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Stop TB Partnership

Annual Report

2005

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List of abbreviations

Acquired immunodeficiency syndrome (**AIDS**)
Advocacy, Communication and Social Mobilization (**ACSM**)
Antiretroviral (**ARV**)
Antiretroviral treatment (**ART**)
Bacille Calmette-Guerin (**BCG**) vaccination
Canadian International Development Agency (**CIDA**)
Centers for Disease Control and Prevention (**CDC**)
Communication for Behavioural Impact (**COMBI**)
Department for International Development (**DFID**)
Direct Procurement Service (**DPS**)
Disability Adjusted Life Years (**DALYs**)
DOTS Expansion Working Group (**DEWG**)
Green Light Committee (**GLC**)
Global Fund to Fight AIDS, Tuberculosis and Malaria (**GFATM**)
Global Drug Facility (**GDF**)
Good medical practice (**GMP**)
Human immunodeficiency virus (**HIV**)
Human resource development (**HRD**)
Intensified Support and Action in Countries (**ISAC**)
Interagency Procurement Services Office (**IAPSO**)
Joint United Nations Programme on HIV/AIDS (**UNAIDS**)
Management Sciences for Health (**MSH**)
Multi-Drug Resistant TB (**MDR-TB**)
National tuberculosis programmes (**NTPs**)
Nongovernmental organizations (**NGOs**)
People Living with HIV/AIDS (**PLWHA**)
President's Emergency Plan for AIDS Relief (**PEPFAR**)
Public-Private Mix (**PPM**)
Public Service Announcement (**PSA**)
Strategic Communication Initiative (**SCI**)
Subgroup for laboratory capacity strengthening (**SLCS**)
Tuberculosis (**TB**)
Tuberculosis and HIV (**TB/HIV**)
Tuberculosis Coalition for Technical Assistance (**TBCTA**)
United Nations Millennium Development Goals (**MDGs**)
United States Agency for International Development (**USAID**)
Working groups (**WGs**)
World Health Organization (**WHO**)

Executive summary

During 2005, the Stop TB Partnership continued to work towards the goal of eliminating TB as a public health problem and obtaining a world free of TB. Through a dynamic network of international organizations, national governments, donors and non-governmental organizations that share this goal, the Partnership strengthened its reputation as an effective force in global TB control.

The major achievement of the Stop TB Partnership in 2005 was the development of the *Global Plan to Stop TB (2006-2015),* a blueprint for TB control over the coming decade. This landmark achievement was the result of intense work by the Partnership's Working Groups and all of its partners and is underpinned by the new Stop TB Strategy of WHO. The Global Plan and the new Stop TB Strategy were both endorsed by the Coordinating Board of the Partnership.

Advocacy, communications and social mobilization (ACSM) and resource mobilization remained at the core of the Partnership's activities. Coordinating Board delegations undertook a number of important advocacy missions on behalf of the Stop TB Partnership including Jakarta (Indonesia), Ottawa (Canada), Addis Ababa (Ethiopia), Maputo (Mozambique), Gaborone (Botswana), Rome (Italy) and Brasilia/Rio (Brazil).

The partnership provide technical assistance to support the preparation of robust funding requests for the 5th round of the GFATM. All twenty two countries whose TB proposals were approved received technical assistance from Stop TB partners. The total two year amount approved was nearly US$200 million, including $35 million specifically for ACSM activities.

Overall, available resources for TB control globally and in the 22 High Burden Countries increased for the fifth consecutive year in parallel with intensified media promotion, parliamentary outreach and stakeholder mobilization including efforts to engage donors on a long term basis. Multi- year agreements with donors for more than US$100 million were signed during 2005 giving the Secretariat increased operational stability.

The Partnership is building a broad network of partners at the global, regional and national level through stronger collaboration and cooperation. As a result, the total number of Stop TB partners increased from approximately 303 in 2004 to 460 in 2005.The Partnership's seven Working Groups continued to innovate and push the boundaries in delivering existing interventions to Stop TB and in the search for new methods and tools for TB control, with real progress made in the areas of diagnostics, drugs and vaccines.

The Global Drug Facility (GDF) built on its reputation as a unique and highly successful initiative. During 2005, the GDF approved 2 million affordable, quality-assured treatments taking the total cumulative number of anti-TB treatments procured by GDF to 6.5 million by the end of the year. Annual GDF procurement for grants was a record US$ 28 million.

During 2005, the Partnership strengthened efforts to streamline its operating costs and financial and reporting mechanisms. The total income of the Partnership was US$34.4 million which represented a 44 % increase over 2004 (US$23.9 million). Of the total cash contributions received in 2005, around US$ 30 million were channeled through the new Stop TB Partnership Trust Fund at WHO. Contributions in-kind increased from US$844,000 to US$3.32 million. The Secretariat biennial work plan for 2006-2007 totaling US$90.7 million (previous biennium US$40 million) was prepared and approved by both its Coordinating Board (CB) and WHO.

A major challenge facing the Partnership is the implementation of the Global Plan. Through mobilization of the financial, human, and physical resources required to realize the targets set out in the Plan, monitoring the plan and keeping the Business model of the Partnership in line with the environment in which it operates, the Partnership hopes to reach all of its targets.

