

## ANNEX 1

### Explanation of the GPSTB Cost Projections and TB Control Analysis

The *Global Plan to Stop TB* (GPSTB) estimates that TB-control activities over the next five years will cost \$9.1 billion, covering all major TB-control activities:

- Expanding DOTS (\$6.2 billion) in all TB high-burden countries and in all other low- and lower middle-income countries<sup>1</sup> (that is, countries with a GNP per capita of \$3,000 per year or less<sup>2</sup>).
- Adapting and improving DOTS (\$1.7 billion) to cope with TB-HIV co-infection and with multidrug-resistant TB.
- Research for new TB diagnostic tools, drugs, vaccines, and operational improvements (\$1.1 billion).
- Partnership initiatives (\$75 million)—including advocacy, communications, coordination, and resource development.

Expanding, adapting, and improving DOTS accounts for 87 percent of the GPSTB costs. This annex explains in brief how cost estimates for these components of the plan were analysed and evaluated. Complete detail of the methodology for cost estimates and the epidemiological projections is being published separately as *The Economic Annex to the Global Plan to Stop TB*.

The financial gap between five-year TB-control costs and the available resources is estimated at \$3.8 billion, roughly 41 percent of total plan costs. The largest component of this gap is associated with DOTS expansion (\$1.6 billion), and is estimated from national TB programme plans that are the basis for WHO's Global DOTS Expansion Plan (GDEP). The GDEP was first published in May 2001, and has been recently revised based on revisions to national TB-control plans (for example, in Indonesia, Pakistan, China, and India). Among these revisions are improved estimates of the general health-system capacity of high-burden countries to support DOTS expansion. The estimated financial gap in this GPSTB is consistent with these new GDEP estimates. The estimated financial gap between needed and available resources for DOTS expansion in other low- and lower-middle income countries is based on an extrapolation from what is known about the capacity in high-burden countries.

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<sup>1</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.

<sup>2</sup> Appaix, Olivier. Tuberculosis Control: Financial Evaluation for the 2001-2005 Period (in Low- and Lower Middle-Income Countries). Economic Annex to the Global Plan to Stop TB Boston: Partners In Health, to be published in 2002.

The estimated financial gap for TB-HIV prophylactic strategies (\$604 million) is projected based on current investment in TB-HIV pilot projects by donors and host governments, but not on any detailed national plans or budgets. Likewise, the gap projected for MDR-TB treatment (\$834 million) is based on assumptions of likely national support for successful and cost-effective DOTS-Plus programmes. The projected gap for research and development efforts (\$708 million) is based on known research and development commitments in 2001, and assuming that those commitments remain in place over five years. The estimated financial shortfall for the Stop TB Partnership (\$65 million) is projected for five years, net of current partnership support, which is assumed to remain constant for the five-year period.

## DOTS EXPANSION

**Modelling DOTS Expansion in 114 Countries:** To accurately capture the costs of TB control in high-burden and low- and lower-middle income countries, the authors of this study constructed a model that projects TB-control costs on a country-by-country basis over the 2001–2005 period. The model builds unit costs for specific TB-control elements in each country, deriving cost from national TB-control programmes plans for 13 high-burden countries, and from health-care cost studies and data from 17 additional low- and middle-income countries. This information was supplemented with questionnaires and personal communications with national programme coordinators from most of the 22 high-burden countries, and with WHO officials around the world. Where specific cost information was lacking, cost estimates for TB-control inputs in specific countries were derived by extrapolating from known costs in neighbouring countries, and/or from countries with analogous socio-economic and epidemiological profiles. Cost projections do not include any inflation adjustments. Costs are calculated in 2000 U.S. dollar equivalents.

*Table 1: Cost Projections for DOTS Expansion<sup>3</sup> (in \$ millions)*

<b>5-Year Costs</b>	
In the 22 high-burden countries	
• TB Programmes	1,560
• General Health Services	3,000
Other low- and middle-income countries	
• TB Programmes	590
• General Health Services	850
DOTS Expansion Working Group	225
<b>Total</b>	<b>6,225</b>

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

The GPSTB estimates costs for all TB-control activities in the 114 countries it covers, including the following:

- All activities of national TB programmes—Training, operational research, diagnostic capacity (such as laboratories and equipment), public education awareness initiatives, and a reliable supply of quality drugs, including drugs supplied through the Global TB Drug Facility.
- Expenses for expanding existing DOTS programmes and establishing new programmes—providing capacity adequate to detect and treat the numbers of patients anticipated by the TB-control goals for 2005 and by WHO epidemiological projections.
- Costs for clinical management of routine TB as it is practiced in each country, including costs for the use of hospitals, clinics, dispensaries, and sanatoriums, regardless of whether they are under the control of the national TB-control programme.
- Administrative expense for the management and supervision of increasingly large and complex programmes.

DOTS expansion costs were estimated on a cash basis: how much will the country spend throughout the 2001–2005 period if it expands DOTS as required to meet the targets? The projections include, therefore, the full capital costs of new laboratories, for example, instead of amortizing depreciation costs over the useful life of these facilities.

Estimating the costs to general health-care systems of treating the expanded caseload is fraught with difficulty, not the least of which is uncertainty about the capacity constraints of existing systems. Being unable to predict whether or by how much general health services will have to expand facilities to treat increased numbers of TB patients, the model generated a range of possible costs. The low end of this cost range (\$3.2 billion) assumed that, with the efficiencies introduced by expanding DOTS, there will be adequate capacity in health service facilities to handle increased patient populations. The high end of this range (\$4.5 billion) assumed that facilities are now at capacity, and that increasing caseloads will require increased capacity. The cost of new capacity was then estimated by assuming that the incremental cost of expansion would be equal to the current average cost (per patient or unit of service) of existing facilities, times the increased number of patients in expanded programmes. In this case therefore, the cost projections include depreciation, and thereby approximate the capital costs of new facilities and equipment.

Within this range—\$3.2 to \$4.5 billion—we chose a midpoint of \$3.85 billion as the estimated cost to general health-care systems of expanded TB control (\$3.0 billion in high-burden countries and \$850 million in other low- and lower middle-income countries). This represents over half the estimated cost of DOTS expansion. It is necessarily a tentative estimate, and will have to be carefully reconsidered as we learn more about health services capacity in individual countries and as DOTS expansion progresses.

The GPSTB cost projections substantially confirm parallel cost estimates made in the World Health Organization's *Global DOTS Expansion Plan* (GDEP), published last year (May, 2001), despite having used a slightly different methodology, and are consistent with updated GDEP cost estimates that will be published in 2002.

There are important limitations in our ability to project TB-control costs:

- Epidemiological uncertainty due to rapid change in factors affecting incidence of TB, MDR-TB, or TB-HIV co-infection. Estimates will change as we improve our ability to predict disease trends, when incidence falls as a result of TB-control investment, or with unexpectedly rapid progression of TB.
- Uncertainty of cost data. The quality of health-care cost information provided by countries varies considerably, and these costs are moving targets as countries reorganize health-care delivery and reallocate resources. Likewise, estimating the share of a nation's general health-care system devoted to TB control requires gross assumptions that provide indicative, but not fully accurate, cost estimates. This is due in part to evolving protocols and practices.

There are reasons to be cautious in estimating TB incidence, as the *WHO Global TB Control Report 2001* points out: “For high-burden countries, the difference between the lower and upper estimates of (TB) incidence is typically twofold.”<sup>4</sup> The GPSTB used the WHO's epidemiological data for 1999 (the most recent available in September 2001). Assuming stable incidence rates, it projected the number of TB cases needed to be detected and treated in each country over the five-year period to achieve the WHO goals for detection of new cases (70 percent) and for successful treatment (85 percent). In 1999, there were an estimated 8.4 million new cases of TB, of which roughly 44 percent were infectious or sputum-smear positive (SS+). Assuming level progress towards the targets, the GPSTB estimates that there will be nearly 43 million new TB cases in the 114 countries covered over the 2000–2005 period, and that 44 percent of cases will be infectious, as shown in Table 2.

*Table 2: TB-Control Projections for 2001–2005 in 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
• Covered by DOTS	8.7	4.7	21.5	10.0
• Covered by other protocols	10.4	3.0	4.5	1.3

As this table shows, the plan projects that TB cases detected and treated under DOTS will more than double, if proposed GPSTB investments are made. DOTS programmes will recruit 850,000 additional TB cases each year, of which at least 350,000 will be infectious

<sup>4</sup> World Health Organization. *Global TB Control: WHO Report 2001*. Geneva: World Health Organization, 2001, p.32.

(SS+ cases)<sup>5</sup>— that is, 5.3 million additional smear positive cases over five years. The projected growth in DOTS programme patients will be a function of two factors, reflecting the WHO goals—an increase in TB case detection (+ 6.9 million cases) and in increased DOTS treatment of TB patients whose cases are now being treated under non-DOTS protocols (+ 5.9 million cases).

DOTS is the recommended and generally accepted strategy for TB control throughout the world, but in many countries it is not the exclusive mechanism. Currently, only 46 percent of patients treated for TB worldwide are cared for under DOTS programmes. The remaining patients are treated by other means—often less efficiently and effectively—in national TB programmes, in private practices, or through general health services. In India, for example, only 6 percent of estimated smear-positive TB cases were notified and treated under DOTS (1999), but the DOTS treatment success rate in India is high (84 percent) and the country is expanding its DOTS coverage rapidly. In Russia, to take a second example, TB case notification rates are quite high, but less than 2 percent of smear-positive cases were notified and treated under DOTS in 1999.

The goal of the GPSTB is for all countries to achieve DOTS coverage of 100 percent of their population by 2005, and that 70 percent at least of all new TB cases will be detected and managed by DOTS programmes. The plan projects that DOTS case detection and treatment in each country will increase on a straight-line basis from current DOTS detection and treatment rates to the 2005 target rates, except in countries where credible projections show that targets will be met earlier. But, as noted, this study does not attempt to predict how quickly or to what extent the existing cost structure for TB control in specific countries will change with the increasing use of DOTS.

If DOTS programmes expand as projected and successfully treat 85 percent of patients, they could save some 3.4 million patients who will otherwise die of TB. As noted above, of the additional patients treated in expanded DOTS programmes, 6.9 million will be the result of increased case detection capability. Roughly 3.6 million of these patients will be SS+, and absent treatment, 65 percent of these patients will likely die, as will roughly 40 percent of the remaining, non-infectious TB patients. These figures alone, adjusted for mortality rates of SS+ patients within DOTS programmes (4 percent), yield a conservative estimate of 3.4 million lives that could be saved through DOTS expansion.

DOTS expansion in the 22 high-burden countries is projected to cost \$6.2 billion over five years, an increase of \$1.66 billion over what is now being spent for TB control. If these cost projections prove accurate, the incremental cost of detecting an additional 6.9 million cases and of treating these patients would thus be \$240/patient, and the incremental cost per life saved would be \$485. Assuming 24 years of life per death averted produces a cost for DOTS expansion of over \$20 per year of life gained, on average.

