Analysis of Stop TB Partnership Working Groups

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Part I: Background

The Stop TB Partnership Working groups are one of the four main components of the Stop TB Partnership together with the Partners' Forum; the Stop TB Partnership Coordinating Board; and the Secretariat.[1]

Working groups contribute significantly to the achievement of partnership aims. There are currently seven such groups with multiple subgroups - DOTS Expansion Working Group; TB-HIV Working Group; MDR-TB working group; the Global Laboratory Initiative; the Working Group on New Drugs; the Working Group on New Diagnostics; and, the Working Group on New Vaccines.[2]

The roles and mission of the Working Groups are defined as[3]:

- To implement research, advocacy and/or operational activities in pursuit of the group's specific area of interest and of the aims of the partnership.
- To collaborate with other elements of the partnership so as to create synergy and value added to actions taken in pursuit of the aims of the partnership.

Membership is open to institutions and expert individuals involved in the specific area focus of the group[4].

Request from the Coordinating Board

During the session on Financing at the 19th Stop TB Partnership Coordinating Board meeting in Johannesburg, South Africa, members of the Coordinating Board requested the Secretariat "to prepare an analysis of the working groups, including their financing and outputs, for the next Coordinating Board meeting in the Spring of 2011"[5].

The analysis should contribute to a better understanding of the current structure, resources and activities of the Stop TB Partnership Working Groups and subgroups.

It should facilitate a discussion on the future (directions) of the working groups and subgroups and resource allocations in order to best serve country needs and to reach the targets of the Global Plan to Stop TB 2011-2015 and the MDGs.

Methods

For the analysis, the Secretariat undertook a desk review of the web pages of the Stop TB Partnership Working Groups (as of 28 January 2011) and subsequently contacted the various Chairs and Secretariats to clarify:

- Structure of the working group and subgroups
- Core group members, affiliation and function within the core group

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[1] http://www.stoptb.org/about/structure.asp
[2] http://www.stoptb.org/about/structure.asp
[3] http://www.stoptb.org/about/structure.asp
[4] http://www.stoptb.org/about/structure.asp
[5] http://www.stoptb.org/assets/documents/about/cb/meetings/19/Decision%20Points%2019th%20CB%20meeting%20Johannesburg%20South%20Africa.pdf

- Terms of Reference
- Financial situation/current level of resources
- Current focus (main activities and products in 2010-2011)
- Country focus (if any special focus)
- Frequency of meetings (full working groups; subgroups, etc.)
- Advocacy activities
- Main challenges and opportunities
- Suggestions for strengthening coordination and collaboration with other working groups and subgroups

Expected outputs of the 20th Coordinating Board meeting:
During the Board meeting in the Spring 2011, the Coordinating Board members will be invited to reflect on the following **discussion points**:

- Discuss whether the current structure, terms of reference, resources, activities and outputs of the working groups are adequate to serve the needs of the Countries and people affected by TB and to reach the targets of the Global Plan to Stop TB 2011-2015 and the Millennium Development Goals.
- Provide suggestions to strengthen the Stop TB Partnership Working Groups and subgroups.
- Suggest ways to improve the coordination and collaboration between the Working Groups and subgroups in particular with respect to cross-cutting issues and outcomes.
- Suggest ways to measure performance of the Working Groups and subgroups.

The Board will be further be invited to make the following **decision**:

- Endorse the creation of a Task Force to revise the structure of the Stop TB Partnership Working Groups and subgroups linked to proper funding and to a performance mechanism.

This would have the following **financial implications**:
2011: Workplans and activities to be implemented as scheduled
2012: 1,8 million USD.

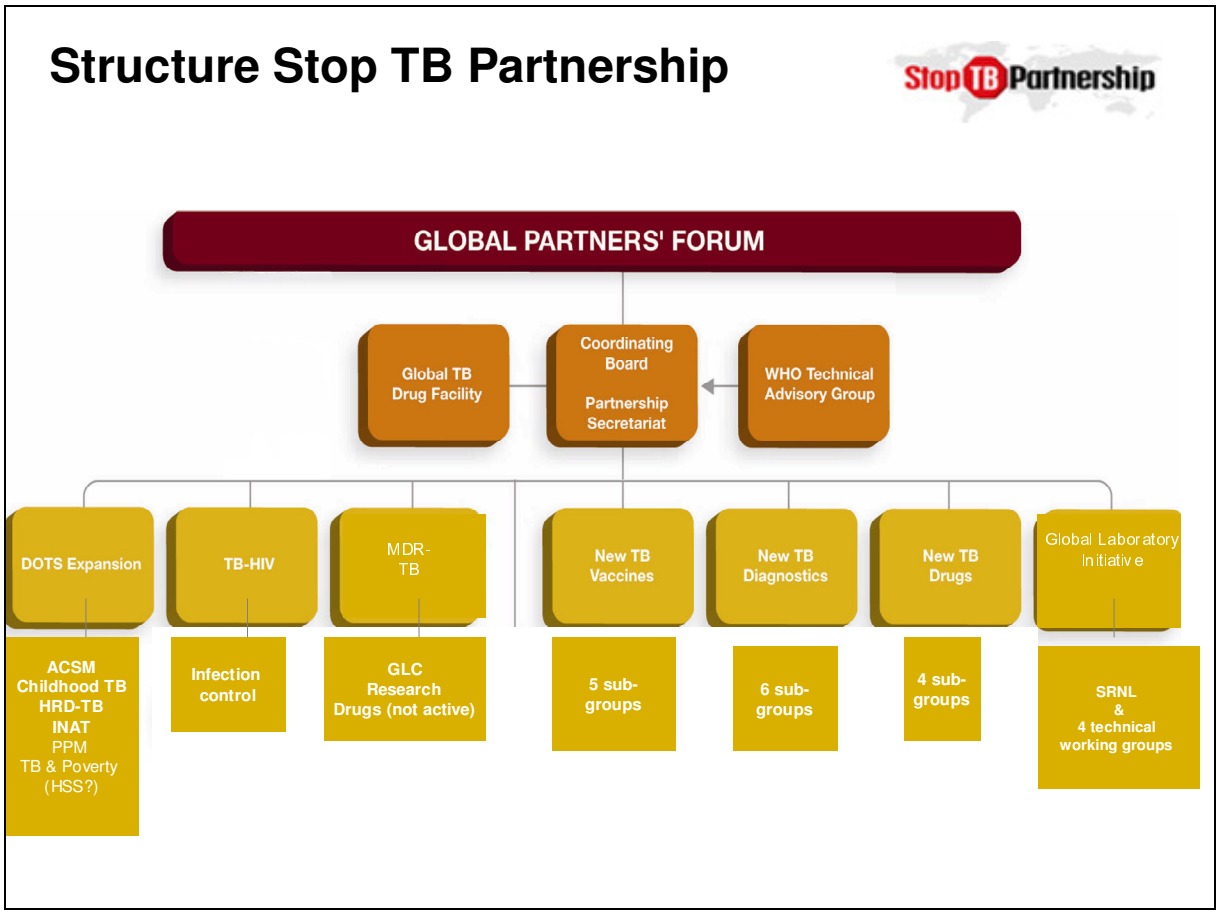
The funding for 2011 is available in the Stop TB Partnership Secretariat. For 2012-2013 new resources are to be raised.

Actions required include:
(i) to establish a Task Force; and,
(ii) To develop a new structure by the next Coordinating Board meeting in the Fall of 2011.

It will be the responsibility of the Stop TB Partnership Secretariat in close collaboration with the Chairs and Secretariats of the Stop TB Partnership Working Groups and subgroups.

Part II: Summary of response from the Stop TB Partnership Working Groups and subgroups (main findings)

Current structure: 7 Stop TB Partnership Working Groups and 20 subgroups



1. DOTS Expansion Working Group
1a. ACSM
1b. Childhood-TB
1c. Human Resources Development for TB (HRD-TB)
1d. Introduction of new approaches and tools (INAT)
1e. PPM
1f. TB & Poverty
1g. HSS (under discussion)

2. TB-HIV Working Group
2a. Infection control

3. MDR-TB Working Group
3a. Green Light Committee (2000)
3b. Research subgroup
3c. Subgroup on Drug Management (not active since 2009)

4. Global Laboratory Initiative
4a. TB Supranational Reference Laboratory Network (SRLN)

Four technical working groups (time-limited)
- Laboratory strengthening country roadmaps
- HR development and training
- Laboratory bio safety
- Laboratory accreditation

5. New TB Diagnostics subgroups (n.b. Current major restructuring from 9 to 6 subgroups!)
5a. Optimizing TB smear microscopy - discontinued
5b. Culture-based diagnostics and resistance - maintained but renamed "Drug susceptibility testing"
5c. Nucleic-acid amplification techniques for diagnosis - discontinued
5d. Diagnostics for Latent TB infection - maintained
5e. Point-of-care diagnostics for TB - maintained
5f. Evidence Synthesis for TB diagnostics - maintained but renamed "Evidence Synthesis and Policy".
5g. TB diagnostics and Poverty - maintained as cross-cutting theme and will also include "community" and "advocacy". New name: "Community, Poverty & Advocacy".
5h.TB diagnostics and HIV - discontinued
5i. Diagnostics and paediatric TB - maintained as cross-cutting theme.