1. Introduction

In 2005, the Stop TB Partnership consolidated and streamlined its structure and operations to become an effective global force in TB control. The Partnership developed the *Global Plan to Stop TB (2006-2015)*, a comprehensive assessment of the action and resources needed to implement the Stop TB strategy and make an impact on the global TB burden. It also successfully launched the Advocacy, Communication and Social Mobilization (ACSM) Working Group, and secured long term funding from a core group of key donors. There was strong evidence to indicate that the Stop TB Partnership is making a real difference in the fight against TB. The Partnership's Secretariat continued to provide high-quality professional support to its partners bringing them together to focus on a coherent global TB control approach namely the new WHO Stop TB Strategy. What follows is an overview account of the major achievements of the Partnership during 2005 in the following areas:

- **Governance and planning**
- **Partner coordination**
- **Advocacy, communications and social mobilization**
- **Working groups**
- **Global Drug Facility**
- **General management**.

2. Governance and planning

Continuing improvements to governance structures and mechanisms were the key drivers of the Partnership's success during the year.

Major areas of work in 2005 included:

1. facilitating technical and logistics support for the bi-annual meetings of the Stop TB Partnership **Coordinating Board (CB);**
2. developing the **Global Plan to Stop TB (2006-2015);**

Coordinating Board

The Coordinating Board is the governing body of the Stop TB Partnership and meets twice yearly.

- At the 8th Coordinating Board meeting in Addis Ababa, Ethiopia, a blueprint for intensified efforts to control TB in Africa was adopted within the context of strategic issues for the development of the *Global Plan to Stop TB (2006-2015)*. Members agreed upon a strategy to promote engagement with world leaders and the European Union through a series of high-level missions and advocacy activities. as well as the establishment of a Coordinating Board Task Force to ensure follow-up and effectiveness. Consensus was also reached on the framework for the new Stop TB Strategy and an application for ISO certification by the GDF.
- At the 9th Coordinating Board meeting in Assisi, Italy, a new chair was elected and Chair Emeritus was appointed. The strategy for the launch and dissemination of the *Global Plan to Stop TB (2006-2015)* was adopted while the decision was taken to expand the scope of resource mobilization to fund the Global Plan. The GDF Strategic Plan for 2006-2015 was endorsed and approval given for the inclusion of diagnostic kits in the GDF catalogue. A mechanism to coordinate the partnership's technical assistance and monitoring and evaluation capacity was approved along with a plan of action on special TB interventions in Europe, the Secretariat biennium work plan (2006-2007) and, an International Standard of TB Care and Patients' Charter. The Annual Stop TB Partnership Kochon Prize was established.
- During 2005, Coordinating Board delegations undertook a number of important advocacy missions on behalf of the Stop TB Partnership including Jakarta (Indonesia), Ottawa (Canada), Addis Ababa (Ethiopia), Maputo (Mozambique), Gaborone (Botswana), Rome (Italy) and Brasilia, Rio (Brazil).

The Global Plan to Stop TB (2006-2015)

The high-profile media launch in January 2006 of the *Global Plan to Stop TB (2006-2015)*, a blueprint for TB control over the next decade, was the result of an intense period of work for the Partnership during 2005. Each of the Partnership's seven Working Groups contributed to the Global Plan under the over-all guidance of a steering committee and the Coordinating Board. The resulting document was

reviewed through a web-based public consultation. The Plan sets out the resources needed to achieve the Partnership's targets by 2015 and is a key stepping stone to the elimination of TB as a global public health problem by 2050. The Plan is underpinned by sound epidemiological analysis with robust budget estimates for planned activities. The Plan promotes long-term planning at regional and country level. The total cost of the Plan is US$56 billion with an estimated US$25 billion likely to be available based on current soft pledges. In the coming years the Partnership will work with national governments and donors to fill the funding gap of US$31 billion.

3. Partner coordination

The Secretariat brings together a wide range of partners and plays a central coordinating role as an advocate and facilitator of activities around the world. In line with its institutional structure, the Secretariat continued to build and coordinate a broad network of partners at the global, regional and national level.

During 2005 the major objectives in this area included:

1. **reaching out to new partners** and **engaging** them in Stop TB Partnership activities;
2. establishing and expanding **regional and national partnerships;**
3. providing assistance to the **Network for Action on TB and Poverty**.

Partner outreach

The Secretariat acts as a bridge between partners around the world by bringing together the technical expertise and resources needed to achieve the common goal of eradicating TB. In 2005, the Partnership expanded from approximately 303 partners in 2004 to more than 460 in 2005 as shown in **Table 1A**. A summary classification of partners according to country is shown in **Table 1B**. Of these, 60% are non-governmental organizations (NGOs), 12% are government organizations, with the remaining 27% made up of academic institutions, businesses, individuals and others.