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<sup>5</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 2 figures are very similar strengthens the validity of both estimates.”

## ADAPTING AND IMPROVING DOTS

Cost estimates for adapting and improving DOTS to cope with multidrug-resistant TB (MDR-TB) and with TB-HIV co-infection are preliminary. Strategies to deal with these health threats are still evolving. Furthermore, epidemiological data on these enormous challenges is more uncertain than that available for routine tuberculosis.

*Table 3: Cost Projections for Adapting and Improving DOTS (in \$ millions)*

	<b>5-Year Cost</b>
<b>TB-HIV Country Needs</b>	<b>630</b>
• Voluntary Counselling and HIV Testing	290
• TB Testing, Screening, and Programme Costs	330
• Drug Cost—INH Preventive Therapy	10
<b>MDR-TB Country Needs</b>	<b>1,070</b>
• Drugs	650
• Other Costs	420
<b>Total</b>	<b>1,700</b>

**TB-HIV Co-infection** TB-HIV co-infection is a terrible and complex problem confronting patients and health workers around the world. There still are too few programmes confronting the deadly synergy of these two diseases, and reliable data on those that are being implemented is still scarce. As a result, predicting the cost of widespread intervention is extremely difficult. Yet a Global Plan to Stop TB could not possibly pass over this central problem of TB control.

The GPSTB begins to estimate the costs of responding—shown above in Table 3— by drawing on preliminary cost information and promising results from ProTEST projects in sub-Saharan Africa and from other preliminary studies. Costs have been projected for voluntary counselling and testing (VCT) of roughly 28 million people in twelve sub-Saharan countries. The twelve countries are four that have established ProTEST projects (Malawi, Uganda, South Africa, and Zambia), four in which ProTEST projects are being established (Mozambique, Ethiopia, Kenya, and Tanzania) and four others (Rwanda, Congo DR, Cote D’Ivoire, and Senegal). An estimated 3.3 million of these patients (12%) are projected to be HIV-positive, and then half of these are projected to be co-infected with TB. These co-infected patients are assumed to receive INH preventive therapy to prevent the onset of active TB.

There are considerable limitations in these estimates. ProTEST provides an excellent model for how TB-HIV co-infection will have to be addressed, but reliable cost data from the projects is not yet available. There are also uncertainties regarding the extent of co-infection, the willingness of patients to volunteer for testing and the extent of the synergy between these two diseases. In addition, treating TB-HIV co-infection will likely require a larger set of

interventions. Cotrimoxazole, for example, is now being used by a number of African countries to prevent bacterial and parasitological complications of HIV. It will likely be used more extensively in the future, as further evidence on its effectiveness is assembled. As a result, the summary table at the end of Chapter 3 notes other likely components of TB-HIV control, even though they have no cost associated with them, in order to highlight their importance and the need for more complete cost information.

**MDR-TB:** Two scenarios were used in estimating the proportion of all TB cases that are multidrug resistant—one providing an MDR-TB rate of 3.2 percent and the second a rate of 4.6 percent. This study assumed the worse incidence, which would result in 1.9 million cases of MDR-TB. The GPSTB urges the rapid expansion of capacity to treat MDR-TB, yet it is very difficult to predict how rapid this DOTS-Plus expansion will be. Hence, we have made a necessarily tentative assumption that 40 percent of all MDR-TB cases detected will be appropriately treated over the next five years (494,000 of the 1.2 million estimated cases detected). This assumption will need to be reviewed in light of the progress of countries in initiating DOTS-Plus programmes.

*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>	<b>1.9</b>	<b>1.9</b>
<b>Cases Detected and Treated</b>	<b>0.9</b>	<b>1.2</b>
• Covered by DOTS-Plus	0.06	0.5
• Not Appropriately Treated	0.9	0.7

Cost estimates for MDR-TB treatment must be derived from very limited data. We have relied mostly on data from programmes in Peru, and have extrapolated those known costs to all other countries with likely MDR-TB problems. As further data is available from Peru and elsewhere, these estimates of treatment costs will need to be revised.

Expensive second-line drugs account for roughly 60 percent of the projected five-year cost estimate of \$1.1 billion. The projected per patient cost for drugs is \$1,317, on average, at current levels for standardized regimens. Other DOTS-Plus costs consist of programme costs of \$170 million (\$344/patient) and general health service system costs of \$250 million (\$507/patient), reflecting likely difficulties of initiating and scaling up DOTS-Plus programmes. These projections will be revised as further data becomes available.

<sup>6</sup> There are now roughly 7,000 patients worldwide being treated for MDR-TB under approved DOTS-Plus programmes.

## Annex 2 Stop TB Working Group Plans and Budgets

Stop TB Working Groups	Lead Agency	Working Group Chair
DOTS Expansion	WHO	Dr. Mario Raviglione (WHO) raviglionem@who.ch
TB-HIV	WHO	Dr. Gijss Elzinga (RIVM) gijss.elzinga@rivm.nl
DOTS-Plus for MDR-TB	WHO	Dr. Jim Yong Kim (Partners in Health) jimkimp@pih.org
TB Diagnostics	TDR	Dr. Carlos Morel (TDR) morelc@who.int
TB Drug Development	Global Alliance for TB Drug Development	Dr. Maria Freire (Global Alliance) maria.freire@tballiance.org
TB Vaccine Development	WHO/TDR	Dr. Ann Ginsberg (NIAID/DMID) AGINSBERG@niaid.nih.gov

## Working Group on DOTS Expansion

**Lead Agency:** *World Health Organization*  
**Chair:** *Dr. Mario Raviglione, Coordinator, WHO STB/TBS*

### Summary 5-Year Work Plan

Objectives	Targets	Activities	Budget (\$)
<p><b>Objective 1:</b> Ensure that countries are provided with technical and strategic assistance for comprehensive DOTS expansion</p>	<ul style="list-style-type: none"> <li>Medium-term: To achieve year 2005 global TB-control targets (70% case detection rate and 85% cure rate)</li> <li>Short-term: By end 2001, at least all high-TB-burden countries will have developed medium term DOTS expansion plans</li> </ul>	<ul style="list-style-type: none"> <li>Further develop and refine interim targets, one year and five year plans</li> <li>Address key challenges to TB-control effectiveness in specific countries through technical assistance, coordination, capacity building, and human resource development</li> <li>Promote and monitor community involvement in TB control by providing guidelines and training material for such programmes</li> <li>Promote and disseminate examples of policies and experiences of engagement of private sectors and other sectors in TB control</li> </ul>	207,000,000
<p><b>Objective 2:</b> Support and coordinate national, regional, and global TB control</p>	<ul style="list-style-type: none"> <li>Establish regional advisory groups and inter-agency coordinating committees</li> <li>Impact of TB control on health sector and poverty</li> </ul>	<ul style="list-style-type: none"> <li>Monitor DOTS expansion progress at global, regional, and country level and define next steps to achieve the global targets by 2005.</li> <li>Monitor the effects of TB control in health sector development and poverty reduction by promoting development and use of outcome indicators.</li> </ul>	16,080,000
<p><b>Objective 3:</b> Monitor and report annually on DOTS expansion and on the progression of the disease</p>	<ul style="list-style-type: none"> <li>Annual updates on country places of action, country needs, and gaps</li> </ul>	<ul style="list-style-type: none"> <li>Organized annually - DOTS Expansion Working Group meeting.</li> </ul>	1,150,000
<p><b>Objective 4:</b> Advocate to increase commitment and financial resources</p>	<ul style="list-style-type: none"> <li>Significant increase in resources to support DOTS expansion</li> </ul>	<ul style="list-style-type: none"> <li>Advocacy campaign and social mobilization</li> </ul>	1,000,000
<b>TOTAL</b>			<b>225,230,000</b>

## Working Group on DOTS Expansion

### 2001 Annual Plan

Activities	Indicators	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Technical Assistance</b> <ul style="list-style-type: none"> <li>Capacity building and human resources development for DOTS implementation</li> <li>Direct NTP assistance, advisors, missions and tools</li> </ul>	<ul style="list-style-type: none"> <li>International training courses including training of consultants</li> <li>Training material, coordination of training</li> <li>In-service training</li> <li>Medium-term plans including budget</li> <li>DOTS coverage</li> </ul>	<b>39,000,000</b> 23,000,000  16,000,000	<b>16,000,000</b> 10,000,000  6,000,000	<b>23,000,000</b> 13,000,000  10,000,000
<b>Objective 2: Support and Coordination</b> <ul style="list-style-type: none"> <li>Regional strategic plans to cover endemic countries</li> <li>Regional Advisory Groups and Inter-agency Committee</li> <li>Updating plans, country needs and gaps for 22 HBC</li> <li>Updating of plans and budget for agencies (WHO/partners) supporting countries in DOTS expansion</li> </ul>	<ul style="list-style-type: none"> <li>Meeting held</li> <li>Plans updated</li> <li>Budget available for agencies</li> </ul>	<b>1,000,000</b> 100,000 600,000 200,000 100,000	<b>500,000</b> 100,000 300,000 50,000 50,000	<b>500,000</b> 0 300,000 150,000 50,000
<b>Objective 3: Monitoring and reporting</b> <ul style="list-style-type: none"> <li>DOTS Expansion WG meeting</li> <li>DOTS Expansion report No. 1</li> <li>DOTS Expansion report</li> </ul>	<ul style="list-style-type: none"> <li>Meeting held</li> <li>Global DOTS Expansion Plan published</li> <li>Global DOTS Expansion Plan published</li> </ul>	<b>230,000</b> 180,000 30,000 20,000	<b>200,000</b> 150,000 30,000 20,000	<b>30,000</b> 30,000 0 0
<b>Objective 4: Advocacy</b>		<b>200,000</b>	<b>100,000</b>	<b>100,000</b>
<b>TOTAL YEAR 2001</b>		<b>40,430,000</b>	<b>16,800,000</b>	<b>23,630,000</b>