6. New TB drugs subgroups
6a. Biology targets subgroup
6b. Candidates subgroup
6c. Critical knowledge and tools subgroup
6d. Clinical trials capacity subgroup

7. New TB Vaccines Working Group Task Forces (operational arms of the working group on new TB vaccines)
7a. Task Force on Harmonization of Assays for TB Vaccine Development
7b. Task Force on Clinical Research Issues in TB Vaccine Development
7c. Task Force on New Approaches to TB Vaccine Development ("out-of-the-box")
7d. Task Force on Economics and Product Profiles for new TB Vaccines
7e. Task Force on Advocacy, Communications and Social Mobilization

History
The DEWG, the TB/HIV working group, the Working Group on New Diagnostics, the Working Group on New Drugs and the Working Group on New Vaccines have been established in 2001.

The MDR-TB working group (2006) grew out of the WHO launched working group on "DOTS-Plus for MDR-TB" which was established in 1999.

GLI was established in 2008. Before 2008, there was a DEWG subgroup on laboratory capacity strengthening which was established in November 2002.

The subgroups were established:
DOTS Expansion Working Group: ACSM (2005); Childhood TB (2004); HRD-TB (2009); INAT (2010); PPM (2002); TB& Poverty (2005)
TB-HIV Working Group: TB-IC (2006)
MDR-TB Working Group: GLC (2000); Research subgroup (2006)
New Diagnostics Working Group: under restructuring (2010)
New Drugs Working Group: Biology targets subgroup (2008); Candidates subgroup (2008); Critical Knowledge and Tools subgroup (2008); and, Clinical Trials Capacity subgroup (2008)
New Vaccines Working Group: Not applicable (The subgroups called "Task Forces" are operational arms of the New Vaccines working group).

Membership
Members of Stop TB Partnership Working Groups are often from the same Stop TB Partner Organizations, donors and Countries but not necessarily the representatives of these Organizations and Countries. With respect to Countries, Working Groups are targeting NTP managers or other NTP staff, NAP managers, and laboratory representatives.

Renewal of membership up to date? Answers focused on membership of the core groups.

DEWG: the membership from HBCs is currently under review.
ACSM: elections are currently being organized to elect a new Chair.
Childhood TB: new Chair has just been elected (March 2011) and the core group under review.
HRD-TB: interim core group until October 2011.
INAT: yes up to date.
PPM: yes, PPM core group was renewed and constituted in January 2011.
TB & Poverty: Yes.

TB-HIV: Yes. TB-IC: membership in process of renewal. Expertise in general infection control and occupational health to be added and representation from high burden countries to increase.

MDR-TB: Yes. GLC: yes. Research subgroup: yes.

GLI: yes. SRLN: yes (the core group includes the heads of the 20 Supranational Reference Laboratories).

New Diagnostics Working Group : recently being updated related to major restructuring. The working group is currently in the process of planning the elections of the subgroup

coordinators and membership of the three technical platforms and the three cross-cutting themes will be updated accordingly.

New Drugs Working Group: Yes. Biology targets subgroup: yes. Candidates subgroup: yes. Critical knowledge and tools subgroup: yes. Clinical trials capacity subgroup: yes. New Vaccines Working Group: yes.

Secretariats are hosted:
DEWG: WHO Stop TB Department (TBC).
ACSM: Stop TB Partnership Secretariat (TBP).
Childhood TB: WHO Stop TB Department (TBC).
HDR-TB: WHO Stop TB Department (TBC).
INAT: WHO Stop TB Department (TBS).
PPM: WHO Stop TB Department (TBS).
TB & Poverty: The Union South East Asia Office.
TB-HIV: WHO Stop TB Department (TBS).
TB-IC: WHO Stop TB Department (TBS).
MDR-TB: WHO Stop TB Department (TBC).
GLC: WHO Stop TB Department (TBC).
Research subgroup: currently in the WHO Stop TB Department (TBC) but it will soon move to another body.
GLI: WHO Stop TB Department (TBL).
SRLN: WHO Stop TB Department (TBL).
Working Group on New Diagnostics and subgroups: FIND (previously in TDR)
Working Group on New Drugs and subgroups: Global Alliance for TB Drug Development.
Working Group on New Vaccines and subgroups: WHO Initiative for Vaccine Research with additional support provided by AERAS.

WHO TBC = Tuberculosis Operations and Coordination
TBS = Stop TB Strategy
TBL = TB Diagnostics and Lab Strengthening

Frequency of meetings?

<u>Full groups:</u>
DEWG: annual except in 2010.
ACSM: annual.
Childhood TB: Annual depending on funding.
HRD-TB: annual (conditional to the availability of funds).
INAT: annually.
PPM: annually if funding allows.
TB & Poverty: annually adjacent to the World Lung Conference.
TB-HIV: The last annual working group meeting was held in 2004. Since 2007, the working group is conducting regional meetings that are tailored to the regional specific

needs to catalyse implementation and nationwide scale up of collaborative TB-HIV activities.
TB-IC: once per year at the World Lung Conference.
MDR-TB: On average every 18 months.
GLC: Almost every two months in person.
Research subgroup: annual face-to-face meeting and teleconferences almost every two months.
GLI: Annual face to face meeting.
SRLN: annual meeting depending on availability of funds.
New Diagnostic Working Group: one a year.
New Drugs Working Group: annually.
New Vaccines Working Group: biannually

Core groups:
DEWG: at least one face to face meeting per year and quarterly conference calls.
ACSM: one per year, back-to-back with full subgroup meeting.
Childhood TB: one face to face meeting per year and a conference call every quarter.
HRD-TB: annual (conditional to the availability of funds).
INAT: 2 core group meetings per year, teleconferences held every quarter.
PPM: twice a year and teleconferences are held every quarter.
TB & Poverty: 4 teleconferences per year and a face-to-face meeting during the World Lung Conference.
TB/HIV: once a year through a face to face meeting and through electronic media as deemed necessary.
TB-IC: One face to face meeting and teleconferences as needed.
MDR-TB: Face to face meetings every four months with teleconferences in between on an ad-hoc basis.
GLC: NA.
Research subgroup: NA.
GLI: monthly teleconference calls and two face-to-face meetings per year.
SRLN: ad hoc based on activities in the four time-limited technical working groups of GLI.
New Diagnostics Working Group: one face to face meeting per year and 3-4 teleconferences. In addition, the chairs of the subgroups are meeting once a year in addition to 3-4 teleconferences.
New Drugs Working Group: quarterly and more frequently as required.
New Vaccines Working Group: Teleconferences 6-8 times per year and in-person once per year.

Total budget for biennium 2010-2011

Funds provided to the Working Groups for Biennium 2010- 2011 Year 2010 (as of January 2011)		
	Approved budget	Provided
		US$
New TB Drugs W. Group	**250,000**	125,000
New TB Diagnostics W. Group	**250,000**	125,000
New TB Vaccines W. Group	**250,000**	125,000
MDR-TB W. Group	**250,000**	250,000
TB/HIV W. Group	**300,000**	150,000
DOTS Expansion W. Group	**650,000**	325,000
GLI	**250,000**	125,000
Total Support to W. Groups	**2,200,000**	**1,225,000**

Estimated in-kind contributions (if possible):

DEWG: none declared.
ACSM: none declared.
Childhood TB: none declared.
HRD-TB: USD 70,000 (including 13% PSC) from TBCARE pending approval of the proposal. INAT: none. PPM: None declared. TB & Poverty: 50,000 USD from The Union.

TB-HIV: The terms of reference of the working group define that partner organizations should also contribute financially and in-kind for the activities of the working group. In this regard, in 2010, more than half of the participants of the regional meetings were covered by other sources. Members of the core group representing organizations (USAID, CDC, CREATE, and KNCV) contributed in sharing the cost of the activities of the working group in 2010.
TB-IC: In 2010, members of the core group (USAID, CDC, and KNCV) participated in the core group meeting at their own expense. In addition, several members of the core

group applied in 2010-2011 to other sources of funding for future activities (in particular TBCARE).

MDR-TB: none declared.
GLC: none declared.
Research subgroup: USD 350,000.

GLI: Difficult to estimate however some partners, e.g. CDC have provided significant in-kind secretariat support to the GLI working group and maintains and updates the GLI website. Staff cost: 61,650 USD: 15% P5 staff (36,900 USD) and 15% P3 staff (24,750 USD).
SRLN: WHO Stop TB Department (TBL) provides in-kind secretariat support to the SRLN subgroup of the GLI working group and co-ordinates the in-country technical assistance provided through the network. Staff costs 61,650 USD: 15% of P5 staff (36,900 USD) and 15% P3 staff (24,750 USD).