TABLE 1: Classification of partners of the Stop TB Partnership

A: By type

Organization Type	Count
Academic Institution	48
Donor Organization	4
For-profit Corporation	30
Governmental Organization-Donor	6
Governmental Organization-Technical	34
Intergovernmental Organization	13
Non-governmental Organization-Foundation	51
Non-governmental Organization-General	198
Non-governmental Organization-Network	45
Other	34
Total	**463**

B. By Country:

Country	Partner
United States	82
India	75
Pakistan	34
Nigeria	25
United Kingdom	19
Ghana	13
Indonesia	11
Kenya	11
Netherlands	11
South Africa	11
Switzerland	10
Bangladesh	10

Canada	9
Other (Countries with < 8 partners)	142
Total	**463**

Regional and national partnerships

The Secretariat places particular emphasis on supporting and strengthening partnerships to build up national TB control capacity in countries. In 2005, national partnerships were launched in Peru and in the Islamic Republic of Iran, joining established national partnerships in Brazil, Canada, Italy, Mexico, Pakistan and Uganda. Efforts continued to promote national-level partnerships that reach beyond the traditional National Tuberculosis Programmes (NTPs) and their immediate partner agencies.

4. Advocacy, communication and social mobilization

The focus during the year was on three major objectives:

1. Boosting political commitment and financial resources for global TB control through **intensive and sustained media promotion, parliamentary outreach and stakeholder mobilization** in the run up to the launch of the *Global Plan to Stop TB (2006-2015)* in January 2006.
2. Providing technical assistance to NTPs for **leveraging multilateral and bilateral funding resources to support communication and social mobilization activities**. Including assisting countries to draft robust funding requests for the 5th round of the GFATM which resulted in nine out of the thirteen countries submitting ACSM proposals and securing US $35 million over two years for ACSM activities.
3. **Strengthening the Advocacy, Communication and Social Mobilization Working Group** (ACSM-WG) and promoting advocacy, communication and social mobilization among countries with high TB rates.

Global, regional and national advocacy and communication

The Partnership continued to build media networks at all levels to increase coverage of TB as a priority health issue. Highlights of global media and political advocacy activities in 2005 are shown in Box 1. Several major initiatives were supported by the Stop TB Partnership Secretariat in 2005, including:

- the launch of an intensive **Strategic Communication Initiative for TB** which seeks to enhance effective ACSM interventions at national and sub-national levels as a means to accelerate TB case detection and improve treatment compliance.
- the launch of the **TB Media Fellowships** project, a collaborative initiative with the Global AIDS Programme of the Panos Institute to enhance the commitment and capacity of journalists in key countries to provide sustained reportage of TB as a major health and development issue.
- a programme of **capacity building activities** to assist TB vulnerable countries to identify ACSM needs, including two regional workshops, one in Moscow and one in Bolivia to inventory national ACSM activities, assess needs for technical assistance and generate input for regional ACSM work plans.
- production of a number of **tools and information materials** for country level communication including an introductory primer on ACSM and a needs assessment primer.
- the launch of the Stop TB e-forum, housed by HD Net and funded through the Secretariat, an interactive platform for open discussion of critical TB issues with a subscribers list of 7500 participants in dozens of countries around the world. The e-forum is hosted and moderated by Health and Development Networks.
- a partnership was established with the **Norwegian Association of Heart and Lung Patients** to identify and initiate activities that can increase empowerment and involvement of patients and their affected community in the fight against TB.

Key highlights of global advocacy activities in 2005

The Secretariat catalysed and coordinated a series of major initiatives to sustain the ongoing TB advocacy campaign, including:

- Production of press and audiovisual materials for World TB Day 2005, and

organization of high-profile media events in four G8 capitals -- London, Ottawa, Paris and Tokyo -- which highlighted the work of the Global Drug Facility and the annual WHO Global TB Control Report and generated broad coverage globally.

- A press conference at the Stop TB Coordinating Board meeting in Addis Ababa in May 2005 focusing on the Blueprint for Africa to address the regional TB crisis.
- Execution of a comprehensive plan to support the declaration of TB as a regional emergency by the WHO Regional Committee for Africa at it annual meeting in Maputo, Mozambique in August 2005. The plan, included production of a special on-site exhibit, preparation and distribution of press and audiovisual materials, and advance briefings for selected journalists, resulting in unprecedented media coverage that included headline reports by BBC World Service and domestic service, CNN, Reuters TV, TV5, more than 12 wire services and hundreds of newspapers.
- Preparation of a coordinated series of global events for the launch of the *Global Plan to Stop TB (2006-2015)* on 27 January 2006 at the World Economic Forum in Davos, Switzerland, including: production of a special information pack on the Global Plan for advocates and media; recruitment of high-profile "champions" to launch the Plan including Gordon Brown, Stephen Lewis, Kenneth Kaunda and Vladimir Shakhrin; and organization with partners of satellite launch events in London, Moscow, Nairobi, Ottawa, Paris, and Washington DC.
- Participation in and support for the ACTION project, a new multiyear initiative with WHO and civil society partners to scale up strategic TB advocacy activities in key donor countries.

Information products

The Secretariat and its partners continued to develop a variety of information products both on and off-line to raise awareness and promote knowledge sharing. Expanding the use of Information Technology (IT) was a key theme for the Secretariat in 2005. A significant amount of new content was added to the Stop TB Partnership website during the year while several e-forums were launched to promote public engagement and collaboration in the TB debate. Subscriptions to the online mailing list rose 25% while general web traffic to the site doubled on the previous year. At the Secretariat's headquarters many internal information systems were strengthened to improve work flow efficiency. The Partner's Directory was upgraded while archives were created to preserve institutional memory.

