

# Introduction

## 1. THE PURPOSE OF THE GLOBAL PLAN

Eliminate tuberculosis (TB) as a public health problem. That and nothing less is the goal of the Global Partnership to Stop TB. We, the members of the Partnership, know it will not happen overnight with a disease that has cast a centuries-long shadow; still, that is our aim—and we can achieve it.

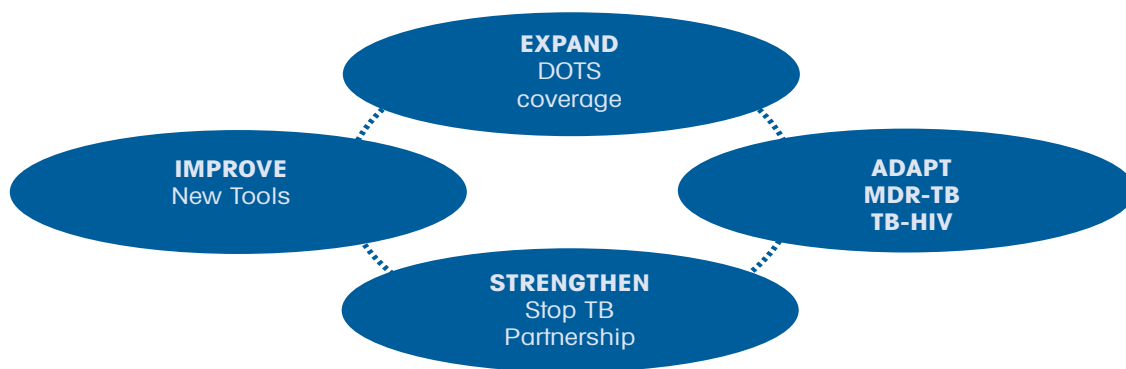
The *Global Plan to Stop TB* (GPSTB) assesses the threat of TB based on the most current global evidence. At the same time, the plan shows why we are confident TB can be controlled and, eventually, eliminated. The Global Plan describes mechanisms and activities that are already in place, as well as resources urgently needed over the course of the next five years to accelerate our efforts to meet the new global TB-control targets.

We can control TB. In contrast to some other modern plagues, with TB we know what must be done, we know how to do it, and we know how much it will cost. If we effectively apply proven, cost-effective strategies for TB control—adapting and improving them to meet the challenges described in this document over the next five years—we will have taken a giant step towards eliminating tuberculosis as a threat to future generations.

## 2. THE OBJECTIVES

*The Global Plan to Stop TB has four objectives:*

- **To expand** our current strategy—DOTS—so that all people with TB have access to effective diagnosis and treatment.
- **To adapt** this strategy to meet the emerging challenges of HIV and TB drug resistance.
- **To improve** existing tools by developing new diagnostics, new drugs, and a new vaccine.
- **To strengthen** the Global Partnership to Stop TB so that proven TB-control strategies are effectively applied.



These objectives guide and prioritise our work as Stop TB Partners. They provide a framework through which Stop TB Partners and donors can assess progress and redirect their efforts as needed. They are also meant to attract and energize new partners who will be catalysed by “the zeal and passion,” in Archbishop Tutu’s words. These partners should see how the day-to-day progress towards shared objectives demonstrates that *this deadly disease can be vanquished*. Our intention in drafting this plan and subsequent updates is to continually highlight progress and gaps. As our campaign gains momentum, we hope new partners will readily fill those gaps.

One current gap is the lack of adequate programmes to deal with TB-HIV co-infection. We urgently need prevention and treatment of both diseases. The *Global Plan to Stop TB* makes a start on plans to integrate care for these closely linked epidemics. It will be updated as we work with ministries of health and colleagues involved in HIV/AIDS control to enhance understanding and effective action.

A plan is only as good as the effective action it generates. If successful, the *Global Plan to Stop TB* will both **accelerate efforts** and **increase investments** in TB control. It must, therefore, be a work in progress. It will be revisited and updated to keep it current in a rapidly changing world. In practical terms, this means that the estimates of disease burden and the impact of interventions will be regularly updated, and cost estimates consistently revised, to reflect new investments and/or new developments in policy, strategy, and research.