New Diagnostics Working Group: No overall figure is available, but in-kind contributions include working time of member travel costs, telecommunication cost and use of premises and equipment, which are provide by member institutions. In addition, FIND is covering 50% of the cost for staffing the Secretariat function.
Subgroup on Drug Susceptibility: working time of the four co-chairs (3-4 hours per week) and the subgroup members involved in ongoing activities.
Subgroup on Diagnostics for Latent TB infection: USD 6,000. Subgroup on point-of-care diagnostics: none declared. Subgroup on evidence synthesis for TB diagnostics: USD 10,000.
Subgroup on TB Diagnostics and Poverty, Community, and Advocacy: none declared.
Subgroup on Diagnostics and Paediatric TB: none declared.

New Drugs Working Group: 204,000 USD from TB Alliance as well as access to facilities, experts on staff, e-mail and phone services, vendors, office supplies and other logistical services; 50-65% discount from Darby Communications for website development and maintenance including blog, event capture of major meetings, video/audio interviews, and administration of online tools; estimated value of 115,000-140,555 USD worth of services for 2010-2011; 40-50 hours of pro-bono time from BLISS PR firm per 6 month contract; Advertising space on Google home page during World TB Day 2009 with over 500,000 impressions/hits from March 24 to April 17 with a value that exceeds the Working Group's ability to determine but is estimated to be upward of $500,000 USD or more; 5-10 hours per month per core team member for Working Group activities; Free access to meeting facilities due to affiliation of core team members.
In addition, the four subgroups (Biology targets subgroup; Candidates subgroup; Critical knowledge and tools subgroup; and, Clinical trials capacity subgroup) report: Access to facilities, experts on staff, e-mail and phone services, vendors, and office supplies from TB Alliance; 50-65% from Darby Communications for website development and maintenance including blog, event capture of major meetings, video/audio interviews, and administration of online tools; 5-10 hours per month of subgroup leader for

subgroup activities; Free access to meeting facilities due to affiliation of core team members.

New Vaccines Working Group: The members of the Vaccines Working Group provide support for a number of its activities. A non-exhaustive list of the financial and in-kind contributions that the Working Group has received or expects to receive in 2011 are listed below. Financial support for Working Group activities for the time period is estimated to be approximately $600,000. This funding supports the following activities:

- Funding from Aeras and the US Food and Drug Administration to conduct research on functional assays for use in TB vaccine clinical trials
- Support from Aeras for Working Group operations and activities, including staff travel to Partnership meetings and Working Group and Task Force teleconferences
- Financial sponsorship to support the Second Global Forum on TB Vaccines was received from Aeras, the Bill & Melinda Gates Foundation, TBVI, Crucell, Emergent BioSolutions, GSK Biologicals, KNCV Tuberculosis Foundation and Sanofi-Pasteur
- Financial support was also received from NIH to sponsor participants from endemic countries to attend the Second Global Forum on TB Vaccines

In addition, Working Group members provide in-kind support primarily through the contribution of staff time to Working Group activities, estimated to be approximately the equivalent of 1.5 FTE. Such support includes:

- Staff time from the WHO Initiative for Vaccine Research to serve as Secretariat
- Staff time from Aeras to support Working Group operations
- Staff time from Aeras and TBVI to coordinate the Second Global Forum on New TB Vaccines in Tallinn, Estonia and to begin coordinating the Third Global Forum on TB Vaccines
- Staff time and support from Aeras, TBVI, SATVI, KNCV Tuberculosis Foundation, and the Bill & Melinda Gates Foundation to coordinate and convene meetings to discuss key Working Group and vaccine development objectives
- Staff time from Aeras and TBVI to coordinate the development of the *Blueprint for TB Vaccine Development*
- Staff time from SATVI to support the development of a comic book on TB vaccine clinical research for use in community outreach and engagement. The Working Group provided funding for the direct costs related to development of the comic book.

Areas of focus (2010-2011)
See terms of references and activities for 2010-2011 identified by each of the groups.

Stop TB Strategy

1. Pursue high-quality DOTS expansion and enhancement - DEWG and GLI
- Secure political commitment, with adequate and sustained financing
- Ensure early case detection, and diagnosis through quality-assured bacteriology
- Provide standardized treatment with supervision, and patient support
- Ensure effective drug supply and management
- Monitor and evaluate performance and impact

2. Address TB/HIV, MDR-TB, and the needs of poor and vulnerable populations - TB/HIV, MDR-TB and DEWG
- Scale-up collaborative TB/HIV activities
- Scale-up prevention and management of multidrug-resistant TB (MDR-TB)
- Address the needs of TB contacts, and of poor and vulnerable populations

3. Contribute to health system strengthening based on primary health care - All
- Help improve health policies, human resource development, financing, supplies, service delivery, and information
- Strengthen infection control in health services, other congregate settings and households
- Upgrade laboratory networks, and implement the Practical Approach to Lung Health (PAL)
- Adapt successful approaches from other fields and sectors, and foster action on the social determinants of health

4. Engage all care providers - DEWG mainly
- Involve all public, voluntary, corporate and private providers through Public-Private Mix (PPM) approaches
- Promote use of the International Standards for Tuberculosis Care (ISTC)

5. Empower people with TB, and communities through partnership - All
- Pursue advocacy, communication and social mobilization
- Foster community participation in TB care, prevention and health promotion
- Promote use of the Patients' Charter for Tuberculosis Care

6. Enable and promote research - All, mainly OR
- Conduct programme-based operational research
- Advocate for and participate in research to develop new diagnostics, drugs and vaccine.

Countries of focus

DEWG and subgroups: 22 TB HBCs.
The HRD-TB subgroup, due to the cross-cutting nature of the group is also focusing on the MDR-TB and TB-HIV priority countries. PPM subgroup is focusing on all low and middle income countries with special attention to the 22 HBCs.

TB-HIV: 63 TB/HIV priority countries.
The TB-IC subgroup is focusing on the 63 TB/HIV priority countries as well as the 27 MDR-TB priority countries (76 together).

MDR-TB: 27 MDR-TB priority countries.
GLI: 27 MDR-TB priority countries.

New Diagnostics Working Group: Global approach to geographical focus.
Subgroup Drug Susceptibility Testing: Asia and Africa (regions as a whole);
Subgroup on Latent TB infection: high burden countries;
Subgroup on evidence synthesis and policy: India.

New Drugs Working Group and subgroups: Global Focus

New Vaccines Working Group: TB vaccine research priority countries are generally those in which clinical trials are being conducted or in which trials are being planned. As of 2011, those countries include: South Africa, Kenya, Uganda, Mozambique, India, The Gambia and Senegal. As vaccine candidates continue to advance through clinical trials, more countries will be added to this list.

Focus countries by implementing working groups:

DEWG NTP managers	TB-HIV NTPs + HIV managers	MDR-TB NTP Managers	GLI NTPs + NRLs.
Afghanistan			
Bangladesh		Bangladesh	Bangladesh
Brazil	Brazil		
Cambodia	Cambodia		
China	China	China	China
DRC	DRC	DRC	DRC
Ethiopia	Ethiopia	Ethiopia	Ethiopia
India	India	India	India
Indonesia	Indonesia	Indonesia	Indonesia
Kenya	Kenya		Kenya
Mozambique	Mozambique		
Myanmar	Myanmar	Myanmar	Myanmar
Nigeria	Nigeria	Nigeria	Nigeria
Pakistan		Pakistan	Pakistan
Philippines		Philippines	Philippines
Russian Federation	Russian Federation	Russian Federation	Russian Federation

South Africa	South Africa	South Africa	South Africa
Thailand	Thailand		
Uganda	Uganda		Uganda
UR Tanzania	UR Tanzania		UR Tanzania
Viet Nam	Viet Nam	Viet Nam	Viet Nam
Zimbabwe	Zimbabwe		
	Angola		
	Bahamas		
	Barbados		
	Benin		
	Belize		
	Botswana		
	Burkina Faso		
	Burundi		
	Cameroon		Cameroon
	Central African Republic		
	Chad		
	The Congo		
	Côte d'Ivoire		Côte d'Ivoire
	Dijbouti		Djibouti
	Dominican Republic		
	Equatorial Guinea		
	Ethiopia		
	Gabon		
	Ghana		
	Guatemala		
	Guinea		
	Guinea-Bissau		
	Guyana		
	Haiti		Haiti
	Honduras		
	Jamaica		
	Lesotho		Lesotho
	Liberia		
	Madagascar		
	Malawi		
	Mali		
	Namibia		
	Niger		
	Panama		
	Rwanda		
	Sierra Leone		
	Somalia		
	Sudan		
	Suriname		
	Swaziland		Swaziland
	Togo		
	Trinidad & Tobago		

	Ukraine	Ukraine	Ukraine
	Zambia		Zambia
		Armenia	Armenia
		Azerbaijan	Azerbaijan
		Belarus	Belarus
		Bulgaria	Bulgaria
	Estonia	Estonia	Estonia
		Georgia	Georgia
		Kazakhstan	Kazakhstan
		Kyrgyzstan	Kyrgyzstan
		Lithuania	
		Latvia	
		Moldova (Rep. of)	Moldova (Rep. of)
		Tajikistan	Tajikistan
		Uzbekistan	Uzbekistan
			Peru
			Senegal

Main achievements since establishment of working groups:

N.B. Kindly note that these are only examples. For a more exhaustive list, kindly consult the detailed responses of every working group and subgroup listed in Part III of this document.