## Working Group on DOTS Expansion

### 2002 Annual Plan

Activities	Indicators	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Technical Assistance</b> <ul style="list-style-type: none"> <li>Capacity building and human resources development for DOTS implementation</li> <li>Direct NTP assistance, advisors, missions and tools</li> </ul>	<ul style="list-style-type: none"> <li>International training courses including training of consultants</li> <li>Training material, coordination of training</li> <li>In-service training</li> <li>Medium-term plans including budget</li> <li>DOTS coverage</li> </ul>	42,000,000	21,500,000	20,500,000
	<ul style="list-style-type: none"> <li>Complete December 2002</li> <li>TAG &amp; ICC meetings</li> <li>GDEP report published</li> <li>Established in regional priority endemic countries</li> </ul>	24,000,000	12,000,000	12,000,000
	<ul style="list-style-type: none"> <li>Regional action plans for 50% of endemic countries</li> <li>Regional Advisory Groups and Inter-Agency Committees</li> <li>Update action plans, country needs/gaps, and budgets for agencies supporting countries in DOTS expansion</li> <li>National inter-agency committees</li> </ul>	18,000,000	9,500,000	8,500,000
	<ul style="list-style-type: none"> <li>Complete December 2002</li> <li>TAG &amp; ICC meetings</li> <li>GDEP report published</li> <li>Established in regional priority endemic countries</li> </ul>	3,770,000	1,370,000	2,400,000
	<ul style="list-style-type: none"> <li>Meeting held</li> <li>Report published</li> </ul>	1,000,000	500,000	500,000
	<ul style="list-style-type: none"> <li>Meeting held</li> <li>Report published</li> </ul>	600,000	300,000	300,000
<b>Objective 3: Monitoring and Reporting</b> <ul style="list-style-type: none"> <li>DOTS Expansion WG meeting in Canada</li> <li>DOTS Expansion report No. 3</li> </ul>	<ul style="list-style-type: none"> <li>Established in regional priority endemic countries</li> </ul>	2,000,000	500,000	1,500,000
	<ul style="list-style-type: none"> <li>Meeting held</li> <li>Report published</li> </ul>	230,000	130,000	100,000
<b>Objective 4: Advocacy</b>	<ul style="list-style-type: none"> <li>Meeting held</li> <li>Report published</li> </ul>	200,000	100,000	100,000
	<ul style="list-style-type: none"> <li>Report published</li> </ul>	30,000	30,000	0
<b>TOTAL YEAR 2002</b>		<b>46,200,000</b>	<b>23,000,000</b>	<b>23,200,000</b>

## Working Group on DOTS Expansion

### 2003 Annual Plan

Activities	Indicators	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Technical Assistance</b> <ul style="list-style-type: none"> <li>Capacity building and human resources development for DOTS implementation</li> <li>Direct NTP assistance, advisors, missions, and tools</li> </ul>	<ul style="list-style-type: none"> <li>International training courses including training of consultants</li> <li>Training material, coordination of training</li> <li>In-service training</li> <li>Medium-term plans including budget</li> <li>DOTS coverage</li> </ul>	<b>42,000,000</b> 24,000,000  18,000,000	<b>21,500,000</b> 12,000,000  9,500,000	<b>20,500,000</b> 12,000,000  8,500,000
<b>Objective 2: Support and Coordination</b> <ul style="list-style-type: none"> <li>Action plans <u>all</u> of endemic countries</li> <li>Regional Advisory Groups and Inter-Agency Committees</li> <li>Update action plans, country needs/gaps and budgets for agencies supporting countries in DOTS expansion</li> <li>National inter-agency committees</li> </ul>	<ul style="list-style-type: none"> <li>Complete by December 2003</li> <li>TAG &amp; ICC meetings</li> <li>GDEP report # 3</li> <li>Established all countries</li> </ul>	<b>3,770,000</b> 1,000,000 600,000  170,000  2,000,000	<b>1,370,000</b> 500,000 300,000  70,000  500,000	<b>2,400,000</b> 500,000 300,000  100,000  1,500,000
<b>Objective 3: Monitoring and Reporting</b> <ul style="list-style-type: none"> <li>DOTS Expansion WG meeting in late 2003</li> <li>DOTS Expansion report No. 4</li> </ul>	<ul style="list-style-type: none"> <li>Meeting held</li> <li>Report published</li> </ul>	<b>230,000</b> 200,000  30,000	<b>130,000</b> 100,000  30,000	<b>100,000</b> 100,000  0
<b>Objective 4: Advocacy</b>		<b>200,000</b>	<b>0</b>	<b>200,000</b>
<b>TOTAL YEAR 2003</b>		<b>46,200,000</b>	<b>23,000,000</b>	<b>23,200,000</b>

## Working Group on DOTS Expansion

### 2004 Annual Plan

Activities	Indicators	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Technical Assistance</b> <ul style="list-style-type: none"> <li>Capacity building and human resources development for DOTS implementation</li> <li>Direct NTP assistance, advisors, missions, and tools</li> </ul>	<ul style="list-style-type: none"> <li>International training courses including training of consultants</li> <li>Training material, coordination of training</li> <li>In service training</li> <li>Medium-term plans including budget</li> <li>DOTS coverage</li> </ul>	<b>42,000,000</b> 24,000,000  18,000,000	<b>21,500,000</b> 12,000,000  9,500,000	<b>20,500,000</b> 12,000,000  8,500,000
<b>Objective 2: Support and Coordination</b> <ul style="list-style-type: none"> <li>WG missions for evaluation of progress (2000-2003) in all endemic countries</li> <li>Regional evaluations, Advisory Groups and Inter-Agency Committees</li> <li>Update country needs/gaps and budgets for agencies supporting countries in DOTS expansion</li> <li>National inter-agency committees</li> </ul>	<ul style="list-style-type: none"> <li>Evaluation report (see below)</li> <li>Reports of visits</li> <li>AG &amp; ICC meetings</li> <li>GDEP report updated</li> <li>National ICC meetings report TB control evaluation</li> </ul>	<b>3,770,000</b> 1,000,000 600,000 170,000 2,000,000	<b>1,370,000</b> 500,000 300,000 70,000 500,000	<b>2,400,000</b> 500,000 300,000 100,000 1,500,000
<b>Objective 3: Monitoring and Reporting</b> <ul style="list-style-type: none"> <li>DOTS Expansion WG meeting in late 2004</li> <li>DOTS Expansion report No. 5</li> </ul>	<ul style="list-style-type: none"> <li>Meeting held</li> <li>Report published</li> </ul>	<b>230,000</b> 200,000 30,000	<b>130,000</b> 100,000 30,000	<b>100,000</b> 100,000 0
<b>Objective 4: Advocacy</b>		<b>200,000</b>	<b>0</b>	<b>200,000</b>
<b>TOTAL YEAR 2004</b>		<b>46,200,000</b>	<b>23,000,000</b>	<b>23,200,000</b>

## Working Group on DOTS Expansion

### 2005 Annual Plan

Activities	Indicators	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Technical Assistance</b> <ul style="list-style-type: none"> <li>Capacity building and human resources development for DOTS implementation</li> <li>Direct NTP assistance, advisors, missions, and tools</li> </ul>	<ul style="list-style-type: none"> <li>International training courses including training of consultants</li> <li>Training material, coordination of training</li> <li>In-service training</li> <li>Medium-term plans including budget</li> <li>DOTS coverage</li> </ul>	<b>42,000,000</b> 24,000,000  18,000,000	<b>21,500,000</b> 12,000,000  9,500,000	<b>20,500,000</b> 12,000,000  8,500,000
<b>Objective 2: Support and Coordination</b> <ul style="list-style-type: none"> <li>Review of action plans for sustainability in <u>all</u> endemic countries</li> <li>Regional Advisory Groups and Inter-Agency Committees</li> <li>Update country needs/gaps and budgets for supporting agencies</li> <li>National inter-agency committees</li> </ul>	<ul style="list-style-type: none"> <li>Plans by December 2005</li> <li>AG &amp; ICC meetings</li> <li>GDEP report updated</li> <li>National ICC established in all countries</li> </ul>	<b>3,770,000</b> 1,000,000 600,000 170,000 2,000,000	<b>1,370,000</b> 500,000 300,000 70,000 500,000	<b>2,400,000</b> 500,000 300,000 100,000 1,500,000
<b>Objective 3: Monitoring and Reporting</b> <ul style="list-style-type: none"> <li>DOTS Expansion WG meeting in late 2005</li> <li>DOTS Expansion report No. 6</li> </ul>	<ul style="list-style-type: none"> <li>Meeting held</li> <li>Report published</li> </ul>	<b>230,000</b> 200,000 30,000	<b>130,000</b> 100,000 30,000	<b>100,000</b> 100,000 0
<b>Objective 4: Advocacy</b>		<b>200,000</b>	<b>0</b>	<b>200,000</b>
<b>TOTAL YEAR 2005</b>		<b>46,200,000</b>	<b>23,000,000</b>	<b>23,200,000</b>

## Working Group on TB-HIV

**Lead Agency:** *World Health Organization*  
**Chair:** *Dr. Gijs Elzinga, The Netherlands*

### Summary 5-Year Work Plan

Objectives	Targets	Activities	Budget (\$)
<b>Objective 1:</b> Develop effective new strategies to combat TB in HIV-infected people	<ul style="list-style-type: none"> <li>New technical framework to guide country strategies, endorsed by WHO &amp; UNAIDS by end 2001</li> <li>Disseminate guidelines on phased implementation of TB &amp; HIV programme collaborations (mid-2002)</li> </ul>	<ul style="list-style-type: none"> <li>Develop framework</li> <li>Model impact of interventions</li> <li>Develop prioritised essential package</li> <li>Develop and disseminate guidelines</li> </ul>	<b>965,000</b>
<b>Objective 2:</b> Promote implementation and scale-up of control programmes responding to the deadly synergy of these diseases	<ul style="list-style-type: none"> <li>Initiate implementation of collaborative activities in 8 sub-Saharan sites (PIA-TB/HIV*), and expand to other high-burden countries by end 2004</li> </ul>	<ul style="list-style-type: none"> <li>Establish pilot projects and coordinate project network</li> </ul>	<b>10,520,000</b>
<b>Objective 3:</b> Promote global partnership for collaboration between TB- and HIV-control programmes	<ul style="list-style-type: none"> <li>Promote national and regional strategies for control of TB in high HIV-prevalence settings linked with DOTS expansion (end 2003)</li> <li>National strategies adapted and scaled up in most high HIV-prevalence countries (end 2005)</li> </ul>	<ul style="list-style-type: none"> <li>Promote international and national partnerships to maximize synergies in health service treatment of co-infected people</li> </ul>	<b>645,000</b>
<b>Objective 4:</b> Advocate for increased resources	<ul style="list-style-type: none"> <li>Raise \$10.25 million by end 2005</li> </ul>	<ul style="list-style-type: none"> <li>Target advocacy and fundraising</li> </ul>	<b>220,000</b>
<b>TOTAL</b>			<b>12,350,000</b>

*\* The phased implementation of TB/HIV activities (PIA-TB/HIV) is the name for the planned collaborative activities to control TB (and HIV) in high-burden countries. It is the successor to the WHO-coordinated ProTEST projects, which are ongoing and which have provided much of the experience on which PIA-TB/HIV is based.*