### 3. PLAN STRUCTURE

*The Global Plan to Stop TB is divided into two parts.*

**Part 1** describes the state of the world’s TB epidemic and calls for urgent action to address it.

- Chapter 1 gives an overview of the global TB epidemic and its profound impact on individuals, families, communities, and nations.
- Chapter 2 describes DOTS—the internationally recommended TB-control strategy—and provides estimates of the investments needed to reach the global TB-control targets by 2005.
- Chapter 3 describes the rapidly emerging co-epidemic of HIV-related TB, which is destroying communities in sub-Saharan Africa. An urgent and effective response to this epidemic is needed.

- Chapter 4 addresses the growing problem of multidrug-resistant TB (MDR-TB), which poses a significant threat to TB control.
- Chapter 5 provides an overview of the action and investments needed in research to accelerate development of new TB-control tools, including diagnostics, drugs, and vaccines.

**Part 2** describes how the *Global Partnership to Stop TB* plans to respond to the challenges described in Part 1.

- Chapter 6 introduces the structure that has been put in place to coordinate efforts to control and eventually eliminate TB—the Global Partnership to Stop TB—and the objectives that must be fulfilled over the next five years.
- Chapter 7 provides details of the plans of action of the six working groups established by the Stop TB Partnership to ensure that the objectives are reached.
- Chapter 8 describes additional elements being put into place to support implementation of the *Global Plan to Stop TB*, including mechanisms and plans for partnership building, advocacy, financing, priority setting, and monitoring.

## 4. PLAN COSTS

Effective TB control cannot be imposed from above. It is a fundamental premise of the *Global Plan to Stop TB* that national governments and local communities take responsibility for planning and implementing their TB-prevention and treatment programmes. In assembling the cost estimates for the Global Plan, we respected this premise by calculating cost estimates on the basis of national TB-control plans prepared by the 22 TB high-burden countries that account for 80 percent of the global TB disease burden. The estimates are based on data available in late 2001.

Effective TB control in the next five years will cost an estimated \$9.1 billion<sup>1</sup>. Most of this amount will be spent treating patients suffering from TB, including multidrug-resistant TB and TB in patients co-infected with HIV. A significant amount (\$1.1 billion) is projected to be spent on research and development of new diagnostic tools, new drugs and new TB vaccines. The Stop TB Secretariat has projected partnership costs of \$75 million for its activities in advocacy, resource development, and TB-control monitoring. In addition, there are six Stop TB working groups that will plan and coordinate the TB-control efforts of national governments, donors, and other Stop TB Partners. Their projected costs (\$314 million in total) are included in Table 1 within the cost estimates for TB-control programmes and for research activities.

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<sup>1</sup>All cost figures included in this plan are in U.S. dollars, unless otherwise noted.

**Table 1: Global Plan to Stop TB Financial Summary (five-year costs, in \$ millions) <sup>2</sup>**

Programme Costs - TB, MDR-TB & TB-HIV	7,953	(87%)
New diagnostics, drugs and vaccines	1,098	(12%)
Stop TB Partnership Activities – advocacy, resource development and monitoring	75	(1%)
<b>Total Plan Costs</b>	<b>9,126</b>	
Current Resources	5,349	
<b>Resource Gap</b>	<b>3,777</b>	

Table 2 provides each component of the projected \$9.1 billion five-year cost for TB control, the resources available, and the resulting resource gap. A draft of this *Global Plan to Stop TB*, presented in October 2000 at the Stop TB Partners’ Forum, showed total plan costs of \$9.3 billion, nearly \$200 million more than this final plan estimate. Revisions since October result principally from improved estimates of DOTS expansion costs and of the capacity of health systems in certain high-burden countries to support it.

At current commitment levels, TB-burdened nations will provide \$4.5 billion (85%) of the approximately \$5.3 billion in resources projected to be committed for TB control. The projected external resources committed to TB control are based on estimates of resources committed in the year 2000. All projections of five-year committed resources rely on one extremely important assumption—that resources currently committed will remain committed for the five years at current levels. If these existing commitments are not renewed at current levels, the resource gap will increase accordingly.

<sup>2</sup> The total estimated plan costs shown in this table exceed the estimate of resources required for global TB control in a recent analysis conducted by WHO (see K. Floyd, L. Blanc, M. Raviglione and J.W. Lee, “Resources Required for Global Tuberculosis Control” Science 2002, in press). This is because the latter focuses on the costs for DOTS implementation, and does not include an assessment of resources needed for MDR-TB, TB/HIV, new diagnostics, drugs and vaccines, and partnership activities. Estimates for DOTS implementation in both publications are similar. In the analysis undertaken by WHO, it is estimated that \$6 billion is required for DOTS implementation in the 22 HBC and in the low- and lower-middle income countries outside the 22 HBC during the period 2001-5 (\$225 million less than is projected in this plan), and that the resource gap is about \$1.5 billion (compared to \$1.6 billion in this plan). The differences arise because the two studies were conducted independently and used slightly different methods to project cases to be treated, costs, and available resources. However, the fact that the two studies are broadly consistent strengthens the validity of both estimates. The main difference lies in the cost estimates for low- and lower-middle income countries outside the 22 HBC. This is to be expected given the limited data and the need for more assumptions in estimating costs for these countries. Both sets of estimates will be updated as more data become available.