DEWG: Stimulated adoption of DOTS in countries as the strategy for TB care and control. Stimulated increase in TB case detection and improvement in treatment outcomes. Initiated and developed the Tuberculosis Technical Assistance Mechanism (TBTEAM).
ACSM: Handbook on ACSM for country programmes and collection of good practices.
Childhood TB: Guidelines and technical assistance to Countries
HRD-TB: Promoted and supported the development of strategic HRD plans for the implementation of the Stop TB Strategy and is developing tools to support the scaling up of the management of MDR-TB.
INAT: Survey on the uptake of new tools and approaches by Countries and field testing of approaches to intensify case detection in five Countries. A guide for Countries outlining when and how to implement major new approaches and tools is under development.
PPM: The International Standards of TB Care, PPM consultant trainings and the PPM toolkit with various tools on the basic aspects of PPM and on engaging specific types of care providers including a PPM guidance document and the tool for a National Situation Assessment.
TB & Poverty: Promote diagnosis free of charge and universal access in all health systems; work on social determinants of TB; contributed to the development of the TBCAP supported patient centred approached; ensuring that new approaches and tools meet the needs of the poor.

TB-HIV: Massive scale up of TB/HIV collaborative activities in all regions including an increase in the number of TB patients tested for HIV, an increase in TB screening among the number of people living with HIV and scale up of Isoniazid Preventive Therapy. Mainstreaming of TB/HIV in key HIV stakeholders including UNAIDS, International AIDS Society and PEPFAR.
TB-IC: Collaborated on the development of the 2009 WHO Policy on TB Infection Control and Advocacy Strategy Document; ensured TB-IC was included in the Beijing Call for Action on MDR-TB and in the workplans of MDR-TB priority countries; modelling of cost of TB-IC activities.

MDR-TB: Inclusion of the programmatic management of MDR-TB in the Stop TB Strategy; advice to WHO for producing and updating the guidelines for the programmatic management of MDR-TB; development of ambitious scale up plans for the programmatic management of MDR-TB.
GLC: none declared.
Research subgroup: Revised prioritized MDR-TB research agenda; various symposia at Union World Lung Conferences; establishment of RESIST-TB.

GLI: Development of comprehensive training package for TB culture and DST and training for External Quality Assessment for AFB smear microscopy; Standard Operating Procedures for critical TB test methods and management information systems; roadmap for implementation of TB diagnostics at country level; bio-safety guidance based on risk assessment of different TB laboratory processes.
SRLN: All 27 MDR-TB priority countries are now formally linked to the SRLN and several countries in the EXPAND-TB project are receiving SRLN technical support.

New Diagnostics Working Group: Endorsement by WHO of several diagnostic technologies including the Xpert MTB/RIF test, LED fluorescence, and front-loaded microscopy, line probe assays for MDR-TB diagnosis; publication of a scientific blueprint for the development of TB diagnostics; contribution to WHO policy guidance on the use of various diagnostic tools implementation of diagnostic tools in various MDR-TB high burden countries; publication of a number of meta-analyses and systematic reviews of different diagnostic tests and evidence-based TB diagnosis website: www.tbevidence.org.

New Drugs Working Group: Support to the advancement of the global pipeline of TB drugs including facilitating critical collaborations between public and private partners; development of a ground-breaking new approach to drug development; sponsoring of key meetings and contributions to publications.

New Vaccines Working Group: established task forces that bring together key stakeholders to discuss key aspects of TB vaccine development e.g. the use of functional assays, a consensus strategy for advancing live vaccines through clinical trials, discussion on economic issues related to new TB vaccines, etc.; stimulated South to South collaboration; convened a Global Forum on TB Vaccines which brought together researchers and other interested parties from over 30 Countries; and addressed regulatory issues to TB Vaccine Development as well as capacity building in this area.

Advocacy activities
Will be addressed in the 20th Stop TB Partnership Coordinating Board session on Strengthening the Strategic Approach to TB Advocacy.

Challenges and opportunities:

	Challenges	Opportunities
DEWG	Funding	Members from HBCs may be encouraged to fund some of the costs for participating in working group activities (such as travel cost) as long as those cost are kept low.
ACSM	ACSM representation is frequently left out in key TB meetings	Country missions; regional NTP managers meetings; The Union World Lung Conferences
Childhood TB	Lack of specific diagnostic tool which would allow health workers at primary care level to diagnose TB in children. There are no good global burden estimates that could be used for advocacy purposes as well as fund raising for the development of new tools.	
HRD-TB	Funding and travel limitations; distribution of HRD guidelines and best practices to other working groups.	Consultation with other working groups and technical partners during the development phase of products and materials to ensure inclusion of HRD best practices.
INAT	Increased coordination with other working groups to streamline the work of INAT into the work of the other groups; lack of resources and commitment.	
PPM	Creating a sense of urgency and priority to expand PPM to increase case detection; lack of resources and commitment to regulating the private drug market.	Increased coordination with other groups to address the engagement of all care providers in all elements of the Stop TB Strategy especially in prevention and management of MDR-TB; collaboration with private sector in the roll out of new diagnostics.

TB & Poverty	Organizing teleconferences and face-to-face meetings; obtaining updates on agreed objectives; working with sub-optimal funds.	
TB-HIV	Most at risk groups in low burden countries are particularly vulnerable when donors are looking for more impact from their funding and when our resources are limited; the convergence of MDR/XDR-TB with HIV and limited response especially those countries where the two epidemics overlap.	The renewed global commitment for effectiveness and integration offers an opportunity to integrate TB and HIV services; examples of rapid scale up of collaborative TB/HIV activities in some outstanding countries like South Africa and India help to further catalyse nationwide scale up in many regions; the improving diagnostic pipeline of TB (E.g. Expert TB).
TB-IC	None declared.	None declared.
MDR-TB	Pending to be agreed.	Pending to be agreed.
GLC	None declared.	None declared.
Research subgroup	Lack of funds for 2011; WHO will not be able to act as Secretariat from 2011 due to lack of staff; need of a financial mechanism to the subgroup not relying on WHO.	
GLI	Additional resources and staff are needed for effective integration of diagnostic services.	Strong willingness of donors to invest in the roll-out of the Xpert MTB/RIF which represents both an opportunity and challenge in terms of coordination of GLI partners to build evidence to enable scale up and widespread implementation; Integration with other laboratory strengthening efforts, especially for HIV/TB diagnostic

		services.
SRLN	None declared.	None declared.
New diagnostics and subgroups	The new Secretariat has no access to the budget which is a problem for day to day operations, work to be initiated by the subgroups and the credibility of the Secretariat. Time limitations and limited funding.	The new structure of the working represents and opportunity for improved functioning, defining more efficient procedures and reactivating subgroups. The new communications tool will allow for higher interaction with the entire working group and for active contributions by members.
New Drugs and subgroups	Competing priorities for Governments and funding agencies; political and economic climate limiting commitment to global health; limited funding committed to research for TB in particular for TB drug development; inadequate support from the Stop TB Partnership. Paedatric TB subgroup: Access to funding for high-quality clinical and operational diagnostic research. There is an urgent need to include children in biomarker studies and call for applications – this needs to be communicated to donors. The Childhood TB Subgroup has further not received any funding to date and have supported its activities through collateral funding.	Engaging higher proportion of membership to actively participate in activities; partnering with other working groups, initiatives and organizations to combine efforts on specific projects. Paedatric TB subgroup: There is enthusiasm and support for childhood TB research.
New Vaccines and subgroups	*Scientific challenges:* The uncertainty about identifying vaccine	

	candidates that provide consistent protection against TB and the lack of experience with new TB vaccines in human populations. In order to increase chances for developing an effective vaccine, the scientific community is pursuing a dual strategy of maintaining support for relevant activities in vaccine discovery research while maximizing the number of candidates introduced into clinical trials. *Operational challenges:* As TB vaccines progress to larger-scale clinical trials in different target populations, multiple trial sites will be necessary to ensure sufficient enrolment for a licensure trial and to address immunological and other responses that may vary by region. These large-scale efficacy and licensure trials require appropriate capacity and infrastructure to enrol, monitor, diagnose and follow-up high numbers of participants. They also require access to accredited microbiological and immunological laboratories, staff that are trained in good clinical practice (GCP), clinical experience with trials and TB diagnosis, radiological expertise and quality control mechanisms. *Financial challenges:* Despite impressive	

	commitments by philanthropic organizations and the public sector, much greater investment will be required to achieve the goal of a new, more effective vaccine. Funds are being prioritized to support the maintenance of the vaccine delivery pipeline, performance of clinical trials, and the creating of an enabling infrastructure. Without increased investment, promising vaccine candidates will not advance through large-scale efficacy trials and new, second generation candidates will not be brought into the pipeline.	

Suggestions for strengthened collaboration and coordination

DEWG: Re-unify TB care and control by reducing the number of working groups and subgroups & re-examine the terms of working groups in line with the recommendations of the McKinsey evaluation. Working groups to be the forums/avenues for developing ideas, sharing experiences and pushing partners to deliver on specific areas. Partners to get the work done. Clarity is needed on what the working groups can be held responsible for.

