIKSHAY data using data quality assurance tool and (ii) contact a random subset of patients to verify, using an independent call center and home visits. For (ii), the IVA will specify sample size and sampling technique acceptable to the Bank in their inception report.
1.2	Treatment success rate of TB patients notified by private providers in targeted states (annual, patients notified in prior calendar year)	**Numerator**: number of new DS TB patients notified by private providers in the prior annual cohort with treatment success (cure or completion) recorded in Nikshay (targeted states) **Denominator**: number of new DS TB patients notified by private providers in the prior annual cohort (targeted states)[25]	RNTCP from Nikshay	WHO	
1.3	Establishment of Technical Support Units (TSU) in CTD and targeted states to support activities related to private sector, DBT, PFMS, and multi-sectorial engagement as per agreed TOR	Contracts and other proof of TSUs establishment submitted to IVA	RNTCP	WHO	IVA will review contracts and qualifications of key individuals to verify that capacity corresponds with functions and capabilities specified in terms of reference

[25] Results achieved in FY2019/20 (Year 1) will be for the cohort of DS TB patients notified by private providers in the year 2018/19 (July 1, 2018 to June 30, 2019).

	DLI	Definition/Description of achievement	Protocol to evaluate achievement of the DLI and data/result verification		
			Data source/agency	Verification entity	Procedure
Rolling out TB Patient Management and Support Interventions					
2.0	Development of Nikshay modules for all 4 DBT schemes (Nikshay Poshan Yojana, Tribal TB Patients, Private Providers and Treatment Supporters)	Modules for 4 schemes (Nikshay Poshan Yojana, Tribal TB Patients, Private Providers and Treatment Supporters) functional in Nikshay. Modules include processing for payment and confirmation of payment.	RNTCP	IVA 2	IVA will conduct desk review of availability and functionality of modules in Nikshay web software and comment on their ability to deploy payments under the four schemes.
2.1	Proportion of districts implementing digital signature certificate (DSC) based approval for DBT payment	**Numerator:** Number of districts in targeted states which implement end-to-end Digital Payments. **Denominator:** Total number of TB districts in targeted states	RNTCP	WHO	IVA will (i) conduct a desk review of programmatic guidance to States and from States to districts to move from manual to full digital payment approval systems (ii) visit a random subset of districts to verify. For (ii), the IVA will specify sample size and sampling technique acceptable to the Bank in their inception report.
2.2	Proportion of TB patients receiving financial support through DBT:				IVA will (i) review Nikshay/PFMS data using data quality assurance tool and (ii) contact a random subset of patients to verify, using an independent Call Centre and field visits. For (ii) IVA will specify sample size and sampling technique acceptable to the Bank in their inception report.
2.2.1	Proportion of TB patients notified by public providers receiving first Nikshay Poshan Yojana payment in targeted states (annual)	**Numerator:** Number of patients for whom at least one DBT payment is confirmed paid by PFMS in the last calendar year in targeted states **Denominator:** Number of patients eligible for DBT disbursements (who have not "surrendered" their benefit) in the last calendar year in targeted states	RNTCP from Nikshay / PFMS	WHO	
2.2.2	Proportion of TB patients notified by private providers receiving first Nikshay Poshan Yojana payment in targeted states (annual)		RNTCP from Nikshay / PFMS	WHO	

	DLI	Definition/Description of achievement	Protocol to evaluate achievement of the DLI and data/result verification		
			Data source/agency	Verification entity	Procedure
Strengthening Detection, Treatment and Monitoring of Drug-Resistant TB					
3.1	***Proportion of notified TB patients tested for RIfampicin susceptibility in targeted states (annual)***	**Numerator:** Number of notified (public and private) TB patients tested for Rifampicin susceptibility (including CBNAAT result of MTB not detected) in the last calendar year target states **Denominator:** Total number of notified (public and private) TB patients in the last calendar year targeted states	RNTCP from Nikshay	WHO	IVA will (i) review NIKSHAY data using data quality assurance tool (ii) visit a random subset of laboratories to verify, by checking primary laboratory records. For (ii), the IVA will specify sample size and sampling technique acceptable to Bank in their inception report.
Strengthening RNTCP Institutional Capacity and Information Systems					
4.0	Nikshay mechanisms developed for (i) deduplication (of patients and providers) and reconciliation of different provider types; and (ii) reconciliation of direct benefit transfer payments through Nikshay versus the public financial management portal for Nikshay Poshan Yojana.	Operational combination of software features to ensure that all TB notifications represent distinct episodes for distinct patients	RNTCP	IVA 2	The IVA will (i) review the software algorithm and operational guidance for ensuring that patients may only be notified once for a given episode of TB, that Private Providers are consistently identified and procedures for local resolution of potential duplicates are in place; (ii) verify if Nikshay can actually carry out said deduplication; and (iii) run scripts at the back end of Nikshay software to ensure that deduplication is taking place.
4.1	**Staffing capacity of the RNTCP strengthened:**				
4.1.1	Development and approval of a multi-year RNTCP Human Resource Plan at CTD and state levels covering the Program states.	RNTCP Human Resources Plan formally approved by MOH&FW, with no objection from the World Bank, with due focus on staff for private sector engagement, DBT, DR-TB and information systems.	RNTCP	WHO	IVA will confirm approval of plan and its dissemination to target states, and comment on extent to which the plan adequately addresses priority issues.
4.1.2	Reduction of the staffing gap identified by the human resource plan for CTD and targeted states	**Numerator**: number of vacancies in the staffing gap identified by the HR plan for CTD and targeted states filled at the end of last calendar year **Denominator:** Total vacancies identified by the HR plan for CTD and targeted states	RNTCP	WHO	IVA will (i) review data on filled posts (“in place”) from CTD and targeted states and compare with approved RNTCP HR plan, and (ii) review proofs of contracts/letter of deputation for such posts.