Table 2: Summary Costs of the Global Plan to Stop TB, 2001–2005 (\$ millions)

Figures for 114 countries	Costs		Current Resources		Gap
	(a)	National	External	Subtotal	(a)-(d)
		(b)	(c)	(d)=(b)+(c)	
<b>DOTS Expansion<sup>3</sup></b>	<b>6,225</b>	<b>4,300</b>	<b>359</b>	<b>4,659</b>	<b>1,566</b>
Country needs <sup>4</sup> – high-burden countries	4,560	3,300	250	3,550	1,010
Country needs – other countries	1,440	1,000	0	1,000	440
DOTS expansion working group	225	0	109	109	116
<b>Adapting and Improving DOTS</b>	<b>1,728</b>	<b>230</b>	<b>60</b>	<b>290</b>	<b>1,438</b>
<b>TB-HIV</b>	642	30	8	38	604
Country needs	630	30	6	36	594
TB-HIV working group	12	0	2	2	10
<b>MDR TB</b>	1,086	200	52	252	834
Country needs	1,070	200	50	250	820
MDR-TB working group	16	0	2	2	14
<b>Research and Development (totals)</b>	<b>1,098</b>	<b>0</b>	<b>390</b>	<b>390</b>	<b>708</b>
<b>New diagnostics</b>	177	0	53	53	124
Research needs	150	0	47	47	103
New diagnostics working group	27	0	6	6	21
<b>New drugs</b>	347	0	136	136	211
Research needs	317	0	130	130	187
New drugs working group	30	0	6	6	24
<b>New vaccines</b>	424	0	96	96	328
Research needs	420	0	95	95	325
New vaccines working group	4	0	1	1	3
<b>Health Policy Systems Research</b>	150	0	105	105	45
<b>Partnership</b>	<b>75</b>	<b>0</b>	<b>10</b>	<b>10</b>	<b>65</b>
Partnership secretariat	27	0	10	10	17
Advocacy <sup>5</sup>	20	0	0	0	20
Resource development and financing <sup>5</sup>	13	0	0	0	13
Monitoring <sup>5</sup>	15	0	0	0	15
<b>TOTALS</b>	<b>9,126</b>	<b>4,530</b>	<b>819</b>	<b>5,349</b>	<b>3,777</b>

<sup>3</sup> See the preceding footnote regarding the separate analysis of DOTS expansion costs, which estimated substantially similar costs using somewhat different methodologies

<sup>4</sup> “Country needs” includes estimates of costs for TB-control programmes, as well as estimates of the economic burden that TB places on the health care system of the country, beyond those specifically identified for TB control.

<sup>5</sup> Plans of partnership task forces for these initiatives are still being reviewed. Figures provided are rough cost estimates and are not yet supported by detailed budgets. See Chapter 8.

What follows is a brief explanation of how cost estimates were derived for each major component of the plan—DOTS Expansion, Adapting and Improving DOTS, Research and Development, and Partnership Activities. The Stop TB Partnership coordinates TB-control work principally through working groups and through the Stop TB Partnership Secretariat. Working groups focus on a specific area of activity, such as DOTS expansion or development of new diagnostics. The plans and budgets of these working groups are summarized in the following sections. More detail on the working groups is provided in Chapter 7 and working group budgets are shown in Annex 2.

*The Economic Annex to the Global Plan to Stop TB* is being published separately and provides complete detail of the methodology and results of GPSTB cost estimates and epidemiological projections. Annex 1 provides a summary of this Economic Annex.

## **DOTS EXPANSION**

DOTS is the WHO-recommended strategy for TB control that has been adopted in 119 countries. DOTS is highly effective—its treatment success is 81 percent on average in high-burden countries—and cost-effective. The strategy has five critical components, discussed in Chapter 2, which are essential to the success of TB control. Expanding DOTS programmes will account for two-thirds of the projected TB-control cost (\$6.2 billion) and nearly half of the \$3.5 billion resource gap.