ACSM: Each ACSM member is already a member of the other working groups most relevant to the topic area. The core group to include key representatives from the other working groups.

Childhood-TB: Due to cross-cutting nature of the work of the subgroup, it is desirable that there would be a childhood TB focal point in each working group (there is already a paediatric subgroup on new diagnostics under the New Diagnostics Working Group).

HRD-TB: Ensure ongoing participation in cross working group conference calls and meetings and in the review of tools and guidelines under development by other working groups.

INAT: Ensure representation of INAT core group members in other working groups on a regular basis.

PPM: In key areas, the PPM core group has requested other working groups to nominate a focal point to join the core group and PPM core group members are participating in other working groups on a regular basis; development of joint work plans addressing the engagement of private providers in various strategic components such as MDR-TB,

TB/HIV, new TB drugs and new TB diagnostics; develop joint products such as practical tools and guidance.
TB & Poverty: adequate and assured funding for the smooth functioning of the secretariat; collaboration with PPM subgroup to engage all care providers and the TB-IC subgroup to address the needs of refugees, internally displaced persons and prisoners.

TB/HIV: Close collaboration already exist with the GLI, the New Diagnostics Working Group and the MDR-TB working group. GLI has a core group member as observer in the TB/HIV core group.
TB-IC: Representatives of HSS, TB/HIV, MDR-TB, laboratory bio-safety and occupational health are invited to annual meetings of the subgroup; the current chair of the TB-IC subgroup is also a core group member of the TB/HIV working group.
It is suggested to welcome TB-IC core group members to other working groups and to organize a meeting between Chairs and Secretariats of the working groups and subgroups to promote networking and cross-fertilization. Working groups to present at Stop TB Partnership Coordinating Board meetings.

MDR-TB: Pending to be agreed.
GLC: none declared.
Research subgroup: Partners to be more engaged and more support required from the Stop TB Partnership Secretariat.

GLI: Strong coordination already exists between GLI and other working groups e.g. participation in each others meetings.
SRLN: Excellent collaboration exists between GLI and the SRLN. The Chair of the SRLN is also a GLI core group member.

New Diagnostics Working Group and subgroups: In addition to joint initiatives, occasional meetings of working group chairs and secretariats would be helpful in order to strengthen coordination and to identify opportunities for collaboration at the subgroup level. Paediatric TB subgroup: Ongoing collaboration with the following groups is envisaged: DEWG Childhood TB Group; IUATLD Childhood TB Training Group; and, TDR MSF and other partners. Participation of the Childhood TB Subgroup in the core group with regular communication would be tremendously helpful; the childhood TB subgroup has been somewhat isolated.

New Drugs Working Group and subgroups: identify areas of shared interest and combining efforts and resources; establish a forum for sharing of strategies, announcements and information to help coordinate efforts between groups; share news and information between groups and the public; hold joint conferences and meetings on topics of common interest e.g. the Working Groups on New Diagnostics and New Vaccines will hold a joint symposium during the World Lung Conference in November 2011.

New Vaccines Working Group and task forces: The Stop TB Partnership New Tools Working Groups held a joint meeting at the Stop TB Partners Forum in Rio de Janeiro in

2009. Joint activities like this can be useful in understanding areas of potential synergy and collaboration, and should be convened at least every other year. In addition, new tools will play an important role in addressing TB in general, and also drug-resistance and TB/HIV co-infection. Opportunities should be sought for greater cooperation and information-sharing between the implementation and research working groups.

At the 2010 Union World Conference on Lung Health in Berlin, the community representatives from the Research Working Groups met with the Working Group Secretariats and advocacy staff from product development partnerships to discuss opportunities for joint messaging and other joint advocacy activities. These efforts should continue and should expand to the other Working Groups via the Community Task Force. The Partnership should ensure sufficient support to the community representatives to enable them to fulfil their mandates and identify opportunities to collaborate across Working Groups.

Part III: Response from the Stop TB Partnership Working Groups and subgroups

1: DOTS Expansion Working Group

(i) Established in: 2001

(ii) DEWG core group members and affiliation

Dr J. Chakaya	Kenya Medical Research Institute, Nairobi, Kenya	Chair
Dr Mohamed Abdel Aziz	The Global Fund, Geneva, Switzerland (soon vacant)	Donor
Dr Netty Kamp	KNCV Tuberculosis Foundation, The Hague, The Netherlands	Chair, ACSM subgroup,
Vacant	USAID	Donor
Prof. Robert Gie	Tygerberg, South Africa	Chair, Childhood TB subgroup
Dr Wanda Walton	CDC, Atlanta, USA	Interim Chair, HRD-TB subgroup
Dr Christy Hanson	USAID, Washington DC, USA	Chair, INAT subgroup
Dr Phil Hopewell	ATS, USA	Chair, PPM subgroup
Mr Pervaiz Tufail	National Group of TB People, Pakistan	Co-chair, TB & Poverty subgroup
Dr Karam Shah	WHO Afghanistan	Chair, TB & Poverty subgroup
Mr Jacob Kayombo	UR Tanzania	Community Representative
Ms Prima Kazoora Musiimenta	Uganda	Community Representative
Dr Mette Klouman	LHL, Norway	
Dr Peter Gondrie	KNCV Tuberculosis Foundation, The Hague, The Netherlands	Permanent member
Dr Nevin Wilson	The Union	Permanent member
Dr Eugene McCray	CDC, Atlanta, USA	Permanent member
Dr Nathan Kapata	NTP manager Zambia	NTP manager TB HBC
Dr Lixia Wang	NTP manager China	NTP manager TB HBC
Dr Noor Ahmad Baloch	Former NTP manager Pakistan (current NTP manager is Dr Ejaz Quadeer)	NTP manager TB HBC
Dr Mao Tan Eang	Cambodia	NTP manager TB HBC
Dr Win Maung/ T. Lwin	Myanmar	NTP manager TB HBC

(iii) Is membership up to date? Membership TB High Burden Countries under review

(iv) Secretariat hosted in: WHO Stop TB Department (TBC)

(v) Frequency of meetings:
(a) Full working group: annual (except in 2010)
(b) Core group: at least one face to face meeting annually and quarterly conference calls

(vi) Terms of reference

- Ensure that countries, starting with the 22 TB high-burden ones, develop, implement and sustain comprehensive TB control in line with the Stop TB Strategy to achieve the MDGs and Stop TB Partnership targets in close collaboration with the Stop TB financial and technical partners.
- Review the status and measure the progress in countries, share experiences between countries and stimulate action when necessary.
- Promote the documentation and dissemination of best practices and lessons learned.
- Assure the involvement of the private medical sector, the community and other sectors in TB control.
- Liaise with and support the work of the DEWG subgroups.
- Ensure that TB control efforts are included in, and contribute to, broader health sector and poverty reduction strategies.
- Liaise with the other Stop TB working groups.

(vii) Resources for biennium 2010-2011:
(a) Approved budget: 650,000 USD
(b) Provided (as of January 2011): 325,000 USD

These funds were distributed among the core group and subgroups as follows:

Budget DEWG and subgroups			
		STB funding	
	Required 2010-2011	Available 2010	Other funds for 2010
DEWG		140,000	
ACSM		30,000	
Childhood -TB		45,000	
HRD-TB		30,000	TBCAP - 39,414
INAT		30,000	
PPM		0	TBCAP - 247,988
TB & Poverty	125,000	50,000	
Total		**325,000**	

c) Estimated in-kind contributions 2010-2011:

(viii) Country focus: 22 TB HBCs

- Afghanistan
- Bangladesh
- Brazil
- Cambodia
- China
- DRC
- Ethiopia
- India
- Indonesia
- Kenya
- Mozambique
- Myanmar
- Nigeria
- Pakistan
- Philippines
- Russian Federation
- South Africa
- Thailand
- Uganda
- UR Tanzania
- Viet Nam
- Zimbabwe

(ix) Priorities in 2010-2011:

- To increase case detection and treatment success rates.

(x) Main achievements since establishment:

1. Stimulated adoption of DOTS in countries as the strategy for TB care control. By 2003, 180 of 212 countries reporting data to WHO had adopted the DOTS strategy and later the Stop TB Strategy.
2. Stimulated increase in TB case detection from 43% in 2001 to 63% in 2009.
3. Stimulated improvement in treatment outcomes , thus treatment success increased from 82% in 2001 to 87% in 2008.
4. Participated in the development of the Global plans to Stop TB.
5. Participated in the revision of the TB handbook.
6. Participated in the revision development of TB treatment guidelines.
7. Initiated and developed the Tuberculosis Technical Assistance Coordination Mechanism (TBTEAM).
8. Developed the framework for early and complete TB case detection.

(xi) 3-5 main (expected) outputs in 2010-2011:

- Coordinate support to countries to expand the implementation of the Stop TB Strategy.
- Promote activities that enhance early case and complete TB case detection and maintain the high treatment success target and ensure their inclusion in country strategic plans.
- Network countries, TB funding agencies and TB technical agencies to share experiences and develop harmonized approaches for DOTS enhancement.