5. Working groups

Progress of the Stop TB Partnership towards the targets of 2015 is principally driven by the activities of its seven Working Groups whose commitment to implementing currently available interventions, cutting-edge technical research, and innovation in TB control is a key factor in its success. During 2005, the Secretariat and WHO continued to support the Working Groups and provide financial assistance to them. Of note was the first Joint Meeting of the Stop TB DOTS Expansion, TB/HIV and DOTS-Plus for MDR-TB Working Groups which was held in Versailles and Paris from 15 to 18 October. This meeting successfully convened over 400 people to jointly plan approaches to implementing the new Stop TB Strategy and Global Plan to Stop TB (2006-2015).

All Working Groups contributed to key elements of the *Global Plan to Stop TB (2006-2015)* specifically, 1) regional scenarios (projected impact and costs of planned activities); 2) the strategic plans of the Working Groups.

The DOTS Expansion Working Group (DEWG) – advises on DOTS expansion within health systems, and encourages partners to increase TB control efforts in countries so that more people have access to DOTS. The group has made a significant contribution to improving case-detection and treatment success rates in line with the global TB targets of 70% case detection and 85% treatment success. Efforts to support the acceleration of DOTS expansion and increase case detection have included expansion of the PPM approach (involving all health care providers) and strengthening human resources and laboratory capacities to ensure access to reliable and high-quality diagnosis, treatment and care.

Highlights of the year were:

- Supporting the preparation of the International Standard of TB Care for Care Providers. Work is ongoing for the adoption of the standards by national medical societies for promotion among members.
- Supporting the formulation of the Stop TB Strategy, this evolved from the successfully expanded DOTS Strategy. The new strategy keeps DOTS as a foundation with components to tackle TB/HIV, MDR-TB, strengthening of health systems, engagement of all health care providers, community and patients' empowerment and promotion of research for new diagnosis, treatment and vaccines.
- Extensive work to prepare the DEWG strategic plan including regional scenarios that form the backbone of the *Global Plan to Stop TB (2006-2015)*.
- DEWG, TB/HIV and DOTS-plus MDR-TB working groups jointly organized a meeting in Versailles and Paris (France) in October 2005 to discuss the new strategy, the plans of different working groups, how to organize activities to address all components of the strategy and the implementation of the *Global Plan to Stop TB (2006-2015)*.
- The third meeting of the Public-Private Mix (PPM) DOTS for TB control subgroup was held in Manila, the Philippines and made recommendations[1] to both the DEWG and to National TB Programmes (NTPs) on how to scale up interventions to engage all health care providers and improve access to DOTS. This sub-group contributed to a WHO document which provides guidance to NTPs on how to implement PPM DOTS activities.
- The meeting of the Childhood TB subgroup was held in conjunction with the joint DEWG, TB/HIV and DOTS-plus working groups meeting. During the meeting guidelines for NTPs were finalized, a new prescribed dose of Ethambutol was agreed, research priorities were reviewed and child-friendly formulations of anti-TB drugs were promoted.
- The strategy for strengthening TB laboratories started to be implemented. Laboratory assessments took place in eight countries, training for heads of national reference laboratories took place in Egypt and training materials were standardized.
- The Secretariat continued to support the Network for Action on TB and Poverty which aims to bring together TB control and poverty experts to identify synergies for more coordinated action in support of countries and the poor. During the year, the network launched a new TB and Poverty website and commissioned a study of the experience of Malawi's National TB Programme incorporating pro-poor approaches in its delivery of services. A new publication on addressing poverty in TB control and options for national TB control programmes [1] which provides strategic guidance and direction on pro-poor approaches to TB control was published during the year. At the end of 2005, the Partnership's TB and Poverty subgroup and partners met to further develop the roadmap to expand access to TB services for poor constituents. As a result, a TB and Poverty Action Plan will be referred to the Stop TB Coordinating Board for endorsement in 2006.

The Working Group on DOTS-Plus for Multi-Drug Resistant TB (MDR-TB) aims to produce feasible, effective and cost-effective approaches to the prevention and management of MDR-TB. During 2005, its efforts focused on developing new guidelines for MDR-TB management in resource-limited settings, producing the Strategic Plan of the Working Group for 2006-2015, refining a guide to policy-making in management of drug resistant tuberculosis and submitting manuscripts on feasibility and cost-effectiveness of MDR-TB pilot projects to peer reviewed journals. The main achievements were:

- New projects for management of MDR-TB were approved for six countries and existing projects were expanded. As of December 2005, there were 47 projects for management of MDR-TB with a total cohort size of 12 215 MDR-TB patients in 29 countries.
- Manuscript reporting results from the first five GLC-approved projects was submitted to a peer-reviewed journal. These results show that MDR-TB management is feasible and adverse events manageable in resource-limited settings while treatment outcomes match those in wealthier settings.
- As part of the pre-qualification of manufacturers of second-line drugs, nine manufacturers applied, 14 dossiers were submitted for assessment, and three inspections took place. The

[1] (WHO/HTM/STB/2005.352),

production plants of two manufacturers of second-line drugs have been approved, though as yet no products have been purchased.