The estimate of TB-control costs for DOTS expansion is built from national TB-control plans from the majority of the 22 TB high-burden countries (HBC).<sup>6</sup> Data from these plans was used to construct an economic model to estimate likely costs of TB-control expansion in 114 low- and lower-middle income countries (with annual per capita GDP less than \$3,000).<sup>7</sup> The model estimates specific costs for expanding TB-control programmes (training, anti-TB drugs, administrative costs, etc.) and also for the costs—in facilities, personnel, equipment, etc.—to general health-care systems that would be incurred in expanding TB control.

The World Health Organization has set TB-control goals for 2005. These goals are to detect 70 percent of all new infectious TB cases worldwide, and to successfully treat 85 percent of all cases detected. Expanding DOTS to meet these goals will require adding an additional 850,000 new cases per year to DOTS programmes, of which 350,000 will be infectious, sputum-smear positive (SS+) cases.<sup>8</sup> This increased volume will come in part from newly detected cases, and in part from diverting patients being treated in non-DOTS programmes into DOTS programmes. The expansion will be substantial, and is the major cost item in TB control. Table 3 shows the detail of this expansion, and Annex 1 provides a more complete discussion of these projections.

The *Working Group on DOTS Expansion* ensures that countries receive needed technical assistance for DOTS expansion; supports and coordinates this assistance throughout the world; monitors its progress; and advocates for resources to implement it. The Working Group has a

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<sup>6</sup> Countries defined as “high-burden” are those countries with the highest estimated number of new TB cases. The 22 high-burden countries account for some 80 percent of all new TB cases. The list of high-burden countries is provided in Annex 3.

<sup>7</sup> A list of the 114 low- and lower-middle income countries is provided in Annex 3.

<sup>8</sup> For comparison, in the Global Tuberculosis Control Report 2002, WHO estimates that an extra 330,000 SS+ cases will need to be treated each year if control targets are to be met. The fact that the two figures are very similar strengthens the validity of both estimates.

*Table 3: TB-Control Projections for 2001–2005 for the 22 HBC and for 114 Other Low- and Lower-Middle Income Countries (cases in millions)*

	Current Level of TB Control		Stop TB Goals	
	All Cases	SS+ Cases	All Cases	SS+ Cases
<b>Number of New Cases (Incidence)</b>	42.9	18.9	42.9	18.9
<b>Cases Detected and Treated</b>	19.1	7.7	26.0	11.3
– Cases Treated under DOTS	8.7	4.7	21.5	10.0
– Cases Treated, non-DOTS	10.4	3.0	4.5	1.3

five-year budget of \$225 million. This amount captures the cost of significant technical assistance and capacity building that will be required to rapidly expand DOTS programmes in high-burden countries. Chapter 7 summarizes the Working Group’s plans and presents a summary of its five-year budget. Annex 2 describes how this budget will be allocated year-by-year.

## **ADAPTING AND IMPROVING DOTS**

**TB-HIV.** The overlapping epidemics of TB and HIV/AIDS are the subject of Chapter 3. The GPSTB projects country needs of roughly \$630 million over the five-year period for counselling, identifying TB-HIV co-infected people, and for therapy to prevent the onset of active TB in these patients. This projection is likely to be revised because Stop TB Partners and their colleagues in HIV/AIDS-control programmes are still working to plan and implement the most effective approaches to TB-HIV co-infection. Furthermore, epidemiological estimates of TB-HIV co-infection are more uncertain than estimates of TB burdens. The cost estimates, which are quite preliminary, are based on early results from a number of promising pilot projects in several sub-Saharan countries.

Plans envision voluntary counselling and HIV testing for large numbers of people in high HIV-prevalence areas, TB testing for HIV-positive patients and providing a six-month isoniazid (INH) prophylactic treatment (IPT) to prevent the onset of active TB in co-infected patients. Included with the costs for this intervention are projected costs for anticipated secondary effects of the treatment, which can be expected in a fraction of the patient population. The plan assumes that some 28 million people will be tested for HIV, that 3.3 million of these people will be HIV-positive patients and will be then tested for TB, and that roughly 1.6 million co-infected patients will be treated with INH. Details are provided in Chapter 3 and in Annex 1. It is important to note that there will be other important costs, such as those for treating opportunistic infections in HIV-positive TB patients, which cannot yet be estimated but will have to be considered at a later date.