	DLI	Definition/Description of achievement	Protocol to evaluate achievement of the DLI and data/result verification		
			Data source/agency	Verification entity	Procedure
4.2	Development and implementation of a performance-based management mechanism between the center and the targeted states	Development of guidelines and issuance of MOH&FW Circular or other proof of approval sent to IVA. Number of targeted states in which at least 75 percent of eligible teams were recognized/rewarded in the past year as per the guidelines	RNTCP	WHO	IVA will review the Guidelines and Circular. IVA will review annual report on the implementation of the mechanism and proof of recognition/reward.

ANNEX 3. PROGRAM ACTION PLAN

Action Description	DLI	Responsibility	Recurrent	Frequency	Due Date	Completion Measurement
Annual surveillance system analysis published; including data quality by district, annual state/CTD surveillance system evaluation, and estimates for potential under-notification and duplication		CTD	Yes	Annual	June 30, 2020 June 30, 2021 June 30, 2022 June 30, 2023 June 30, 2024	Annual Surveillance System Analysis Report Approved by the Bank
GOI and World Bank agree to a multi-year capacity building plan Capacity building plan executed annually		CTD	Yes		September 30, 2019 (initial plan) Yearly Execution	Capacity Building Plan Approved by MOH&FW AS
Central, State and District TB Forum strengthened to improve learning and accountability. Central, State and District TB forum strengthened per the TOR agreed to with the World Bank.		States and CTD	Yes	Annual	December 31, 2019 (CTD shares final TORs with the Bank for review and clearance) Annual Fora in Program States and at CTD by the following: June 30, 2020 June 30, 2021 June 30, 2022 June 30, 2023 June 30, 2024	Government approval of the revised TORs for State and national TB Fora

Action Description	DLI	Responsibility	Recurrent	Frequency	Due Date	Completion Measurement
CTD Strengthens Data Collection and Monitoring of Tribal Population Transport Reimbursement. - Annual CTD report which capture coverage and trends in DBT for tribal populations		CTD	Yes	Continuous		Data Collection and Monitoring Plan for Tribal Populations Annual TB Report with data on DBT for Tribal Populations
Development and adoption of framework for TB and gender in a manner and substance satisfactory to the Bank. This will include: a) Analysis of context specific, socio-cultural norms and overlapping health concerns (such as malnutrition, exposure to fumes, etc.) that are likely to amplify the incidence of TB amongst women disaggregated by caste and geography in participating states. b) Monitoring of gender related interventions by adding them in the Central Level Internal Evaluation Format, and State Level Internal Evaluation Format that are being used by the RNTCP.		CTD	No		June 30, 2019	Framework for TB Among Women Adopted by CTD for Program Management Purposes Gender specific data for TB monitoring reported by CTD in annual reports.
The CTD formulates and adopts health and safety guidelines for staff/workers involved in the transport of sputum		CTD	No		June 30, 2019	Health and Safety Guidelines for Sputum Transportation Published on RNTCP

Action Description	DLI	Responsibility	Recurrent	Frequency	Due Date	Completion Measurement
						website and disseminated to State TB Offices for implementation
Servicing Standard Operating Procedures of key lab equipment (BSC, AHU, centrifuge, autoclaves) [only where there is health and safety implications for workers]		CTD	No		June 30, 2019	Standard operating procedures for lab equipment published on RNCTP websites and disseminated to states
Process evaluation of the implementation and effect of DBT on adherence to TB treatment and success rate.		CTD	No		June 30, 2021 June 30, 2023	Process Evaluation Report
Operating Procedures for Grievance Redressal developed and adopted by CTD in a manner and substance satisfactory to the Bank.		CTD	No		December 31, 2019	Approved Grievance Redressal Policy
Strengthen the capacity of Central Medical Services Society (CMSS) to manage the procurement and supply chain management for drugs and equipment in line with increased workload emanating from the Program.		CMSS	No		September 30, 2019	a) Filling the five vacant staff positions and maintain full staff strength thereafter; (b) Expanding number of laboratories to conduct post destination quality assurance (presently five labs); and (c) enhancing