- A plan for convergence of the drug procurement unit of the GLC mechanism with the Global Drug Facility (GDF) was agreed for implementation in 2006.
- Advice to WHO has enabled the production of new WHO Guidelines for the management of drug-resistant tuberculosis. These guidelines will be in print in 2006.
- Through assistance to countries, several high TB and MDR-TB burden countries were approved for MDR-TB management in the 5th round of the GFATM including China, Bangladesh, Indonesia and several countries of the former Soviet Union.
- Important modifications to the governance of the Working Group were introduced: drug resistance was included in the TORs of the Group, the Core Group was expanded with representatives of the community and the acting chair, Dr Thelma Tupasi was confirmed.
- The first training for consultants on MDR-TB management was conducted at the newly established WHO Collaborating Centre for MDR-TB Control in Riga, Latvia
- The guidelines to conduct surveys on resistance to TB drugs were revised, and new surveys were conducted in several high priority countries such as India, Russia and China.

The TB/HIV Working Group works to reduce the global burden of HIV-related TB through effective collaboration between TB and HIV programmes and communities, and evidence-based collaborative TB/HIV activities. It also facilitates the sharing of experience and disseminates lessons learnt in order to accelerate the implementation of collaborative TB/HIV activities. During 2005, the group continued to monitor and promote country-level implementation of collaborative TB/HIV activities and the development of a sound evidence base, together with responsive policies to provide quality care for HIV-infected TB patients. Advocacy efforts to increase the visibility of TB, particularly within the HIV/AIDS community, were also carried out.

Key achievements were:

- In collaboration with WHO's Stop TB Department and Department of HIV/AIDS and the UNDP/UNICEF/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR), the Working Group convened an Expert Consultation on TB/HIV Research Priorities in Resource-limited Settings and defined TB/HIV research priorities.
  In close collaboration with the DOTS Expansion Working Group, it initiated ongoing policy discussions to improve current practices in the diagnosis of TB particularly in people living with HIV.
- A comprehensive training strategy, with the necessary materials, has been developed for training TB and HIV managers globally. Approximately 130 participated in at least six international training courses held in Ethiopia, Italy, Jamaica, Thailand and France. Coordination and collaboration with the Integrated Management of Adult Illness (IMAI) team in the WHO HIV Department is ongoing

- The mechanism to monitor the implementation of collaborative TB/HIV activities was strengthened and information on TB/HIV activities was collected as part of the WHO annual TB report. Of all countries in the world, 106 indicated that they were at least starting to implement a policy of offering HIV testing and counselling to all TB patients. Of the 41 countries that were sent an extended questionnaire, 32 provided data for all three years from 2002 and 2004 and among these TB/HIV collaboration improved steadily. The number of countries that had a TB/HIV focal person in the NTP increased to 23 and the number that had a policy of referring HIV-positive people to TB clinics and carrying out intensified case-finding rose. The number of countries that had a policy of providing HIV treatment and care, CPT and ART for HIV positive TB patients grew between two or three times over the 2004 baseline.

The Working Group on New TB Diagnostics coordinated by the Foundation for Innovative New Diagnostics (FIND) and the Special Programme for Research and Training in Tropical Diseases (WHO-TDR), facilitates the development of priority diagnostic tools for TB control. The vision of the Working

Group is to develop and introduce cost-effective and appropriate new diagnostic tools that will contribute towards improved control of the global TB epidemic and achieving quality of patient care.

Key achievements include:

- WHO-TDR completed a head-to-head laboratory based evaluation of 19 commercially available rapid serologic tests for TB.
- In September 2006, the DOTS Expansion Laboratory Sub-group Secretariat, the TB-HIV Working Group Secretariat, WHO-TDR and FIND jointly organized two parallel expert meetings/consultations on improving the diagnosis of TB through i) optimizing smear microscopy and ii) addressing the diagnostic challenge posed by smear negative TB in high HIV and resource constrained settings.
- A collaboration amongst several working group members and partners (University of California, Francis J Curry National Tuberculosis Centre, WHO-TDR, FIND and the WHO STOP TB Department) resulted in the submission of articles to the *Lancet Infectious Diseases* monthly journal, submission of recommendations to the Stop TB Partnership for improving the diagnosis of TB through optimization of sputum microscopy, and the development of a research agenda to address critical gaps in knowledge
- Expansion of the WHO-TDR TB Specimen Bank to six new, high-quality enrolment sites and replenishment of the central repository
- FIND and Biotech Laboratories announced the launch in selected markets of the FAST Plaque-Response test for rapid rifampicin resistance testing from AFB-positive sputum, and the NOA antimicrobial supplement which has been developed for use with the test to control contamination.
- Progress was made by the London School of Hygiene and Tropical medicine on a low cost 'in-house' phage test to screen TB isolates for resistance to rifampicin.
- FIND following its agreement with EIKEN Laboratories in Japan started field evaluation of the first amplification based technology which can be used at the lower levels of the public health systems.
- FIND / CREATE multi-country demonstration projects on MGIT culture systems got underway in 3 countries (Zamstar) for case detection and in four countries for drug susceptibility testing. Some 120 000 tests are expected to be completed by end 2006.
- Span Diagnostics reported further improvements of their lateral flow test for identification of *M. tuberculosis*.