## Working Group on TB-HIV

### 2001 Annual Plan

Activities	Indicators	Budget (\$)	Funding (\$)	Resource Gap (\$)
<p><b>Objective 1: Develop and Adapt TB/HIV Strategy</b></p> <ul style="list-style-type: none"> <li>• Development of strategic framework for TB/HIV</li> <li>• Commence modelling impact of interventions to inform development of prioritised essential package</li> <li>• Produce revised TB/HIV estimates</li> </ul>	<ul style="list-style-type: none"> <li>• Draft finalised, 2001</li> <li>• First draft, 2001</li> <li>• Complete paper, 2001</li> </ul>	<b>125,000</b>	<b>125,000</b>	<b>0</b>
<p><b>Objective 2: Promote Implementation</b></p> <ul style="list-style-type: none"> <li>• Develop ProTEST project evaluation framework</li> <li>• Plan implementation of post-ProTEST activities (PIA-TB/HIV)</li> <li>• First draft of technical guidelines for establishment of PIA-TB/HIV projects (including a generic protocol)</li> <li>• Coordinate network of ProTEST pilot projects</li> <li>• Monitor existing projects in Africa</li> <li>• Plan development of training tools and education materials</li> </ul>	<ul style="list-style-type: none"> <li>• Completed 2001</li> <li>• First workshop, Feb. 2002</li> <li>• Concluded 2001</li> <li>• Regional plan ready</li> <li>• Regional plan ready End 2001</li> </ul>	<b>730,000</b>	<b>730,000</b>	<b>0</b>
<p><b>Objective 3: Form Global Partnership</b></p> <ul style="list-style-type: none"> <li>• Hold 1st annual meeting of Global TB/HIV Working Group</li> <li>• Appoint Working Group Coordinator</li> </ul>	<ul style="list-style-type: none"> <li>• Met April 2001</li> <li>• WG Coordinator appointed Oct 2001</li> </ul>	<b>25,000</b>	<b>25,000</b>	<b>0</b>
<p><b>Objective 4: Advocacy for Increased Resources</b></p> <ul style="list-style-type: none"> <li>• Advocacy for ProTEST projects</li> </ul>	<ul style="list-style-type: none"> <li>• Plan complete mid-2002</li> </ul>	<b>20,000</b>	<b>20,000</b>	<b>0</b>
<b>TOTAL YEAR 2001</b>		<b>900,000</b>	<b>900,000</b>	<b>0</b>

## Working Group on TB-HIV

### 2002 Annual Plan

Activities	Indicators	Budget (\$)	Funding (\$)	Resource Gap (\$)
<p><b>Objective 1: Develop and Adapt TB/HIV Strategy</b></p> <ul style="list-style-type: none"> <li>Complete, develop consensus on, publish, and disseminate strategy, technical, and clinical guidelines</li> <li>Adapt framework for different regions</li> <li>Two meetings of scientific panel (guidelines on recurrence of TB among HIV+ patients and operational research)</li> <li>Complete modelling of, focus for, and impact of interventions to inform development of prioritised essential package</li> <li>Publish new TB/HIV estimates (no cost)</li> </ul>	<ul style="list-style-type: none"> <li>By end 2002</li> <li>By end 2002</li> <li>Draft by end 2002</li> <li>By end 2002</li> <li>By mid 2002</li> </ul>	<p><b>290,000</b></p> <p>80,000</p> <p>50,000</p> <p>60,000</p> <p>100,000</p>	<p><b>260,000</b></p> <p>80,000</p> <p>50,000</p> <p>30,000</p> <p>100,000</p>	<p><b>30,000</b></p> <p>0</p> <p>0</p> <p>30,000</p> <p>0</p>
<p><b>Objective 2: Promote Implementation</b></p> <ul style="list-style-type: none"> <li>Establish PIA-TB/HIV projects in four additional countries</li> <li>Coordinate network of PIA-TB/HIV projects</li> <li>Monitor existing ProTEST projects</li> <li>Completion of ProTEST project evaluation</li> <li>WHO regional office support</li> <li>Develop human resource plan</li> </ul>	<ul style="list-style-type: none"> <li>Implement mid-2003</li> <li>Consultant visits 'Q4</li> <li>Ongoing</li> <li>Report, end-2002</li> <li>AFRO TB/HIV plan, end-2002</li> <li>End, 2002</li> </ul>	<p><b>1,390,000</b></p> <p>1,000,000</p> <p>200,000</p> <p>40,000</p> <p>80,000</p> <p>20,000</p> <p>50,000</p>	<p><b>1,005,000</b></p> <p>665,000</p> <p>200,000</p> <p>40,000</p> <p>80,000</p> <p>20,000</p> <p>0</p>	<p><b>385,000</b></p> <p>335,000</p> <p>0</p> <p>0</p> <p>0</p> <p>0</p> <p>50,000</p>
<p><b>Objective 3: Form Global Partnership</b></p> <ul style="list-style-type: none"> <li>Five virtual and one actual meeting for core group of Working Group</li> <li>Hold 2nd annual meeting of Global TB/HIV Working Group</li> <li>First meeting of inter-agency collaboration group</li> </ul>	<ul style="list-style-type: none"> <li>As scheduled</li> <li>As scheduled</li> <li>As scheduled</li> </ul>	<p><b>155,000</b></p> <p>30,000</p> <p>75,000</p> <p>50,000</p>	<p><b>55,000</b></p> <p>30,000</p> <p>25,000</p> <p>0</p>	<p><b>100,000</b></p> <p>0</p> <p>50,000</p> <p>50,000</p>
<p><b>Objective 4: Advocacy for Increased Resources</b></p>	<ul style="list-style-type: none"> <li>\$1.25 million raised</li> </ul>	<p><b>50,000</b></p>	<p><b>0</b></p>	<p><b>50,000</b></p>
<b>TOTAL YEAR 2002</b>		<b>1,885,000</b>	<b>1,320,000</b>	<b>565,000</b>

## Working Group on TB-HIV

### 2003 Annual Plan \*

Activities	Indicators	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Develop and Adapt TB/HIV Strategy</b>				
<ul style="list-style-type: none"> <li>• Adaptation of framework and guidelines for different regions</li> <li>• Dissemination of guidelines</li> <li>• Two meetings of scientific panel</li> <li>• Economic modelling to compare interventions</li> </ul>	<ul style="list-style-type: none"> <li>• Adapted for 3 regions, early 2003</li> <li>• As scheduled</li> <li>• Report by mid-2003</li> </ul>	<b>230,000</b> 50,000 20,000 60,000 100,000	<b>0</b> 0 0 0 0	<b>230,000</b> 50,000 20,000 60,000 100,000
<b>Objective 2: Promote Implementation</b>				
<ul style="list-style-type: none"> <li>• Establish new PIA-TB/HIV projects</li> <li>• Technical support to existing PIA-TB/HIV projects</li> <li>• Maintain and coordinate network of PIA-TB/HIV projects</li> <li>• Monitor and evaluate country-level PIA-TB/HIV projects</li> <li>• Support implementation of human resource development plan</li> <li>• Report and publish results on country projects</li> </ul>	<ul style="list-style-type: none"> <li>• 9 new projects by end 2003</li> <li>• Consult reports, end 2003</li> <li>• Report to WG 2003</li> <li>• Mentors reports to WG 2003</li> <li>• Training plan implemented, end 2003</li> <li>• As scheduled</li> </ul>	<b>2,800,000</b> 1,000,000 1,000,000 250,000 250,000 200,000 100,000	<b>0</b> 0 0 0 0 0 0	<b>2,800,000</b> 1,000,000 1,000,000 250,000 250,000 200,000 100,000
<b>Objective 3: Form Global Partnership</b>				
<ul style="list-style-type: none"> <li>• Five virtual and one actual meeting for core group of WG</li> <li>• Hold 3rd annual meeting of Global TB/HIV WG</li> <li>• 2nd meeting of TB/HIV interagency collaboration group</li> <li>• Coordinate with regional and national inter-agency coordination groups (no cost)</li> </ul>	<ul style="list-style-type: none"> <li>• As scheduled</li> <li>• As scheduled</li> <li>• As scheduled</li> <li>• TB/HIV integrated with DOTS expansion plans</li> </ul>	<b>155,000</b> 30,000 75,000 50,000	<b>0</b> 0 0 0	<b>155,000</b> 30,000 75,000 50,000
<b>Objective 4: Advocacy for Increased Resources</b>				
<ul style="list-style-type: none"> <li>• Advocacy for ProTEST projects</li> </ul>	<ul style="list-style-type: none"> <li>• Various (\$2 million raised)</li> </ul>	<b>50,000</b>	<b>0</b>	<b>50,000</b>
<b>TOTAL YEAR 2003</b>		<b>3,235,000</b>	<b>0</b>	<b>3,235,000</b>

\* Estimates as of January 2002. At least \$1.3 million will likely be obtained from existing sources, but as yet there are no firm pledges.

## Working Group on TB-HIV

### 2004 Annual Plan \*

Activities	Indicators	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Develop and Adapt TB/HIV Strategy</b>		<b>160,000</b>	<b>0</b>	<b>160,000</b>
<ul style="list-style-type: none"> <li>Two meetings of scientific panel</li> <li>Further mathematical modelling for strategic decision-making</li> </ul>	<ul style="list-style-type: none"> <li>As scheduled</li> <li>Reports published</li> </ul>	60,000 100,000	0 0	60,000 100,000
<b>Objective 2: Promote Implementation</b>		<b>2,800,000</b>	<b>0</b>	<b>2,800,000</b>
<ul style="list-style-type: none"> <li>Technical support to existing PIA-TB/HIV projects</li> <li>Maintain and coordinate network of PIA-TB/HIV projects</li> <li>Monitor and evaluate country-level PIA-TB/HIV projects</li> <li>Support implementation of human resource development plan</li> <li>Report preparation and publication of results</li> </ul>	<ul style="list-style-type: none"> <li>Project and consultant reports for each country, end 2004</li> <li>Consultant and trainer reports end 2004</li> <li>3 peer-reviewed publications</li> </ul>	2,000,000 250,000 250,000 200,000 100,000	0 0 0 0 0	2,000,000 250,000 250,000 200,000 100,000
<b>Objective 3: Form Global Partnership</b>		<b>155,000</b>	<b>0</b>	<b>155,000</b>
<ul style="list-style-type: none"> <li>Five virtual and one actual meeting for core group of WG</li> <li>Hold 4th annual meeting of Global TB/HIV WG</li> <li>3rd meeting of TB/HIV inter-agency collaboration group</li> <li>Coordinate with regional and national inter-agency coordination groups</li> </ul>	<ul style="list-style-type: none"> <li>As scheduled</li> <li>As scheduled</li> <li>As scheduled</li> <li>Reports of these bodies</li> </ul>	30,000 75,000 50,000	0 0 0	30,000 75,000 50,000
<b>Objective 4: Advocacy for Increased Resources</b>		<b>50,000</b>	<b>0</b>	<b>50,000</b>
	<ul style="list-style-type: none"> <li>\$3 million raised</li> </ul>			
<b>TOTAL YEAR 2004</b>		<b>3,165,000</b>	<b>0</b>	<b>3,165,000</b>

\* Estimates as of January 2002. At least \$1.3 million will likely be obtained from existing sources, but as yet there are no firm pledges.