The *Working Group on TB-HIV* provides a forum for the coordination of activities aimed at promoting interventions to decrease the dual burden of TB and HIV. Under the overall umbrella of the Working Group, Stop TB Partners take the lead in developing and disseminating policies, developing innovative approaches, scaling up proven, cost-effective interventions, and developing, producing, and disseminating training materials and a manual for clinical care. The Working Group has a five-year budget of \$12.3 million. Chapter 7 summarizes the Working Group’s plans. Annex 2 provides the Working Group’s budget.

**MDR-TB.** Chapter 4 is devoted to the growing threat of multidrug-resistant TB (MDR-TB). Country needs for treating MDR-TB have been estimated at \$1,070 million over the five-year period. This cost was projected using a high-end estimate (4.6 percent) of the proportion of all TB cases that are MDR. The plan projects that half a million of these cases will be treated under DOTS-Plus programmes, in part through diversion into DOTS-Plus programmes of patients who would otherwise be inappropriately treated.

*Table 4: MDR-TB-Control Projections for 2001–2005 in Low- and Lower-Middle Income Countries (cases in millions)*

	Current Level of TB Control	Stop TB Goals
<b>Number of New Cases (Incidence)</b>	1.9	1.9
<b>Cases Detected and Treated</b>	0.9	1.2
– Covered by DOTS-Plus	0.0 <sup>9</sup>	0.5
– Not Appropriately Treated	0.9	0.7

The cost estimates for treating these patients and for scaling up DOTS-Plus programmes have been derived from very limited data, mostly from Peru. While drug costs have been greatly reduced, they are still high in comparison to first-line TB drugs, and account for 60 percent of the aggregate cost estimate. Further decreases in drug prices would reduce the aggregate estimate significantly but, in any event, these estimates will need to be revised as further data emerges on the cost of large-scale initiatives to treat patients with MDR-TB.

The *Working Group on MDR-TB* was established in 1999. Its aims are to approve, conduct, and oversee pilot projects to treat MDR-TB. The Working Group has a scientific panel, which has prepared guidelines for pilot projects designed to treat MDR-TB. In addition, the Working Group has established the Green Light Committee (GLC), which strives to improve access to second-line anti-TB drugs for DOTS-Plus pilot projects. The group approves, conducts, and oversees pilot projects based on scientific guidelines prepared by the scientific committee. The Working Group has a five-year budget of \$16 million. Chapter 7 summarizes the Working Group’s plans. Annex 2 provides the Working Group’s budget.

## RESEARCH AND DEVELOPMENT

Research and development costs are projected in this plan at nearly \$1.1 billion for new diagnostic tools (\$177 million); new TB drugs (\$347 million); a new TB vaccine (\$424 million); and for health policy, systems, and services research (\$150 million).

The objectives of **TB diagnostics** research are improving the detection of infectious TB, latent TB, and drug resistance. A rough estimate of the investment required to develop significantly improved diagnostic tests for TB comes to \$150 million for the 2001–2005 period. The objectives and strategies of diagnostic research are described in Chapter 5, and the activities of the *Working Group on TB Diagnostics* are described in Chapter 7. The Working Group has set a budget of \$27 million, which is provided in Annex 2.

<sup>9</sup> There are now roughly 7,000 patients worldwide being treated for MDR-TB under approved DOTS-Plus programmes.

The objectives of new **TB drug development** research are the development of drugs to shorten and/or simplify TB treatment, more effectively treat MDR-TB, and treat latent infection. The *Global Alliance for TB Drug Development* has set a goal of having at least one new TB drug registered by 2010, and available in high-burden settings two years later. The costs of developing one or more new drugs by 2010, including the cost of failures, are estimated to be up to \$240 million. The cost estimate in this GPSTB (\$317 million) represents a projected five-year research cost for developing one or more new drugs for TB treatment, of a different class than those currently known, by 2010, plus a \$30 million cost estimate for the Working Group on Drug Development. The objectives of TB drug development are described in more detail in Chapter 5. The activities of the Working Group are provided in Chapter 7 and its budget is provided in Annex 2.

The objective of the **TB vaccine** effort is to have a safe, effective, and reasonably priced TB vaccine licensed for global distribution by 2015, and to have it widely used in high-burden countries five years later. Chapter 5 describes the considerable challenges of developing a TB vaccine and explains that it is unlikely to be achieved for less than \$1 billion. Costs are likely to be \$700 million over ten years for developing better animal models, expanding testing facilities, increasing knowledge of pathogenesis, and developing correlates of protection. Clinical trials through 2005 are likely to require \$10 million per year. The \$420 million estimate in this plan for vaccine research represents an amount that could be invested in the first five years of this effort. It is unavoidably imprecise, but is roughly half the ten-year projection of known costs, adjusted for some likely front-loading of investment. The *Working Group on TB Vaccine Development* began its work in 2001. It has set a budget of \$4.5 million. A summary of the Working Group's activities is included in Chapter 7 and year-by-year budget estimates are provided in Annex 2.