The Working Group on New TB Vaccines– works to accelerate the development of an improved vaccine to provide long-lasting protection against TB. During the year, work focused on stimulating and supporting the progression of candidate TB vaccines to phase I/II clinical trials and preparations for future phase III efficacy trials. It is anticipated that 5-10 candidates will undergo phase I/II testing and one candidate will go forward to a phase III trial by 2007.
Key achievements included:

- A vaccine based on a secreted antigen (Ag85A) of *Mycobacterium (M.) tuberculosis* was developed at Oxford University and completed its initial phase I clinical evaluation in The Gambia in 2005. Another vaccine candidate that was developed by the Statens Serum Institute in Copenhagen entered a first phase I clinical trial in The Netherlands. The number of new TB vaccine candidates undergoing human testing reached four by the end of 2005. At least two more candidates are in late preclinical development.

- In 2005, the clinical trials task force worked towards the definition of immunological assays to be used in clinical trials of new TB vaccines. The task force helped to identify three consensus assays to be used in all trial sites. The regulatory task force initiated a meeting with staff from endemic country national regulators for biologicals. This resulted in the publication of a 'White Paper', identifying regulatory bottlenecks to TB vaccine development and proposing solutions for high quality regulatory review in endemic developing countries.

The Working Group on New TB Drugs is a network of more than 90 individuals committed to accelerating the development of effective and affordable new therapeutics for TB. The Working Group acts as a forum to facilitate global collaborations and discussions on the development of new TB drugs.

During the year, the members participated in several projects, gatherings and other initiatives. Major achievements included:

- Significant progress was made in advancing the global pipeline of TB drugs. An unprecedented six compounds are currently in clinical testing, paving the way for the first new TB regimen in 40 years. This robust pipeline also contains 16 discovery and five preclinical projects in development by dozens of institutions around the globe.
- The Working Group published its Strategic Plan for the next 10 years following consultation with all members. As a result of this dialogue, the Working Group adopted a ground-breaking new approach to drug development specifically early combination-testing of drug candidates to minimize delay in registering new TB regimens.
- The annual meeting of the Working Group was held on October 19, 2005 in Paris. Approximately 50 members attended the meeting which reviewed the year's activities. Attendees reviewed the 10-year plan and identified three priority activities in 2006: (1) updating the global portfolio; (2) initiating discussion on regulatory issues; and (3) assessing clinical trials capacity.
- With support from the Stop TB Partnership, the Working Group co-sponsored an annual symposium with the TB Alliance in October at the IUATLD World Conference. The symposium reviewed recent developments in the field of TB drug development and featured three Working Group members as presenters.
- Addressing a key priority identified in the Strategic Plan and at the annual meeting, the Working Group co-sponsored an Open Forum on regulatory hurdles to TB drug development on 6-7 December 2005. The Working Group Secretariat, in coordination with the TB Alliance and the Bill and Melinda Gates Foundation, helped to plan and organize the event.

The Working Group on Advocacy, Communication and Social Mobilization (ACSM-WG) was formally created during 2004. The first meeting of the ACSM-WG was organized, supported and hosted by the Stop TB Partnership Secretariat in Geneva in February 2005. The meeting attracted more than 60 participants representing all major constituencies – global advocacy partners, special CSM technical organizations, donors, national TB programs, patient communities and other WGs. The agenda included a complete day of group work in two areas: 1) global advocacy for resource mobilization, and 2) country communications and support.

The first meeting of the Advocacy, Communication and Social Mobilization Subgroup at Country Level took place in Mexico City September 2005. The meeting gathered together more than 35 participants representing a diverse cross-section of the constituencies. The meeting focused on four main areas: 1) the adoption of a 10-year strategic framework to be a compendium document for Global Plan 2006-2015; 2) examining the current state of ACSM at country level, 3) debate on the development of a technical assistance framework to support countries with strategic ACSM work plans and funded budgets and 4) ratification of the subgroup's terms of reference, governance structures and operating procedures.

The Global Drug Facility

The Global Drug Facility (GDF) is a unique initiative which aims to save 25 million lives and prevent 50 million new TB cases by 2020. The GDF offers a novel approach to expand access to, and availability of, high-quality and low cost anti-TB drugs to facilitate sustainable global DOTS expansion. The number of patient treatments approved via GDF Grant and Direct Procurement services in 2005 was 2,024,000. This raises the cumulative total of such treatments to the world's poorest people, approved via GDF services, since 2001 to 6,506,269. The GDF also promotes the standardization of treatment, such as standardized drug products to avoid the development of drug resistant TB and user-friendly packaging.

During 2005, the GDF continued to make a considerable contribution to global TB control through the three main services it offers:

- provision of first-line drugs to support DOTS expansion through approved 3-year grants to countries that are donor-dependent for some or all of their drug supply.