(xii) Advocacy activities:

a) Description of WG's advocacy activities for 2011

Advocacy will not be a core activity of the DEWG. It will be carried out by the ACSM

sub group and the STP secretariat.

b) Main targets of advocacy
See above.

c) Key advocacy challenges
See above.

d) Upcoming advocacy opportunities
See above.

(xiii) Main challenges and opportunities:
1. Funding for the WG activities is a major challenge, limiting networking activities.
2. Modern technologies may be used to promote exchange of information among members (an opportunity).
3. Members of the WG from HBC countries may be encouraged to fund some of the costs for participating in WG activities (such as travel costs), as long as those costs are kept low. Such cost may be included in GF grants (wishful thinking may be), an opportunity .

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:
1) Re-unify TB care and control by reducing the number of WGs and subgroups. Many subgroups are struggling to recruit members. My suggestion - have two major working groups: an TB Care and Control Implementation WG that examines and follow up all aspects of progress in TB care and control (including TB /HIV and MDRTB) and a TB new tools development (or research) WG that examines and follows up progress in the development and uptake of new drugs, vaccines and diagnostics. All current groups and subgroups can be fitted into the two working groups model as long term subgroups or time limited task forces.
2) Re-examine the TORs of WGs in line with the recommendation of the McKinsey evaluation. I see these WGs as forums/avenues for developing ideas, sharing experiences and pushing partners to deliver on specific areas. It is partners (countries, WHO, Funding agencies, Technical agencies, etc.) who get the work done. The WGs by themselves by themselves cannot deliver much. There needs to be clarity on what the WG (the chair, the secretariat and the core group) will be held responsible for.

1a: Subgroup on Advocacy Communications and Social Mobilization (ACSM):

(i) Established in: 2005 as country level sub group of a wider ACSM Working Group, in 2008 continued as ACSM sub group of DEWG after the dismantling of ACSM WG.

(ii) Core group members and affiliation (2008-2010)

Dr Netty Kamp	KNCV Tuberculosis Foundation, The Hague, The Netherlands	Chair
Elisa Canqui Mollo	Independent Consultant	Representing Indigenous Populations
Chibuike Amaechi	The Good Neighbour Inc., Nigeria	NGO representative
Alka Dev	Independent contractor	Consultant
Ogechi Eronini	Media and Events Network, Nigeria	NGO representative
Elena McEwan	Catholic Relief Services	Consultant
Hara Mihalea	PATH	Consultant
Austin Arinze Obiefuna	National Partnerships Network, Ghana	Representative of STB Partnerships network
Dr Héctor Oswaldo Jave Castillo	National TB Program, Peru	Country representative TB program
Dr Mao Tan Eang	Director, National Center for TB and Leprosy Control, Cambodia	Country representative TB program
Lana Velebit	Community involvement in TB care and prevention, (STD) WHO, Geneva, Switzerland	Technical Officer
Monica Yesudian	WHO Stop TB Department (TBS), Geneva, Switzerland	Public-Private Mix Sub Group

(iii) Is membership up to date?
Elections for Chair are currently being organized. Core group membership is until 30 September 2011. The Subgroup member list has been updated end 2010 and currently has 93 members.

(iv) Secretariat hosted in: Stop TB Partnership Secretariat (TBP)

(v) Frequency working group meetings:
(a) Full sub working group: 1 per year (travel of SG members not paid)
(b) Core group: 1 per year (back-to-back with SG meeting)

(vi) Terms of reference:

1. To provide countries and partners with guidance and necessary tools for the strategic implementation of Component 5 of the Stop TB Strategy "Empower people with TB, and communities through partnership" which includes advocacy, communication and social mobilization, community and patient involvement in TB care and prevention and the Patient's Charter for Tuberculosis Care.

2. To provide the evidence for and advocate at country-level for prioritization and more financial commitment to the strategic implementation of Component 5, currently the newest component in most countries.

3. To develop an ongoing forum for discussion and sharing of lessons learnt and best practices on the most effective and appropriate ACSM strategies and methodologies to achieve key behavioural and social changes that will contribute to preventing TB infection and increasing case detection and cure rates in a sustainable fashion.

(vii) Resources for biennium 2010-2011:

a) Approved budget: 50,000 USD

b) Provided (as of January 2011): 30,000 USD

c) Estimated in-kind contributions 2010-2011:

(viii) Country focus: 22 TB HBCs

- Afghanistan
- Bangladesh
- Brazil
- Cambodia
- China
- DRC
- Ethiopia
- India
- Indonesia
- Kenya
- Mozambique
- Myanmar
- Nigeria
- Pakistan
- Philippines
- Russian Federation
- South Africa
- Thailand
- Uganda
- UR Tanzania
- Viet Nam
- Zimbabwe

(ix) Priorities in 2010-2011:

- Building evidence-base for strategic ACSM: collecting and documenting ACSM good practices (first collection launched in 2010, submissions for second collection underway).
- Guidance document for monitoring and evaluating ACSM activities and pilot testing of the document planned.
- Strengthen support to countries to improve ACSM portion of proposals (GFATM, TB REACH, etc); analysis of past proposals for weak areas, revision of guidance documents.

(x) Main achievements since establishment:

- ACSM Symposium included in Union Conference 2010 agenda. 2-hour Symposium featured six varying examples of innovative ACSM strategies.

- ACSM Good Practice document launched in 2010 - highlighting effective work of partners at the country level in ACSM and community involvement.
- Publication of "Working with the media: how to make your messages on tuberculosis count"
- Publication of "ACSM for TB control: a handbook for country programmes"
- Publication of "ACSM for TB control: a guide to developing knowledge, attitude and practice surveys"
- Regional ACSM planning workshops held in all WHO Regions. The purpose of the workshops was to provide participants with the tools and skills they need to plan, implement, and evaluate ACSM activities to support effective TB control and the implementation of their Global Fund grants.
- TBTEAM expert roster criteria - re-defined competencies and requirements for ACSM experts.

(xi) 3-5 main (expected) outputs in 2010-2011:

- Publication of M&E for ACSM document
- Publication of 2nd collection of ACSM good practices
- Highlighting ACSM at the Union Conference in Lille (workshop on M&E and Symposium on partnering)
- Increased involvement in GFATM proposal preparation, mock reviews and update of guidance documents.

(xii) Advocacy activities:

a) Description of WG's advocacy activities for 2011

- The ACSM Subgroup's main advocacy goal for 2011 is to advocate for increased commitment and resource allocation for country-level ACSM. There is a need for implementers (NTPs, NGOs, etc.) to see ACSM as a set of strategic activities that, as part of the Stop TB Strategy, are critical in addressing specific TB, TB/HIV and MDR-TB control challenges. This advocacy push needs to be supported with evidence of effective ACSM in TB control.

b) Main targets of advocacy

- NTPs (focus on HBCs), Country's authorities and major implementing NGOs.
- GFATM, other donors, technical partners

c) Key advocacy challenges

- Lack of ACSM representation in country missions and meetings where such advocacy could take place (for example country joint review missions or key international TB meetings)

d) Upcoming advocacy opportunities

- Country missions to Viet Nam, Thailand, Peru, China, Uganda, Cambodia
- Regional NTP Managers Meetings
- Union Conference sessions (Symposium, Workshop)

(xiii) Main challenges and opportunities:

- Challenge: ACSM representation, being a cross cutting issue, is frequently left out in key TB meetings (such as STAG, MDR meeting)
- Opportunities: listed in section 'd'

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:

- Each ACSM Core Group member is already a member of each of the most relevant Working Groups or Subgroups (PPM, MDR-TB, TB/HIV, DEWG, New TB Drugs, New TB Vaccines, New TB Diagnostics, Childhood TB).
- When the next election for the new Core Group is held in late 2011, the composition of the Core Group will include key representatives from other Working Groups (presently, there are representatives from Community TB Care and PPM).

1b. Subgroup on Childhood-TB:

(i) Established in: 2004?

(ii) Core group members and affiliation

Prof Robert Gie	Head, Department of Paediatrics & Child Health, University of Stellenbosch, South Africa	Outgoing Chair
Dr Davide Manisero	Unit of Sceientific Advice European Centre for Disease Prevention and Control, Stockholm, Sweden	
Ms Penny Enarson	The Union	
Dr Steven Graham	Centre for International Child Health, University of Melbourne, Australia	Chair elected in March 2011
Dr Clydette Powell	USAID, USA	
Dr Mary Reichler	Division of Tuberculosis Elimination, Centers for Disease Control and Prevention, USA	
Dr Cleotilde Hidalgo How	Professor, Department of Pharmacology & Toxicology, University of the Philippines, College of Medicine, The Philippines	
Dr Lucia Alvarez	Mexico	
Dr Charles Mwansambo	Head, Department of Paediatrics, Lilongwe Central Hospital, Malawi	
Ms Claire Wingfield	TB/HIV Project, Treatment Action Group, New York, USA	
Dr Anneke Hesseling	Senior researcher, Desmond Tutu TB Centre, Stellenbosch University, South Africa	co-chair, Peadiatric subgroup of the New Diagnostics Working group

(iii) Is membership up to date? Elections for (new) chair are currently being organized and core-group's composition will be revised after the subgroup's annual meeting on 16 March 2011.