While we await the discovery of new TB diagnostics, drugs, and vaccines, research into **health policy, systems, and service** delivery promises significant gains in TB control—in far less time and at far lower cost. There are a range of challenges in adopting and adapting DOTS to the economic, institutional, social, and epidemiological profiles of diverse countries, and in moving beyond DOTS to cope with the challenges of HIV and/or MDR-TB in particular countries. Low-cost research has historically made an important difference in the success of disease control. Chapter 5 discusses the objectives and the rationale for this research and provides examples of what this research has already achieved. The plan projects that it would cost \$110 million over five years for national TB programmes in each of the high-burden countries to establish these research initiatives, and an additional \$100 million to establish parallel programmes in other countries with a high incidence of TB. Of this \$210 million that would be spent in TB-burdened countries, \$180 million has been budgeted as a cost of DOTS expansion. The remaining \$30 million is a component of the \$150 million of health policy systems research expense in this plan. The balance of the health policy systems research cost (\$120 million) is the projected investment in international technical assistance to countries that will be required to scale up operational research.

## **PARTNERSHIP ACTIVITIES**

The **Stop TB Secretariat** coordinates and supports the work of the more than 200 Stop TB Partners under the guidance of a Stop TB Coordinating Board. The Secretariat builds the Partnership, communicates with partners, tracks the progress of TB control and of other

partnership goals, manages the Global TB Drug Facility, and is responsible for coordinating advocacy and resource mobilization. The Secretariat has a five-year budget of \$27.5 million, excluding Global Drug Facility costs that are included as part of DOTS expansion.

Chapter 8 describes the Secretariat's four important objectives in carrying out the *Global Plan to Stop TB*—Partnership Building, Information and Communication, Advocacy, and Resource Mobilization. The *Global Plan to Stop TB* envisions a tremendous expansion of TB-control activity, advocacy, and resource mobilisation, without which the plan goals cannot be achieved. The Stop TB Secretariat has organised task forces to plan the Partnership's supplemental work in each of these areas in the coming years, and summaries of those draft plans are provided in Chapter 8. However, these plans are still being reviewed and have not yet been approved by the Stop TB Coordinating Board. Rough estimates by the task forces of likely supplemental costs totalling \$48 million have been built into this plan for advocacy (\$20 million), resource development (\$13 million), and monitoring (\$15 million). Because these plans and budgets have not yet been finalized or approved, no details on these estimates have been provided.

## 5. WHAT WILL BE ACCOMPLISHED?

This plan lays out what must be done over the 2001–2005 period if we are to control TB and eventually eliminate it as a public health problem. It describes the strategies and the mechanisms to achieve our goals and what these accomplishments will cost.

What will have been accomplished if we meet the goals of this plan?

- The 22 high-burden countries that account for 80 percent of the world's TB burden will have rapidly expanded DOTS and met control targets—detecting 70 percent of people with infectious TB, and successfully treating 85 percent of those detected.
- Some 3.4 million deaths from TB will be averted, and millions more people will be cured of their tuberculosis—through detection and treatment in newly expanded DOTS programmes. If DOTS programmes are not expanded, these patients will not be treated for their disease. They will suffer and die, and will infect numerous close contacts and family members.
- Some 12.8 million additional people will have been treated for TB at a projected cost of just over \$238 per person, and 3.5 million lives saved for about \$485 each.
- We will have defined, adopted, and implemented effective strategies to address HIV-related TB.
- We will have incorporated DOTS-Plus protocols for MDR-TB into the DOTS strategy.
- We will have an improved TB diagnostic test for use in high-burden countries.
- Five new anti-TB drug candidates will have completed pre-clinical trials.
- There will be at least one TB-vaccine candidate in clinical trials to test efficacy.

These are enormous accomplishments, planned to counter an enormous threat to the health, well-being, and development of communities throughout the world. We can control TB. With this Global Plan, Stop TB Partners around the world are on the way to doing so. But we need your help. Come join us in delivering this “splendid gift” to the generations of the Third Millennium.