- a Direct Procurement Service for countries that have sufficient finances to purchase TB drugs but lack adequate procurement or quality-assurance systems
- the GDF *White List* of prequalified manufacturers of high-quality TB drugs for countries that have sufficient finances and good procurement mechanisms but lack a robust quality assurance system.

Contributions for Direct Procurement of anti-TB drugs increased to US$13.4 million from US$6.6 million in 2004. Over the course of 2005, 1.85 million quality-assured patient treatments were delivered by the GDF. Annual GDF procurement for grants stood at a record US$28 million.

The GDF Technical Review Committee (TRC) reviewed and approved 16 applications from countries for new or continued support. Outside the regular TRC meetings, 24 monitored countries were reviewed and approved for an additional year of support. The number of patient treatments approved through GDF grant and direct procurement mechanisms in 2005 was approximately 2 million, bringing the cumulative total of such treatments procured by GDF since 2001 to 6.5 million.

The GDF also further expanded its Direct Procurement Service established in 2003 to provide support to governments purchasing TB drugs with national resources. Following marketing of this service to countries, NTPs, WHO representatives, GFATM portfolio managers and others, four countries decided to take advantage of the service, raising the number of countries using the service to 25. In 2005, Direct Procurement orders were delivered for more than 575,000 patients with an approximate value of US$ 13.4 million.

As part of assessment and monitoring, the GDF carried out 7 pre-delivery country visits and 42 monitoring missions during 2005. Of the latter, 38 were in countries still in one of the three grant years, and four were conducted in Direct Procurement Service countries. Monitoring dossiers were produced and submitted to GDF partner agencies for desk audit. The total number of consultants provided by partners free of charge for GDF missions was 48.

Additionally in 2005, the GDF and Stop TB Partner Management Sciences for Health (MSH) conducted two TB drug management workshops. On 19 October 2005 at the 36th annual World Lung Health Conference in Paris over 80 participants attended a full day workshop entitled "Strengthening Medicine Supply in National TB Programmes: Practical Guidelines and Tools." A five- day workshop in drug management for GDF consultants was held in Hanoi, Vietnam from 7 to 11 November 2005.

General management

During 2005, as the demands of the Global Plan became clear, the Secretariat redesigned its management structure to better align itself to the emerging environment. This will facilitate, accountability, and encourage efficient use of resources. It will also enable the Partnership to stabilize resource mobilization activities and to strategically align available resources with its mission, goals and priorities in accordance with the following key objectives:

1. strengthening **resource mobilization** by integrating ACSM work into the resource mobilization effort;
2. developing and implementing relevant systems of **internal financial control** in line with the Partnership's adopted financial management policy and preparing periodic financial reports to underpin decision-making within the WHO's approved programme budget.
3. **systematic reporting to donors** on both technical and financial matters.

Resource mobilization

During 2005, efforts to shape a robust and effective policy dialogue with donors on the priorities and needs of the Stop TB Partnership to facilitate resource mobilization were taken to another level. Closer relationships were developed with existing donors through the submission of regular progress reports on the performance of the Secretariat during the year. Long term donor commitments totalling US$112 million were signed with a core group of donors namely CIDA, DFID, USAID and the World Bank.

The Secretariat identified work plan needs of US$40 million for the biennium 2004-2005. As a result of sustained resource mobilization efforts, the funds available to the Partnership

Secretariat over this period surpassed this amount. A work plan budget of US$90 million was approved by the Coordinating Board and WHO for the biennium 2006-2007. The Secretariat has commenced work to mobilize these resources.

Financial management

The Stop TB Partnership Trust Fund was formally set up in February 2005. It became fully operational during the year and now is the principal financing vehicle for the operations and projects of the Secretariat. The interim trust fund was closed in January 2005 and the new trust fund started receiving money from February 2005. It operates with a much reduced Programme Support Costs (PSC) of 3% for drugs and 6% for other activities, and was designed to enhance the flow of financial resources to the Partnership.

A revised and much-improved contract with the UNDP Interagency Procurement Services Office (IAPSO) for the procurement of TB control drugs was also signed. The establishment of periodical financial reporting and regular reviewing of cash positions improved internal financial control.

During 2005, the total income of the Partnership was US$34.4 million which represented a 44 % increase over 2004 (US$23.9 million).Of the total cash contributions received in 2005, around US$30 million were channeled through the Stop TB Partnership Trust Fund. Contributions in-kind increased from US$844,000 to US$3.32 million due, in part, to donations of anti-TB drugs procured for Tanzania by Novartis to the amount of US$2.6 million.

In the same period, the operating expenditure of the Secretariat was US$36.7 million which led to a deficit of US$2.3 million. This was covered by US$9 million brought forward from year 2004. Summary of income and expenditures for the year is shown in Annex I, while Annex II gives the summary statement of income, contributions for direct procurement through the Global Drug Facility.

8. Challenges and future priorities

For the future, the main challenges facing the Secretariat are the design and development of concrete steps to support the Working Groups in the implementation of the *Global Plan to Stop TB (2006-2015)*. This will require that the Secretariat's structure and processes are kept dynamically aligned to the requirements of the changing global environment. The business model of the Partnership will need to be reviewed so that this global coalition of the stakeholders is able to add value to the individual efforts of the Partners over the foreseeable future. The positioning of the GDF to meet global TB drug needs will have to be carefully assessed to understand if its products and services and the delivery modality are meeting stakeholder needs. Assisting partners to secure funds for implementing TB control activities will be a priority for the Partnership in 2006.