## Working Group on TB-HIV

### 2005 Annual Plan \*

Activities	Indicators	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Develop and Adapt TB/HIV Strategy</b>		<b>160,000</b>	<b>0</b>	<b>160,000</b>
<ul style="list-style-type: none"> <li>Two meetings of scientific panel</li> <li>Further mathematical modelling for strategic decision-making</li> </ul>	<ul style="list-style-type: none"> <li>As activities</li> <li>Reports for publication</li> </ul>	60,000 100,000		60,000 100,000
<b>Objective 2: Promote Implementation</b>		<b>2,800,000</b>	<b>0</b>	<b>2,800,000</b>
<ul style="list-style-type: none"> <li>Technical support to existing PIA-TB/HIV projects</li> <li>Maintain &amp; coordinate network of PIA-TB/HIV projects</li> <li>Monitor &amp; evaluate country-level PIA-TB/HIV projects</li> <li>Support implementation of human resource development plan</li> <li>Report preparation and publication of results from countries</li> </ul>	<ul style="list-style-type: none"> <li>Project &amp; consultant reports for each country end 2004</li> <li>Consultant &amp; trainer reports end 2004</li> <li>3 peer-reviewed publications</li> </ul>	2,000,000 250,000 250,000 200,000 100,000		2,000,000 250,000 250,000 200,000 100,000
<b>Objective 3: Form Global Partnership</b>		<b>155,000</b>	<b>0</b>	<b>155,000</b>
<ul style="list-style-type: none"> <li>Five virtual and one actual meeting for core group of WG</li> <li>Hold 4th annual meeting of Global TB/HIV Working Group</li> <li>3rd meeting of TB/HIV inter-agency collaboration group</li> <li>Coordinate with regional and national inter-agency coordination groups</li> </ul>	<ul style="list-style-type: none"> <li>As scheduled</li> <li>As scheduled</li> <li>As scheduled</li> <li>Reports of these bodies</li> </ul>	30,000 75,000 50,000		30,000 75,000 50,000
<b>Objective 4: Advocacy for Increased Resources</b>		<b>50,000</b>	<b>0</b>	<b>50,000</b>
	<ul style="list-style-type: none"> <li>\$4 million raised</li> </ul>			
<b>TOTAL YEAR 2005</b>		<b>3,165,000</b>	<b>0</b>	<b>3,165,000</b>

\* Estimates as of January 2002. At least \$1.3 million will likely be obtained from existing sources, but as yet there are no firm pledges.

## Working Group on DOTS-Plus for MDR-TB

**Lead Agency:** *World Health Organization*  
**Chair:** *Dr. Jim Yong Kim, Partners in Health*

### Summary 5-Year Work Plan

Objectives	Targets	Activities	Budget \$
<ul style="list-style-type: none"> <li><b>Objective 1:</b> Initiate and support pilot projects, through partner organizations, for the diagnosis and treatment of MDR-TB</li> </ul>	<ul style="list-style-type: none"> <li>Pilot project guidelines issued: 2000</li> <li>Continue to expand number of pilot projects at a rate of approximately 3-6 per year</li> </ul>	<ul style="list-style-type: none"> <li>Six MDR-TB pilot projects underway</li> <li>Nine new MDR-TB projects scheduled</li> <li>Continue to revise and improve DOTS-Plus project guidelines</li> <li>Provide ongoing technical advice on clinical issues of MDR-TB management</li> </ul>	<b>7,800,000</b>
<ul style="list-style-type: none"> <li><b>Objective 2:</b> Establish drug access system to provide and prevent misuse of high-quality, second-line drugs</li> </ul>	<ul style="list-style-type: none"> <li>Prices reduced on many drugs</li> <li>Two procurement mechanisms operating</li> <li>GLC to meet 12 times p.a. on country applications, and to discuss operational activities</li> </ul>	<ul style="list-style-type: none"> <li>Make recommendations for increasing access/lowering price of second-line drugs</li> <li>Establish and monitor procurement mechanisms</li> </ul>	<b>1,190,000</b>
<ul style="list-style-type: none"> <li><b>Objective 3:</b> Coordinate and monitor implementation of DOTS-Plus pilots; assess data; and help produce policy recommendations</li> </ul>	<ul style="list-style-type: none"> <li>Regular data collection and review of pilot projects at least once a year</li> </ul>	<ul style="list-style-type: none"> <li>Pre-approval site visits to projects applying for GLC drugs</li> <li>Monitoring visits for GLC-approved projects</li> <li>Develop DOTS-Plus data clearinghouse</li> <li>Coord. operational research studies from projects</li> </ul>	<b>6,890,000</b>
<ul style="list-style-type: none"> <li><b>Objective 4:</b> Advocacy and resource development for new DOTS-Plus projects</li> </ul>	<ul style="list-style-type: none"> <li>Increase visibility of the GLC and the working group</li> <li>Increased funding for projects</li> </ul>	<ul style="list-style-type: none"> <li>Increase visibility of DOTS-Plus efforts</li> <li>Work with funders to provide an evidence-based approach to drug-resistant TB</li> </ul>	<b>600,000</b>
<b>TOTAL</b>			<b>16,480,000</b>

## Working Group on DOTS-Plus for MDR-TB

### 2001 Annual Plan

Activities	Indicators	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Pilot Projects</b> <ul style="list-style-type: none"> <li>Establish three pilot projects (\$200,000 per project)</li> <li>Training sessions in clinical management</li> <li>Piloting of new diagnostic tools</li> </ul>	<ul style="list-style-type: none"> <li>Projects established (Philippines, Peru, Ore)</li> <li>4 sessions held in HBCâs</li> <li>In-pilot projects</li> </ul>	<ul style="list-style-type: none"> <li>2,100,000</li> <li>600,000</li> <li>500,000</li> <li>1,000,000</li> </ul>	<ul style="list-style-type: none"> <li>100,000</li> <li>100,000</li> <li>0</li> <li>0</li> </ul>	<ul style="list-style-type: none"> <li>2,000,000</li> <li>500,000</li> <li>500,000</li> <li>1,000,000</li> </ul>
<b>Objective 2: Drug Access System</b> <ul style="list-style-type: none"> <li>Technical assistance for GLC applications, and monitoring of projects</li> <li>Evaluate drug-procurement process</li> <li>Staff IDA for registration and procurement activities</li> </ul>	<ul style="list-style-type: none"> <li>Application training for 3 countries, and monitoring visits to 4 projects</li> <li>Procurement strategies developed</li> <li>Drug prices down by over 90%</li> <li>As placed</li> </ul>	<ul style="list-style-type: none"> <li>330,000</li> <li>200,000</li> <li>50,000</li> <li>80,000</li> </ul>	<ul style="list-style-type: none"> <li>130,000</li> <li>100,000</li> <li>30,000</li> <li>0</li> </ul>	<ul style="list-style-type: none"> <li>200,000</li> <li>100,000</li> <li>20,000</li> <li>80,000</li> </ul>
<b>Objective 3: Monitoring and Policy Development</b> <ul style="list-style-type: none"> <li>Collect and analyse data</li> <li>Operational research</li> <li>Annual meetings of working group</li> <li>Preparation and publication of policy document</li> </ul>	<ul style="list-style-type: none"> <li>Papers submitted on Peru programme</li> <li>Protocols implemented</li> <li>Annual meeting held</li> </ul>	<ul style="list-style-type: none"> <li>1,650,000</li> <li>50,000</li> <li>1,500,000</li> <li>100,000</li> </ul>	<ul style="list-style-type: none"> <li>200,000</li> <li>20,000</li> <li>150,000</li> <li>30,000</li> </ul>	<ul style="list-style-type: none"> <li>1,450,000</li> <li>30,000</li> <li>1,350,000</li> <li>70,000</li> </ul>
<b>Objective 4: Advocacy and Resource Development</b> <ul style="list-style-type: none"> <li>Advocacy for pilot projects</li> <li>Advocacy for GLC</li> </ul>	<ul style="list-style-type: none"> <li>Press releases and newsletters</li> <li>Press releases and newsletters</li> </ul>	<ul style="list-style-type: none"> <li>200,000</li> <li>100,000</li> <li>100,000</li> </ul>	<ul style="list-style-type: none"> <li>70,000</li> <li>20,000</li> <li>50,000</li> </ul>	<ul style="list-style-type: none"> <li>130,000</li> <li>80,000</li> <li>50,000</li> </ul>
<b>TOTAL YEAR 2001</b>		<b>4,280,000</b>	<b>500,000</b>	<b>3,780,000</b>

## Working Group on DOTS-Plus for MDR-TB

### 2002 Annual Plan

Activities	Indicators	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Pilot Projects</b> <ul style="list-style-type: none"> <li>• Establish three pilot projects (\$200,000 each)</li> <li>• Training sessions in clinical management</li> <li>• Piloting of new diagnostic tools</li> <li>• Support to ongoing pilot projects</li> </ul>	<ul style="list-style-type: none"> <li>• As established</li> <li>• Hold sessions in 2 countries</li> <li>• In-pilot projects</li> </ul>	<b>2,400,000</b> 600,000 500,000 1,000,000 300,000	<b>150,000</b> 100,000 0 0 50,000	<b>2,250,000</b> 500,000 500,000 1,000,000 250,000
<b>Objective 2: Drug Access System</b> <ul style="list-style-type: none"> <li>• Technical assistance for GLC applications, and monitoring of projects</li> <li>• Evaluate drug-procurement process</li> <li>• Staff IDA registration and procurement</li> </ul>	<ul style="list-style-type: none"> <li>• Training session at working group meeting and in-country training in 2 countries monitoring visits to 3 projects</li> <li>• Report on drug-procurement progress</li> <li>• As placed</li> </ul>	<b>330,000</b> 200,000 50,000 80,000	<b>130,000</b> 100,000 30,000 0	<b>200,000</b> 100,000 20,000 80,000
<b>Objective 3: Monitoring and Policy Development</b> <ul style="list-style-type: none"> <li>• Collect and analyse data</li> <li>• Operational research</li> <li>• Annual meetings of working group</li> <li>• Preparation and publication of policy document</li> </ul>	<ul style="list-style-type: none"> <li>• Establish data clearinghouse at WHO</li> <li>• Protocols accepted and established</li> <li>• Annual meeting in Estonia</li> </ul>	<b>1,650,000</b> 50,000 1,500,000 100,000	<b>200,000</b> 20,000 150,000 30,000	<b>1,450,000</b> 30,000 1,350,000 70,000
<b>Objective 4: Advocacy and Resource Development</b> <ul style="list-style-type: none"> <li>• Advocacy for pilot projects</li> <li>• Advocacy for GLC</li> </ul>	<ul style="list-style-type: none"> <li>• Press releases and newsletters</li> <li>• Press releases and newsletters</li> </ul>	<b>200,000</b> 100,000 100,000	<b>70,000</b> 20,000 50,000	<b>130,000</b> 80,000 50,000
<b>TOTAL YEAR 2002</b>		<b>4,580,000</b>	<b>550,000</b>	<b>4,030,000</b>