(iv) Secretariat hosted in: WHO Stop TB Department (TBC)

(v) Frequency working group meetings:
a) Full working group: once per year (depending on availability of funding)
b) Core group: conference call once every quarter and 1 face to face meeting per year

(vi) Terms of reference:

- To develop and promote the implementation of NTP guidelines which include the coverage of childhood TB as part of routine NTP activities.
- To promote mobilization of human resources for implementation of the recommended childhood TB activities as part of routine NTP activities.
- To advise on policy development regarding case finding, diagnosis, treatment and overall case management of children with TB, contact tracing of children at high risk of TB for preventive TB treatment, and inclusion of childhood TB cases in routine NTP recording and reporting activities, with particular consideration of the challenges posted by HIV in these areas.
- To promote research in the fields of epidemiology, health policy, systems and services, and development of new tools (diagnosis, drugs and vaccines).
- To promote collaboration with partners working in relevant fields (including maternal and child health, the extended programme on immunization, and HIV).
- To promote the mainstreaming of childhood TB throughout the activities of the Global Partnership to Stop TB, including activities concerning HIV-related TB, drug-resistant TB, laboratory diagnosis, and anti-TB drug formulation and packaging.

(vii) Resources for biennium 2010-2011:
a) Approved budget:
b) Provided (as of January 2010): 45,000 USD
c) Estimated in-kind contributions 2010-2011: none

(viii) Country focus: 22 TB HBCs

- Afghanistan
- Bangladesh
- Brazil
- Cambodia
- China
- DRC
- Ethiopia
- India
- Indonesia
- Kenya
- Mozambique
- Myanmar
- Nigeria
- Pakistan
- Philippines
- Russian Federation
- South Africa
- Thailand
- Uganda
- UR Tanzania
- Viet Nam
- Zimbabwe

(ix) Priorities in 2010-2011:

1. Technical cooperation with ministries of health, NTP managers, professional associations, and other national stakeholders to promote and support the

implementation of childhood TB management within the framework of the national TB programme.

2. Technical assistance to countries to assess the extent of childhood TB and needs for programme implementation, including training, development of national guidelines and manuals.
3. Pursue the research agenda through including childhood TB research needs in the update of the Global Plan to Stop TB for the development of new diagnostics, drugs and vaccines.
4. Promoting the availability of child-friendly formulations of anti-TB drugs in collaboration with GDF and through the inclusion of paediatric fixed-dose combinations (FDC) in the Essential Medicines List (EML).
5. Promotion of childhood TB:
    - at the international scientific conferences and other meetings
    - other working groups and task forces (under the Stop TB Partnership)

(x) Main achievements since establishment:

- development and publication of several sets of guidelines (2006, 2007, 2010)
- technical assistance provided to several countries in revising their childhood TB policies and strategies
- inclusion of childhood TB in external reviews and monitoring missions in more than 30 countries
- raising awareness at national and international levels on the need to address childhood TB

Tools developed in 2010:

- Guidance for national tuberculosis and HIV programmes on the management of tuberculosis in HIV-infected children: Recommendations for a public health approach - The Union and WHO
- Desk-guide for the diagnosis and management of TB in children - The Union
- Rapid Advice: Treatment of tuberculosis in children - WHO
- Guidelines for intensified tuberculosis case-finding and isoniazid preventive therapy for people living with HIV in resource-constrained settings - WHO
- IGRA guidance (including use of IGRA in children - ECDC

<u>Technical assistance to countries:</u>
Africa - Zimbabwe, Kenya, Ethiopia, Mozambique, Botswana
Asia - Bangladesh
Eastern Europe - Ukraine
EU - Estonia, Finland

<u>Training</u>
International Child Tuberculosis (TB) training course (4-8 October 2010) - Stellenbosch University and the Union

Postgraduate courses, symposia, workshops and poster sessions at the Union's conference in Berlin

Annual meeting of the subgroup - 9 November 2010, Berlin Germany

(xi) 3-5 main (expected) outputs in 2010-2011:

- revision, publication and dissemination of the revised guideline on treatment of TB in children (with newly recommended dosing of basic anti-TB drugs)
- development of a generic training material for health workers at general health care setting on diagnosis and treatment of childhood TB
- national TB guidelines revised to include chapters on childhood TB in at least 10 high burden countries

(xii) Advocacy activities:

a) Description of WG's advocacy activities for 2011 - the sub-group is of a technical nature, therefore, it does not have "pure" advocacy activities per se.
Although, the subgroup tries bring the message of an unmet needs in childhood TB to high level audience, such as the donors, politicians, ministries of health in high burden countries and national TB programmes.

b) Main targets of advocacy

Donors, ministries of health in high burden countries, national TB programmes

c) Key advocacy challenges

Childhood TB is low priority for national TB programmes, because it is perceived difficult to diagnose (only a small proportion of children with TB would be smear positive); it is usually non-infectious and most patients would not be referring to NTPs, but to hospitals or private sector.

d) Upcoming advocacy opportunities

Childhood TB conference organized jointly by the sup-group and the European Centre for Disease Prevention and Control (ECDC) with the main objectives to:

1. Identify and highlight the gaps, challenges and needs in childhood TB control.
2. Prepare the scientific rationale for the need of advocacy and to identify the key areas where more advocacy and targeted engagement with stakeholders is needed.
3. Reach a consensus on how to advocate for childhood TB control in light of the MDG 4 for child survival and how to bring forward the voice of the children

(xiii) Main challenges and opportunities:

The main challenge for childhood TB is lack of a specific diagnostic tool which would allow health workers at primary care level diagnose TB in children. Therefore, most of the children with TB are either under-diagnosed or diagnosed and treated in the hospitals or the private sector, who do not report to the NTP. For that reason, there are no good global burden estimates that could be used for advocacy reason as well as for fund raising needed for the development of new tools (specifically diagnostics and new drugs) that could be used to detect and treat TB in children.

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:

The activities of subgroup are cross cutting as childhood TB includes all aspects of the disease (including TB/HIV and MDR-TB). It would therefore be desirable that there is a childhood TB focal point in each working group (we already have a paediatric sub-group on new diagnostics in the New Diagnostics Working Group).

1c Subgroup on HRD-TB:

(i) Established in: October 2009

(ii) Core group members and affiliation

Dr Wanda Walton	CDC, Atlanta, USA	Interim Chair
Dr Walid Abubaker	EMRO, Cairo, Egypt	
Dr Jeremiah Chakaya	Kenya Medical Research Institute	
Dr Jamshed Chhor	The Union, Paris, France	
Dr Norbert Dreesch	WHO Lima, Peru	
Ms Ineke Huitema	KNCV Tuberculosis Foundation, The Hague, The Netherlands	
Dr Janet Phillips	USAID, Washington DC, USA	
Dr Julia Seyer	World Medical Association	
Dr Jim McCaffery	Capacity Project, Washington DC, USA	

(iii) Is membership up to date?
The members listed above constitute the interim core group. The formal core group is expected to be constituted during the planned expanded core group face to face meeting in October 2011.

(iv) Secretariat hosted in: WHO Stop TB Department (TBC)

(v) Frequency of working group meetings:
a) Full working group: Annual (conditional to the availability of funds)
b) Core group: Annual (conditional to the availability of funds)

(vi) Terms of reference (2010-2014):
The subgroup will, through the collaboration between Stop TB partners and other partners working in relevant fields (including overall Human Resources for Health (HRH); health system development; and the Global Health Workforce Alliance), promote global and national overall HRD, as well as HRD-TB research and policy development, the formulation and implementation of HRD-TB guidelines and other tools, and the mobilization of human and financial resources for HRD-TB within the context of renewed Primary Health Care (PHC).

More specifically, the subgroup will have the following functions during the next five years (2010-2014):
1. Provide advice on global, regional, and national development and revision of evidence-based policy and program guidance to address HRD for the implementation of the Stop TB Strategy in support of universal access within the context of primary health care.

2. Promote the planning and implementation of NTP guidelines and strategic plans which include all aspects of human resource development (HRD) for the implementation of all components of the Stop TB Strategy as part of routine NTP activities.

3. Promote overall short and long term comprehensive planning of HRH including all intersectoral aspects of human resource development for the implementation of all components of the Stop TB Strategy.

4. Promote and encourage research in building a critical evidence base in the field of HRD for TB prevention, care, and control within overall health system development (including public, private, and non governmental organizations (NGOs)) to enable an effective and responsive workforce to deliver quality TB prevention, care and control services.

5. Increase the global, regional and national visibility of HRD for the implementation of the Stop TB Strategy through advocacy and the mainstreaming of HRD activities in TB prevention, care and control efforts.

6. Promote collaboration with technical and financial partners working in relevant fields (e.g. Human Resources for Health; Health System Development; the Global Health Workforce Alliance, other disease prevention and control specific areas such as maternal and child health, the expanded programme on immunization, and HIV; professional organizations), communities, and people affected by TB.

7. Promote mobilization of resources for the implementation of the recommended integrated HRD TB strategic plans as part of routine NTP activities.