Annex I

Stop TB Partnership Secretariat
Financial Management Report
Statement of Income and Expenditures

For the year ending 31 December 2005
(All figures in US$'000)

	Notes	2004	2005
Voluntary Contributions in Cash			
Governments & their Agencies	1	22,042	29,859
Multilateral Organizations	2	700	700
Foundations and Others	3	286	470
Sub-total		**23,028**	**31,029**
Voluntary Contributions In-kind			
Governments	4	213	169
Multilateral Organizations, Foundations	5	631	547
In-kind Contribution for Drugs (Novartis)	6	-	2,605
Sub-total		**844**	**3,321**
Total Income		**23,872**	**34,350**
Expenditures			
Partnership	7	2,518	3211
Advocacy and Communication		1,096	929
Global Drug Facility (net of WHO professional service charge)	8	9,918	31,347
General Management and Administration	9	1,251	1,173
Total Expenditures		**14,783**	**36,660**
Surplus/(Deficit) of Income over Expenditures		**9,089**	**(2,310)**

Notes to the Financial Management Report

	2004	2005
1. Voluntary Contributions from Governments & their Agencies		
a) Global Drug Facility (GDF)		
CIDA	11,347	20,642
Norway	810	743
USAID	3,000	4,700
Sub-total	**15,157**	**26,085**
b) Partnership Secretariat		
CIDA (ISAC)	2,736	351
USA-CDC	183	182
USA-USAID	744	640
DFID	1,815	176
WHO [1]	1,407	2,425
Sub-total	**6,885**	**3,774**
Total Contributions	**22,042**	**29,859**
2. Multilateral Organizations		
World Bank	700	700
3. Foundations and Other Income		
American Lung Association	10	-
Kochon Foundation	-	100
Open Institute	-	200
RESULTS	-	170
Other income	276	-
Sub-total	**286**	**470**
4. In-kind Contributions from the Governments		
These were received in the form of services of staff and direct support to projects of Partnership Secretariat as follows:		
Netherlands	213	133
Norway	-	36
Sub total	**213**	**169**

[1] The 2005 contributions comprise contributions from Italy, the Netherlands and Switzerland. In 2004, contributions comprise unspecified donations from Australia, Germany Japan, The Netherlands, Switzerland and United Kingdom.

5. In-kind Contributions from Multilateral Organizations, Foundations and Others		
Management Science for Health for GDF ((staff service)	188	188
WHO for Partnership	443	359
Sub total	**631**	**547**
6. Novartis contribution for drugs procured for Tanzania	-	2,605
7. Partnership		
National partnership coordination	429	300
General partnership management	1,501	606
ISAC	-	1,312
Governance	100	470
Working Groups [1]	488	523
	2,518	**3,211**
8. Global Drug Facility		
This covers expenditures in the following areas:		
Procurement of TB drugs [2]	8,000	28,367
Quality assurance and prequalification	114	123
Technical Assistance monitoring and salaries	1,036	1,649
Advocacy and communications	102	57
WHO professional service charges	412	1,151
World bank service charge	254	-
Total	**9,918**	**31,347**
9. General management and administration cost		
General management & administration cost comprises of:		
Salaries	620	710
Activities	124	87
WHO professional service charge	481	376
World Bank service charge	26	-
Total	**1,251**	**1,173**

[1] In 2004 & 2005 Stop TB Partnership allocated US$1.5 million for working groups out of which the groups drawn US$1.01 million

[2] GDF expenditure does not include the direct procurement totaling 13 million which is reported in GDF statement.

Annex II

Stop TB Partnership
Global Drug Facility
Financial Management Report

Statement of Income, Contributions received for Direct Procurement and its Expenditures
For the year ending 31 December 2005
(All figures in US$'000)

	Notes	2004	2005
Income			
Governments and their Agencies – Specified		15,157	26,085
In-kind Contribution for Drugs from Novartis		-	2,605
Contributions for Direct Procurement	1	6,613	13,433
Other Income		446	188
Total Income		**22,216**	**42,311**
Expenditures			
Grant Procurement of Anti-TB Drugs		8,000	28,367
Direct Procurement		6,613	13,433
Quality Assurance and Pre-qualification		114	123
Technical Assistance, Monitoring and Salaries		1,036	1,649
Advocacy and Communications		102	57
Indirect Costs		666	1,151
Total Expenditures		**16,531**	**44,780**
Surplus/(Deficit) of Income over Expenditures	2	**5,685**	**(2,469)**

Notes:

1 Contributions for Direct Procurement were received from Afghanistan, Albania, Armenia, Azerbaijan, Bangladesh, Cote d'Ivoire, Djibouti, Ethiopia, Georgia, Indonesia, Kenya, Liberia, Micronesia, Moldova, Mongolia, Namibia, Nepal, Nigeria, Philippines, Sudan and Tajikistan

2 Deficit of income over expenditures in 2005 arose due to late remittance of pledged money. The pledge amount from DFID was received in January 2006.