## Working Group on DOTS-Plus for MDR-TB

### 2003 Annual Plan

Activities	Indicators	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Pilot Projects</b> <ul style="list-style-type: none"> <li>• Training sessions in clinical management</li> <li>• Piloting of new diagnostic tools</li> <li>• Support to ongoing pilot projects</li> </ul>	<ul style="list-style-type: none"> <li>• Hold sessions in 2 countries</li> <li>• In-pilot projects</li> </ul>	<b>1,800,000</b> 500,000 1,000,000 300,000	<b>50,000</b> 0 0 50,000	<b>1,750,000</b> 500,000 1,000,000 250,000
<b>Objective 2: Drug Access System</b> <ul style="list-style-type: none"> <li>• Technical assistance for GLC applications, and monitoring of projects</li> <li>• Evaluate drug procurement process</li> <li>• Staff IDA registration and procurement</li> </ul>	<ul style="list-style-type: none"> <li>• Training session (at working group meeting); training in 2 countries.</li> <li>• Visits to 3 projects</li> <li>• Report on procurement progress</li> <li>• As placed</li> </ul>	<b>330,000</b> 200,000 50,000 80,000	<b>130,000</b> 100,000 30,000 0	<b>200,000</b> 100,000 20,000 80,000
<b>Objective 3: Monitoring and Policy Development</b> <ul style="list-style-type: none"> <li>• Collect and analyse data</li> <li>• Operational research</li> <li>• Annual meetings of working group</li> <li>• Preparation and publication of policy document</li> </ul>	<ul style="list-style-type: none"> <li>• Establish clearinghouse at WHO</li> <li>• Protocols accepted and established</li> <li>• As scheduled</li> </ul>	<b>1,750,000</b> 50,000 1,500,000 100,000 100,000	<b>250,000</b> 20,000 150,000 30,000 50,000	<b>1,500,000</b> 30,000 1,350,000 70,000 50,000
<b>Objective 4: Advocacy and Resource Development</b> <ul style="list-style-type: none"> <li>• Advocacy for GLC</li> </ul>	<ul style="list-style-type: none"> <li>• Press releases and newsletters</li> </ul>	<b>100,000</b> 100,000	<b>50,000</b> 50,000	<b>50,000</b> 50,000
<b>TOTAL YEAR 2003</b>		<b>3,980,000</b>	<b>480,000</b>	<b>3,500,000</b>

## Working Group on DOTS-Plus for MDR-TB

### 2004 Annual Plan

Activities	Indicators	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Pilot Projects</b> <ul style="list-style-type: none"> <li>• Training sessions in clinical management</li> <li>• Piloting of new diagnostic tools</li> </ul>	<ul style="list-style-type: none"> <li>• Hold sessions in 2 countries and at working group meeting</li> <li>• In-pilot projects</li> </ul>	<b>1,500,000</b> 500,000 1,000,000	<b>0</b> 0 0	<b>1,500,000</b> 500,000 1,000,000
<b>Objective 2: Drug Access System</b> <ul style="list-style-type: none"> <li>• Technical assistance for GLC applications, and monitoring of projects</li> </ul>	<ul style="list-style-type: none"> <li>• Training session (at working group meeting); training in 2 countries.</li> <li>• Visits to 3 projects</li> </ul>	<b>200,000</b> 200,000	<b>100,000</b> 100,000	<b>100,000</b> 100,000
<b>Objective 3: Monitoring and Policy Development</b> <ul style="list-style-type: none"> <li>• Collect and analyse data</li> <li>• Operational research</li> <li>• Annual meetings of working group</li> <li>• Preparation and publication of policy document</li> </ul>	<ul style="list-style-type: none"> <li>• Protocols accepted and established</li> <li>• As scheduled</li> </ul>	<b>1,750,000</b> 50,000 1,500,000 100,000 100,000	<b>240,000</b> 20,000 150,000 30,000 40,000	<b>1,510,000</b> 30,000 1,350,000 70,000 60,000
<b>Objective 4: Advocacy and Resource Development</b> <ul style="list-style-type: none"> <li>• Advocacy for GLC</li> </ul>	<ul style="list-style-type: none"> <li>• Press releases and newsletters</li> </ul>	<b>100,000</b> 100,000	<b>50,000</b> 50,000	<b>50,000</b> 50,000
<b>TOTAL YEAR 2004</b>		<b>3,550,000</b>	<b>390,000</b>	<b>3,160,000</b>

## Working Group on DOTS-Plus for MDR-TB

### 2005 Annual Plan

Activities	Indicators	Budget (\$)	Funding (\$)	Resource Gap (\$)
Objective 1: Pilot Projects		0	0	0
Objective 2: Drug Access System		0	0	0
<b>Objective 3: Monitoring and Policy Development</b> <ul style="list-style-type: none"> <li>• Annual meetings of working group</li> <li>• Preparation and publication of policy document</li> </ul>	<ul style="list-style-type: none"> <li>• As scheduled</li> <li>• As published</li> </ul>	<b>90,000</b> 90,000	<b>30,000</b> 30,000	<b>60,000</b> 60,000
Objective 4: Advocacy and Resource Development		0	0	0
<b>TOTAL YEAR 2005</b>		<b>90,000</b>	<b>30,000</b>	<b>60,000</b>

## Working Group on TB Diagnostics

**Lead Agency:** *UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases*  
**Chair:** *Dr. Carlos Morel, TDR*

### Summary 4-Year Work Plan

Objectives	Targets	Activities	4-Year Budget (\$)
<p><b>Objective 1: Facilitation</b>            To promote and facilitate the development, evaluation, and appropriate use of improved TB diagnostics to assist disease control in endemic settings, including:</p> <ul style="list-style-type: none"> <li>• Simpler, faster, or more sensitive case detection tools</li> <li>• Faster and less laborious drug susceptibility testing methods</li> <li>• More practical and more predictive latent infection detection tests</li> </ul>	<ul style="list-style-type: none"> <li>• At least 5 diagnostic candidates identified and evaluated in phase I/II trials by 2005</li> <li>• Evidence base for best use of TB diagnostics (timing and target populations) for improved disease control developed by 2004</li> <li>• Phase III trials of at least 1 case detection tool and at least 3 new drug susceptibility testing methods completed by 2005</li> <li>• International system for evaluation of TB diagnostics in place by 2005</li> <li>• Guidelines for use of new TB tests published by 2007</li> </ul>	<ul style="list-style-type: none"> <li>• Coordinating outputs of discovery research and facilitating commercial uptake</li> <li>• Multi-step facilitation of commercial R&amp;D for TB diagnostics relevant for DECIs</li> <li>• Providing reagents and technical support to enhance the quality of diagnostics being developed</li> <li>• Developing diagnostics trial capacity and coordinating evaluation of new tools</li> <li>• Streamlining and strengthening the diagnostics regulatory process</li> <li>• Advocacy and establishment of an information resource centre</li> <li>• Planning and coordination by working group and ad hoc task forces</li> </ul>	<b>25,855,000</b>
<b>Objective 2: Advocacy and Information</b>			<b>600,000</b>
<b>Objective 3: Coordinate Activities</b>			<b>600,000</b>
<b>TOTAL</b>			<b>27,055,000</b>

## Working Group on TB Diagnostics

### 2002 Annual Plan

Activities	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Facilitation</b>	<b>6,780,000</b>	<b>2,130,000</b>	<b>4,650,000</b>
<ul style="list-style-type: none"> <li>• Develop consortium to evaluate sputum processing methods</li> <li>• Develop antigen discovery and evaluation programme</li> <li>• Maintain bank of clinical reference materials for case detection tool R&amp;D</li> <li>• Perform market analysis, global use portrait, and economic analysis</li> <li>• Coordinate phase III trials of DST methods</li> <li>• Coordinate laboratory evaluation of case detection tools</li> <li>• Coordinate programme to strengthen DEC laboratory capacity to evaluate and use new diagnostics in a network of trial sites</li> <li>• Develop MTB strain bank to facilitate R&amp;D and testing of DST methods</li> <li>• Model impact of new case detection tools</li> <li>• Coordinate multinational measure of TB diagnostic delay and dropout</li> <li>• Coordinate phase III trials of case detection tool</li> <li>• Regulatory harmonization workshops</li> <li>• Develop strategy for global evaluation system for TB diagnostics marketed in developing countries</li> <li>• Develop a comprehensive advocacy and information strategy for new TB diagnostics</li> </ul>	<ul style="list-style-type: none"> <li>60,000</li> <li>400,000</li> <li>450,000</li> <li>800,000</li> <li>750,000</li> <li>250,000</li> <li>1,600,000</li> <li>550,000</li> <li>60,000</li> <li>250,000</li> <li>950,000</li> <li>400,000</li> <li>60,000</li> <li>200,000</li> </ul>	<ul style="list-style-type: none"> <li>30,000</li> <li>150,000</li> <li>250,000</li> <li>150,000</li> <li>250,000</li> <li>100,000</li> <li>350,000</li> <li>300,000</li> <li>20,000</li> <li>150,000</li> <li>300,000</li> <li>50,000</li> <li>10,000</li> <li>20,000</li> </ul>	<ul style="list-style-type: none"> <li>30,000</li> <li>250,000</li> <li>200,000</li> <li>650,000</li> <li>500,000</li> <li>150,000</li> <li>1,250,000</li> <li>250,000</li> <li>40,000</li> <li>100,000</li> <li>650,000</li> <li>350,000</li> <li>50,000</li> <li>180,000</li> </ul>
<b>Objective 2: Advocacy and Information</b>	<b>150,000</b>	<b>20,000</b>	<b>130,000</b>
<b>Objective 3: Coordination</b>	<b>150,000</b>	<b>0</b>	<b>150,000</b>
<ul style="list-style-type: none"> <li>• Annual working group meeting</li> <li>• Ad hoc meetings of regional task forces</li> </ul>			
<b>TOTAL YEAR 2002</b>	<b>7,080,000</b>	<b>2,150,000</b>	<b>4,930,000</b>