Action Description	DLI	Responsibility	Recurrent	Frequency	Due Date	Completion Measurement
						CMSS/Supplier interface and overall procurement efficiency
Decentralize data entry on TB drug stock in the Nikshay Aushadhi software at TU level.		CTD	No		September 30, 2019	Nikshay Aushadi data entry decentralized to TU levels in targeted states.
Ensure proper testing by empaneled independent Quality Assurance Lab and monitor the time taken by the labs		CMSS & CTD	Yes	Annual		Drug quality testing report
Implementation of PFMS to monitor and track real time fund utilization, including preparation of expenditure reports from PFMS, in a manner and substance satisfactory to the Bank.		CTD and states	Yes	Annual	September 30, 2019 (initial report) Yearly Execution	Expenditure reports produced from PFMS
Regular FM review by CTD of the state and district TB cells, pursuant to scope, protocols and standards agreed with the Bank.		CTD and States	Yes	Every 6 months	September 30, 2019, (initial review) Execution every 6 months	FM review completed
Scale-up RNTCP call center from 50 to 100 seats		CTD	NO		June 30, 2019	Contract effective and staff in place for 100 seat call centers.

Action Description	DLI	Responsibility	Recurrent	Frequency	Due Date	Completion Measurement
Updated supervision and monitoring guidelines to include integration of routine assessment and improvement of data completeness and quality in a manner and substance satisfactory to the Bank.		CTD	NO		December 30, 2019	Updated supervision and monitoring guidelines to include integration of routine assessment and improvement of data completeness and quality
Beneficiary Satisfaction Survey as the TOR agreed with the World Bank.		CTD	YES	Every six months	September 30, 2019 (First survey)	Beneficiary satisfaction survey report.
Strengthen RNTCP Guidelines to include protocols/standard operating procedures for standardization in servicing and replacing/decommissioning key lab safety equipment		CTD	No	One time	December 31, 2019	Standard operating procedures for lab equipment published on RNTCP website and disseminated to states.
Update the Tribal Action Plan in a manner and substance satisfactory to the Bank		CTD	No	One time	December 31, 2019	Updated Tribal Action Plan approved at CTD and disseminated to states.

Recommendations documented in section IV not included in the PAP do not significantly impact implementation and/or achievement of the PDO. Implementation of such recommendations will be monitored through standard implementation support and supervision missions.

ANNEX 4. IMPLEMENTATION SUPPORT PLAN

1. The success of the Program will depend on a detailed implementation plan supported by a framework for implementation. This framework/plan for the Program is based on: (a) needs assessment for TA; (b) development of an operational plan to achieve results; (c) development of a system of open and regular communication between different stakeholders to maximize coordination; (d) learning from implementation through knowledge exchanges and operational research; (e) regular and systematic review missions, technical consultations, and monitoring. The World Bank will ensure that timely support is provided to the Program to ensure that implementation progress is not hindered, and results are achieved. The World Bank will leverage its technical partnership with key partners to mobilize relevant technical and implementation support for the Program.

Focus of Implementation Support

Time	Focus	Skills Needed	Resource Estimate	Partner Role
First twelve months	• Implementation and technical support to CTD and states on private sector, DR-TB and DBT • Fiduciary monitoring capacity • Systems to monitor safeguards • Systems for reporting on Results Framework & DLIs Institutional arrangements	Technical; fiduciary; institutional; Env & social	• Experts in private sector contracting, TB control, quality of care, and information systems, health systems • Operations officer • Fiduciary specialists; Env & social safeguards specialists	BMGF Specialists and Consultant on private sector WHO and Global Fund Experts on TB Control
12-48 months	• TB program performance review with emphasis on private sector, Direct Benefit Transfer and DR-TB • Monitoring of fiduciary and safeguards areas • Institutional arrangements	Technical; fiduciary; institutional; Env & social	• Experts in private sector contracting, TB control, quality of care, and information systems, health systems • Operations officer • Fiduciary specialists; Env & social safeguards specialists	BMGF Specialists and Consultants on private sector WHO and Global Fund Experts on TB Control
Other				

Role of Partners in Program Implementation

Name	Institution/Country	Role
Bill and Melinda Gates Foundation	USA & India	Technical & IVA
WHO	Switzerland and India	IVA and Technical Support