## Working Group on TB Diagnostics

### 2003 Annual Plan

Activities	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Facilitation</b>	<b>6,210,000</b>	<b>1,300,000</b>	<b>4,910,000</b>
• Support consortium to evaluate sputum processing methods	60,000	0	60,000
• Develop antigen discovery and evaluation programme	300,000	100,000	200,000
• Maintain bank of clinical reference materials	400,000	100,000	300,000
• Complete market analysis, global use portrait, and economic analysis	800,000	150,000	650,000
• Coordinate phase III trials of DST methods	750,000	250,000	500,000
• Coordinate laboratory evaluation of case detection tools	200,000	100,000	100,000
• Coordinate programme to strengthen DEC laboratory capacity to evaluate and use new diagnostics in a network of trial sites	1,600,000	0	1,600,000
• Maintain MTB strain bank to facilitate R&D and testing of DST methods	250,000	100,000	150,000
• Model impact of new case detection tools	60,000	20,000	40,000
• Coordinate multinational measure of TB diagnostic delay and dropout	150,000	50,000	100,000
• Coordinate phase III trials of case detection tools	950,000	300,000	650,000
• Regulatory harmonization workshops	400,000	50,000	350,000
• Develop strategy for global evaluation system for TB diagnostics marketed in developing countries	150,000	40,000	110,000
• Complete a comprehensive advocacy and information strategy for new TB diagnostics	100,000	20,000	80,000
• Model early detection impact on disease transmission	40,000	20,000	20,000
<b>Objective 2: Advocacy and Information</b>	<b>150,000</b>	<b>20,000</b>	<b>130,000</b>
<b>Objective 3: Coordination</b>	<b>150,000</b>	<b>0</b>	<b>150,000</b>
• Annual working group meeting			
• Ad hoc meetings of regional task forces			
<b>TOTAL YEAR 2003</b>	<b>6,510,000</b>	<b>1,320,000</b>	<b>5,190,000</b>

## Working Group on TB Diagnostics

### 2004 Annual Plan

Activities	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Facilitation</b>	<b>6,140,000</b>	<b>1,090,000</b>	<b>5,050,000</b>
<ul style="list-style-type: none"> <li>Maintain consortium to evaluate sputum processing methods</li> <li>Complete antigen discovery and evaluation programme</li> <li>Maintain bank of clinical reference materials</li> <li>Circulate market analysis, global use portrait, and economic analysis</li> <li>Coordinate phase III trials of DST methods</li> <li>Coordinate laboratory evaluation of case detection tools</li> <li>Coordinate programme to strengthen DEC laboratory capacity to evaluate and use new diagnostics in a network of trial sites</li> <li>Distribute MTB strain bank to facilitate R&amp;D and testing of DST methods</li> <li>Coordinate phase III trials of case detection tools</li> <li>Regulatory harmonization workshops</li> <li>Implement strategy for global evaluation system for TB diagnostics marketed in developing countries</li> <li>Develop expert advisor team for diagnostics assistants to NTP</li> <li>Collect field data to determine kinetics of community TB transmission</li> <li>Model early detection impact on disease transmission</li> </ul>	150,000 400,000 450,000 200,000 750,000 250,000 800,000  250,000 1,000,000 300,000 350,000  600,000 600,000 40,000	0 0 150,000 0 250,000 100,000 0  0 300,000 50,000 100,000  0 120,000 20,000	150,000 400,000 300,000 200,000 500,000 150,000 800,000  250,000 700,000 250,000 250,000  600,000 480,000 20,000
<b>Objective 2: Advocacy and Information</b>	<b>150,000</b>	<b>20,000</b>	<b>130,000</b>
<b>Objective 3: Coordination</b>	<b>150,000</b>	<b>0</b>	<b>150,000</b>
<ul style="list-style-type: none"> <li>Annual working group meeting</li> <li>Ad hoc meetings of regional task forces</li> </ul>			
<b>TOTAL YEAR 2004</b>	<b>6,440,000</b>	<b>1,110,000</b>	<b>5,330,000</b>

## Working Group on TB Diagnostics

### 2005 Annual Plan

Activities	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Facilitation</b>	<b>6,725,000</b>	<b>1,440,000</b>	<b>5,285,000</b>
<ul style="list-style-type: none"> <li>• Support technology transfer of improved diagnostics</li> <li>• Maintain bank of clinical reference materials</li> <li>• Coordinate phase III trials of DST methods</li> <li>• Coordinate evaluation of latency surrogates</li> <li>• Coordinate programme to strengthen DEC laboratory capacity to evaluate and use new diagnostics in a network of trial sites</li> <li>• Distribute MTB strain bank to facilitate R&amp;D and testing of DST methods</li> <li>• Model impact of new case detection tools on transmission</li> <li>• Coordinate phase IV trials of case detection tools</li> <li>• Implement strategy for global evaluation system for TB diagnostics marketed in developing countries</li> <li>• Model early detection impact disease transmission</li> <li>• Diagnostic trial support programme</li> <li>• Develop usage guidelines for new diagnostics</li> <li>• Develop expert advisor team for diagnostics assistants to NTP</li> <li>• Collect field data to determine kinetics of community TB transmission</li> </ul>	<ul style="list-style-type: none"> <li>700,000</li> <li>250,000</li> <li>350,000</li> <li>400,000</li> <li>800,000</li> <li>150,000</li> <li>60,000</li> <li>1,350,000</li> <li>750,000</li> <li>40,000</li> <li>300,000</li> <li>75,000</li> <li>600,000</li> <li>900,000</li> </ul>	<ul style="list-style-type: none"> <li>130,000</li> <li>50,000</li> <li>150,000</li> <li>100,000</li> <li>0</li> <li>0</li> <li>20,000</li> <li>200,000</li> <li>100,000</li> <li>20,000</li> <li>200,000</li> <li>50,000</li> <li>200,000</li> <li>220,000</li> </ul>	<ul style="list-style-type: none"> <li>570,000</li> <li>200,000</li> <li>200,000</li> <li>300,000</li> <li>800,000</li> <li>150,000</li> <li>40,000</li> <li>1,150,000</li> <li>650,000</li> <li>20,000</li> <li>100,000</li> <li>25,000</li> <li>400,000</li> <li>680,000</li> </ul>
<b>Objective 2: Advocacy and Information</b>	<b>150,000</b>	<b>20,000</b>	<b>130,000</b>
<b>Objective 3: Coordination</b>	<b>150,000</b>	<b>0</b>	<b>150,000</b>
<ul style="list-style-type: none"> <li>• Annual working group meeting</li> <li>• Ad hoc meetings of the regional task forces</li> </ul>			
<b>TOTAL YEAR 2005</b>	<b>7,025,000</b>	<b>1,460,000</b>	<b>5,565,000</b>

## Working Group on TB Drug Development

**Lead Agency:** *Global Alliance for TB Development*  
**Chair:** *Dr. María Freire, Global Alliance*

### Summary 4-Year Work Plan

Objectives	Targets	Activities	Budget (\$)
<p><b>Objective 1: Develop new drug(s) to:</b></p> <ul style="list-style-type: none"> <li>• Shorten and/or simplify the treatment of TB disease</li> <li>• Develop more effective treatment(s) for MDR-TB</li> <li>• Develop more effective treatment(s) of latent TB infection.</li> </ul>	<ul style="list-style-type: none"> <li>• Have at least 5 drug candidates through preclinical trials by 2005</li> <li>• Have at least 3 drugs through phase I and II by 2007</li> <li>• Have 2 drugs in phase III by 2010</li> <li>• Have at least one new drug registered by 2010</li> </ul>	<ul style="list-style-type: none"> <li>• Map activities in TB Drugs R&amp;D; establish and update drug database</li> <li>• Establish partnership with industry</li> <li>• Undertake studies to define surrogate markers</li> <li>• Develop High Endemic Countries Network for clinical trials</li> <li>• Promote introduction of surrogate markers in regulatory package</li> </ul>	<b>27,300,000</b>
<b>Objective 2: Advocacy and Information</b>		<ul style="list-style-type: none"> <li>• Advocacy for TB Drugs R&amp;D</li> </ul>	<b>2,000,000</b>
<b>Objective 3: Coordination: Annual working group meeting</b>		<ul style="list-style-type: none"> <li>• Working group activities</li> </ul>	<b>400,000</b>
<b>TOTAL</b>			<b>29,700,000</b>

## Working Group on TB Drug Development

### 2002 Annual Plan

Activities	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Facilitation /Enabling the Environment</b>	<b>7,200,000</b>	<b>1,550,000</b>	<b>5,650,000</b>
<ul style="list-style-type: none"> <li>• Map activities in TB drug R&amp;D: establish and update drug data base</li> <li>• Establish partnership with industry</li> <li>• Undertake studies to define surrogate markers for clinical activity</li> <li>• Develop HEC clinical trials network and strengthen laboratory capacity</li> <li>• Promote introduction of surrogate markers within the regulatory harmonization process</li> </ul>	500,000 200,000 3,000,000 3,000,000 500,000	150,000 100,000 350,000 700,000 250,000	350,000 100,000 2,650,000 2,300,000 250,000
<b>Objective 2: Advocacy and Information</b>	<b>500,000</b>	<b>250,000</b>	<b>250,000</b>
<b>Objective 3: Coordination: Annual working group meeting</b>	<b>100,000</b>	<b>0</b>	<b>100,000</b>
<b>TOTAL YEAR 2002</b>	<b>7,800,000</b>	<b>1,800,000</b>	<b>6,000,000</b>

## Working Group on TB Drug Development

### 2003 Annual Plan

Activities	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 3: Facilitation /Enabling the Environment</b>	<b>7,200,000</b>	<b>1,550,000</b>	<b>5,650,000</b>
<ul style="list-style-type: none"> <li>• Map activities in TB drug R&amp;D: establish and update drug data base</li> <li>• Establish partnership with industry</li> <li>• Undertake studies to define surrogate markers for clinical activity</li> <li>• Develop HEC clinical trials network and strengthen laboratory capacity</li> <li>• Promote introduction of surrogate markers within the regulatory harmonization process</li> </ul>	500,000 200,000 3,000,000 3,000,000 500,000	150,000 100,000 350,000 700,000 250,000	350,000 100,000 2,650,000 2,300,000 250,000
<b>Objective 2: Advocacy and Information</b>	<b>500,000</b>	<b>250,000</b>	<b>250,000</b>
<b>Objective 3: Coordination: Annual working group meeting</b>	<b>100,000</b>	<b>0</b>	<b>100,000</b>
<b>TOTAL YEAR 2003</b>	<b>7,800,000</b>	<b>1,800,000</b>	<b>6,000,000</b>

## Working Group on TB Drug Development

### 2004 Annual Plan

Activities	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Facilitation /Enabling the Environment</b>	<b>6,700,000</b>	<b>1,300,000</b>	<b>5,400,000</b>
<ul style="list-style-type: none"> <li>• Map activities in TB drug R&amp;D: establish and update drug data base</li> <li>• Establish partnership with industry</li> <li>• Undertake studies to define surrogate markers for clinical activity</li> <li>• Develop HEC clinical trials network and strengthen laboratory capacity</li> </ul>	500,000 200,000 3,000,000 3,000,000	150,000 100,000 350,000 700,000	350,000 100,000 2,650,000 2,300,000
<b>Objective 2: Advocacy and Information</b>	<b>500,000</b>	<b>250,000</b>	<b>250,000</b>
<b>Objective 3: Coordination: Annual working group meeting</b>	<b>100,000</b>	<b>0</b>	<b>100,000</b>
<b>TOTAL YEAR 2004</b>	<b>7,300,000</b>	<b>1,550,000</b>	<b>5,750,000</b>

## Working Group on TB Drug Development

### 2005 Annual Plan

Activities	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Facilitation /Enabling the Environment</b> <ul style="list-style-type: none"> <li>• Establish partnership with industry</li> <li>• Undertake studies to define surrogate markers for clinical activity</li> <li>• Develop HEC clinical trials network and strengthen laboratory capacity</li> </ul>	<b>6,200,000</b>  200,000 3,000,000 3,000,000	<b>500,000</b>  0 0 500,000	<b>5,700,000</b>  200,000 3,000,000 2,500,000
<b>Objective 2: Advocacy and Information</b>	<b>500,000</b>	<b>250,000</b>	<b>250,000</b>
<b>Objective 3: Coordination: Annual working group meeting</b>	<b>100,000</b>	<b>0</b>	<b>100,000</b>
<b>TOTAL YEAR 2005</b>	<b>6,800,000</b>	<b>750,000</b>	<b>6,050,000</b>

## Working Group on TB Vaccine Development

**Lead Agency:** *World Health Organization/TDR*  
**Chair:** *Dr. Ann Ginsberg, US-NIH/NIAID*

### Summary 4-Year Work Plan

Objectives	Targets	Activities	Budget (\$)
<b>Objective 1: Facilitation</b>	<ul style="list-style-type: none"> <li>• An improved TB vaccine to:               <ul style="list-style-type: none"> <li>• provide long-lasting primary protection</li> <li>• prevent disease in individuals already infected</li> </ul> </li> <li>• Stimulate and support the study of 5 – 10 vaccine candidates in phase I/II trials by 2005.</li> <li>• Launch phase III efficacy trials of at least one TB vaccine candidate by 2007</li> </ul>	<ul style="list-style-type: none"> <li>• Pre-clinical evaluation of vaccine candidates</li> <li>• Preparation of clinical evaluation of candidate vaccines and correlates of protection</li> <li>• Validation and distribution of standardized reagents</li> <li>• Coordination of fast-track transition of vaccine candidates from academia to industry</li> </ul>	<b>3,400,000</b>
<b>Objective 2: Advocacy and Information</b>		<ul style="list-style-type: none"> <li>• Advocacy and establishment of an information resource centre</li> </ul>	<b>700,000</b>
<b>Objective 3: Coordinate Activities</b>		<ul style="list-style-type: none"> <li>• Planning and coordination by working group and ad hoc task forces</li> </ul>	<b>400,000</b>
<b>TOTAL</b>			<b>4,500,000</b>

## Working Group on TB Vaccine Development

### 2002 Annual Plan

Activities	Budget (\$)	Funding (\$)	Resource Gap (\$)
<p><b>Objective 1: Facilitation</b></p> <ul style="list-style-type: none"> <li>• Establish a primate TB vaccine testing network</li> <li>• Identify potential clinical phase III testing sites</li> <li>• Vaccino-economic analysis and cost-effectiveness modelling</li> <li>• Coordinate/build international consensus on standardized reference reagents. Support development and distribution.</li> </ul>	<p><b>850,000</b></p> <p>400,000</p> <p>250,000</p> <p>50,000</p> <p>150,000</p>	<p><b>250,000</b></p> <p>100,000</p> <p>100,000</p> <p>0</p> <p>50,000</p>	<p><b>600,000</b></p> <p>300,000</p> <p>150,000</p> <p>50,000</p> <p>100,000</p>
<p><b>Objective 2: Advocacy and Information</b></p> <ul style="list-style-type: none"> <li>• Develop a comprehensive advocacy and information strategy for new TB vaccines</li> </ul>	<p><b>200,000</b></p>	<p><b>50,000</b></p>	<p><b>150,000</b></p>
<p><b>Objective 3: Coordination of Activities</b></p> <ul style="list-style-type: none"> <li>• Annual meeting of the working group</li> <li>• Ad hoc meetings of preclinical and clinical task forces</li> </ul>	<p><b>100,000</b></p>	<p><b>50,000</b></p>	<p><b>50,000</b></p>
<b>TOTAL YEAR 2002</b>	<b>1,150,000</b>	<b>350,000</b>	<b>800,000</b>

## Working Group on TB Vaccine Development

### 2003 Annual Plan

Activities	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Facilitation</b> <ul style="list-style-type: none"> <li>• Establish a primate TB vaccine testing network</li> <li>• Validate primate testing facilities</li> <li>• Establish network of potential phase III clinical testing sites</li> <li>• Build capacity for clinical testing of vaccine candidates</li> <li>• Develop Points-to-Consider document for clinical trial protocols</li> <li>• Coordinate/build international consensus on standardized reference reagents.</li> <li>• Identify available GMP manufacturing capacity for pilot lots of vaccine candidates</li> <li>• Coordinate/facilitate transition of potential candidates from academia to private sector, as appropriate and necessary</li> </ul>	<b>1,050,000</b> 100,000 300,000 100,000 200,000 50,000 150,000  50,000  100,000	<b>200,000</b> 50,000 50,000 50,000 0 0 50,000  0 0	<b>850,000</b> 50,000 250,000 50,000 200,000 50,000 100,000  50,000  100,000
<b>Objective 2: Advocacy and Information</b> <ul style="list-style-type: none"> <li>• Develop a comprehensive advocacy and information strategy for new TB vaccines</li> </ul>	<b>150,000</b>	<b>50,000</b>	<b>100,000</b>
<b>Objective 3: Coordination of Activities</b> <ul style="list-style-type: none"> <li>• Annual meeting of the working group</li> <li>• Ad hoc meetings of task forces</li> </ul>	<b>100,000</b>	<b>50,000</b>	<b>50,000</b>
<b>TOTAL YEAR 2003</b>	<b>1,300,000</b>	<b>300,000</b>	<b>1,000,000</b>

## Working Group on TB Vaccine Development

### 2004 Annual Plan

Activities	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Facilitation</b> <ul style="list-style-type: none"> <li>• Validate primate testing facilities</li> <li>• Build capacity for clinical testing of vaccine candidates</li> <li>• Develop adult immunization strategy</li> <li>• Coordinate fast-track transition of vaccine candidates from academia to industry</li> <li>• Identify and support development of needed GMP manufacturing capacity</li> </ul>	<b>750,000</b> 100,000 300,000 150,000 150,000 50,000	<b>100,000</b> 50,000 50,000 0 0 0	<b>650,000</b> 50,000 250,000 150,000 150,000 50,000
<b>Objective 2: Advocacy and Information</b> <ul style="list-style-type: none"> <li>• Develop a comprehensive advocacy and information strategy for new TB vaccines</li> </ul>	<b>150,000</b>	<b>50,000</b>	<b>100,000</b>
<b>Objective 3: Coordination of Activities</b> <ul style="list-style-type: none"> <li>• Annual meeting of the working group</li> <li>• Ad hoc meetings of task forces</li> </ul>	<b>100,000</b>	<b>50,000</b>	<b>50,000</b>
<b>TOTAL YEAR 2004</b>	<b>1,000,000</b>	<b>200,000</b>	<b>800,000</b>

## Working Group on TB Vaccine Development

### 2005 Annual Plan

Activities	Budget (\$)	Funding (\$)	Resource Gap (\$)
<b>Objective 1: Facilitation</b> <ul style="list-style-type: none"> <li>• Capacity building for clinical testing of vaccine candidates</li> <li>• Coordination of fast-track transition of vaccine candidates from the academic/industrial interface</li> <li>• Building awareness among national TB control staff</li> <li>• Building in-country infrastructure for monitoring and ethical review of clinical trials</li> </ul>	<b>750,000</b> 300,000 150,000  100,000 200,000	<b>100,000</b> 50,000 0  0 50,000	<b>650,000</b> 250,000 150,000  100,000 150,000
<b>Objective 2: Advocacy and information</b> <ul style="list-style-type: none"> <li>• Develop a comprehensive advocacy and information strategy for new TB vaccines</li> </ul>	<b>200,000</b>	<b>50,000</b>	<b>150,000</b>
<b>Objective 3: Coordination of Activities</b> <ul style="list-style-type: none"> <li>• Annual meeting of the working group</li> <li>• Ad hoc meetings of task forces</li> </ul>	<b>100,000</b>	<b>50,000</b>	<b>50,000</b>
<b>TOTAL YEAR 2005</b>	<b>1,050,000</b>	<b>200,000</b>	<b>850,000</b>

## ANNEX 3 COUNTRIES INCLUDED IN THE GPSTB ANALYSIS

### High-burden and low- and lower-middle income countries(1)

Clusters	All low- and lower-middle income countries, excluding 22 High-Burden Countries		22 High-Burden Countries
Sub-Saharan Africa	45	Angola, Benin, Botswana <sup>(2)</sup> , Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo, Côte d'Ivoire, Djibouti, Eritrea, Gambia, Ghana, Guinea, Guinea-Bissau, Guinea (Equatorial), Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique (b), Namibia, Niger, Rwanda, Sao Tome & Principe, Senegal, Sierra Leone, Somalia, Sudan, Swaziland, Togo, Zambia	Congo DR, Ethiopia, Kenya, Nigeria, Uganda, South Africa, Tanzania (United Rep. of), Zimbabwe
Middle East & Northern Africa	12	Algeria, Egypt, Gaza & West Bank, Iran, Iraq, Jordan, Libya, Morocco, Syria, Tunisia, Turkey, Yemen	
Eastern Europe and the Newly Independent States	19	Albania, Armenia, Azerbaijan, Belarus, Bosnia-Herzegovina, Bulgaria, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Macedonia, Moldova, Romania, Tajikistan, Turkmenistan, Ukraine, Uzbekistan	Russian Federation
Latin America & the Caribbean	19	Belize, Bolivia, Colombia, Costa Rica, Cuba, El Salvador, Ecuador, Guatemala, Guyana, Haiti, Honduras, Jamaica, Nicaragua, Paraguay, Dominican Republic, St. Vincent & Grenadines, Suriname	Brazil, Peru <sup>(3)</sup>
Asia	19	Bhutan, Korea (DPRK), Laos, Maldives, Mongolia, Nepal, Papua New Guinea, Sri Lanka	Afghanistan, Bangladesh, Cambodia, China, India, Indonesia, Myanmar, Pakistan, Philippines, Thailand, Viet-Nam
<b>Total</b>	<b>114</b>	<b>92</b>	<b>22</b>

(1) Countries are grouped as shown only for the purpose of the GPSTB economic analysis.

(2) Botswana had a GNP/capita of \$3,240 per year in 1999. However, it was included in the present evaluation given the very high burden of TB in the country (the highest incidence rate in the world as of 2000 with approximately 7% of its population being dually infected by MTB and HIV).

(3) Mozambique joined the 22 HBC list in 2001, replacing Peru. However, cost estimates used for the GPSTB are based on the list for the year 2000, which included Peru but not Mozambique.

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