8. Document and promote the exchange of best practices and experiences in HRD-TB activities among members and other stakeholders in order to catalyse implementation.

(vii) Resources for biennium 2010-2011:
a) Approved budget:
Budget as part of the DEWG.
b) Provided (as of January 2011): USD 39,414 (including 13% PSC) through USAID TBCAP APA5 (Oct '09 - Sept '10).
c) Estimated in-kind contributions 2010-2011:
Pending approval : US$ 70 000 (including 13% PSC) from TBCARE

(viii) Country focus: 22 TB HBCs, please see below. However, due to the crosscutting nature of the group the MDR-TB and TB-HIV HBC are also included in country focus

- Afghanistan
- Bangladesh
- Brazil
- Cambodia
- China
- DRC
- Ethiopia
- India

- Indonesia
- Kenya
- Mozambique
- Myanmar
- Nigeria
- Pakistan
- Philippines
- Russian Federation
- South Africa
- Thailand
- Uganda
- UR Tanzania
- Viet Nam
- Zimbabwe

(ix) Priorities in 2010-2011:
The group is in the "building up" face, thus priorities will be evolving. The current priorities are:
- Expanding the interim core team.
- Organize a face-to-face meeting with an expanded core team.
- Create and market HRD Sub Group webpage.
- Developing tools to support the scaling up of the management of MDR-TB.

(x) Main achievements since establishment:
- In 2010, an interim core group was established with representatives of key Stop TB partners and partners from the field of Human Resources for Health. An interim chair person was elected.
- Fundraising enabling two face to face meetings of the interim core group in 2010
- The group has promoted and supported the development of strategic HRD plans for the implementation of the Stop TB strategy and the need for close collaboration between National Tuberculous Control programmes and Departments of Human Resources for Health in the Ministries of Health and is developing tools to support the scaling up of the management of MDR-TB.

(xi) 3-5 main (expected) outputs in 2010-2011:
- Expanded face to face core group meeting organized and awareness of the group broadened
- Tools to support the scaling up of the management of MDR-TB developed and distributed
- HRD Sub Group webpage created and marketed.

(xii) Advocacy activities:

a) Description of WG's advocacy activities for 2011
- Participation in other workgroup meetings to ensure inclusion of HRD best practices.
- Participation in global and regional meetings to ensure inclusion of HRD best practices.

b) Main targets of advocacy
Donors and partners

c) Key advocacy challenges
Expand knowledge of HRD best practices to partners and donors, i.e., beyond concept of

training of existing health care workers

d) Upcoming advocacy opportunities
European Collaborative meeting; Global IUATLD meeting

(xiii) Main challenges and opportunities:
- Challenges: funding and travel limitations
- Distribution of HRD Guidelines and Best Practices to other workgroups, partners, and organizations.
- Consultation with other workgroups on HRD best practices.
- Consultation and technical assistance to partners during the development phase of products and materials to ensure inclusion of HRD best practices.

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:
Ensure ongoing participation in cross workgroup conference calls and meetings; and review of tools and guidelines in development by other workgroups

1d. Subgroup on Introduction of New Approaches and Technologies (INAT):

(i) Established in: 2010 (it grew out of the Retooling Task Force that was established by the Stop TB Partnership Coordinating Board in 2006)

(ii) Core group members and affiliation

Christy Hanson	Chief, Infectious Disease Division, USAID, Washington DC, USA	Chair
Claire Wingfield	Assistant Director, TAG's TB/HIV Advocacy Project	
Anne Detjen	Technical Consultant, The Union	
Jerod Scholten	Senior TB Consultant, KNCV Tuberculosis Foundation, The Hague, The Netherlands	
Rachel Bauquerez	Public Health Officer, Knowledge Management Unit, The Global Fund, Geneva, Switzerland	
Dr Paranji R Narayanan	Former Director Tuberculosis Research Center, Chennai, India	Co-Chair
Marina Shulgina	Individual specialist, Russian Federation	
Elisabeth Gardiner	Vice President, Market Access, Global Alliance for TB Drug Development	
Draurio Barreira	NTP Manager, Brazil	Country representative

(iii) Is membership up to date? Yes, the new core group was elected only in 2010

(iv) Secretariat hosted in: WHO Stop TB Department (TBS)

(v) Frequency of working group meetings:
a) Full working group: Annually.
b) Core group: Two core group meetings a year, teleconferences held every quarter.

(vi) Terms of reference:
- To solicit information from NTPs and other implementing partners on the challenges being faced with evaluating, adopting, introducing or implementing new tools or approaches as an integral part of accelerating progress towards the MDGs
- To prioritize and coordinate a concerted response to the operational challenges identified including:

- ☞ Ensure that relevant technical support is provided to countries or made available within countries with respect to "retooling"; including ensuring that strategic planning, resource mobilization, and routine monitoring and supervision includes consideration of new tools and approaches (note: to be coordinated with TB TEAM and other implementation WGs), and building capacity for 'retooling' among technical assistance partners
- ☞ Formulate and include guidance related to the introduction of new tools and approaches in upcoming technical guidelines, operational tools (e.g. budgeting tool) and policies of WHO and other normative bodies; develop other guidance as requested by countries
- ☞ Coordinate the compilation and dissemination of information on emerging new tools and approaches, as requested by countries and in a manner consistent with national planning for DOTS expansion (note: to be coordinated with other WGs)

- To prioritize operational and evaluation research that will facilitate the widescale implementation of new approaches and tools, notably responding to the gap between the endpoints for research conducted by product developers and the integration of new tools into country programmes; advocate for and coordinate the implementation of priority research
- To identify and implement solutions to the absence or weakness of global and country-level regulatory mechanisms for new tools, including coordinating support to county level policy processes
- To track progress in the uptake and expansion of new policies and approaches, coordinating with countries, implementing partners, and WHO regional offices to promote the expansion of these new tools

(vii) Resources for biennium 2010-2011:
a) Approved budget: None
b) Provided (as of January 2011): 30,000 USD
c) Estimated in-kind contributions 2010-2011: None

(viii) Country focus: 22 TB HBCs

- Afghanistan
- Bangladesh
- Brazil
- Cambodia
- China
- DRC
- Ethiopia
- India
- Indonesia
- Kenya
- Mozambique
- Myanmar
- Nigeria
- Pakistan
- Philippines
- Russian Federation
- South Africa
- Thailand
- Uganda
- UR Tanzania
- Viet Nam
- Zimbabwe

(ix) Priorities in 2010-2011:

(x) Main achievements since establishment:

- The first meeting of the Subgroup on Introducing New Approaches and Tools was held in Stockholm in February 2010. The main objective of the meeting was to develop a concrete work plan and map the way forward for the subgroup.
- A core group of the INAT Subgroup was formed, after a call for nominations. The core group met for the first time in Berlin, Germany on 12 November 2010.
- A survey was undertaken on the uptake of new tools and approaches by countries
- Activities on intensified TB case detection have been initiated in five countries to field test three specific approaches (linkage with large hospitals, TB contact investigation, and TB screening in high risk groups).
- An operational guide that compiles information on how / when to implement major new approaches and tools recommended by WHO is under development.

(xi) 3-5 main (expected) outputs in 2010-2011:

- Developed an operational guide that compiles information on how / when to implement major new approaches and tools
- Communications plan developed
- Updated new tools pipelines consolidated and widely disseminated
- M&E framework for tracking uptake of new tools

(xii) Advocacy activities:

a) Description of WG's advocacy activities for 2011

- Development of case studies and/or best practices from operational and implementation research projects
- Promote INAT at various NTP manager meetings and conferences such as the Union conference
- Development of simple fact sheets describing use, benefits, and requirements for each new tool or strategy
- Update INAT website

b) Main targets of advocacy

- National TB programmes
- Regional Offices
- Partners
- Donors

c) Key advocacy challenges

- Documenting results and analysing the impact
- Funding

d) Upcoming advocacy opportunities

- Union Conference in Lille
- World TB Day

(xiii) Main challenges and opportunities:

- Increased coordination with other groups to streamline the work of INAT in that of other groups
- Lack of resources and commitment

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:

- Ensure representation of INAT core group members in other Partnership working groups on a regular basis

1e. Public Private Mix (PPM) subgroup:

(i) Established in: 2002

(ii) Core group members and affiliation

Name	Organization
Chair	
Hopewell Phil	ATS
National TB Programmes	
Vianzon Lynn	NTP Philippines
Qadeer Ejaz	NTP Pakistan (TBC)
Kabir Mansur	NTP Nigeria (TBC)
Mustikawati Dyah Erti	NTP Indonesia
Stop TB Technical/Funding Partners	
Kamineni Vishnu	The Union
Mitra P.K	GLRA
Stallworthy Guy	GATES Foundation
Vincent Cheri	USAID
Voskens Jan	KNCV
Shimouchi Akira	RIT/JATA
Perla Isagani	University Research Corporation
Krishnan Nalini	REACH
Richardson D'Arcy	PATH
SS Lal	The Global Fund
Schilthuis Herbert	Private sector representative on the Stop TB Partnership's Coordinating Board
Suarez Pedro	Management Sciences for Health
Wells William	Global Alliance for TB Drug Development (TB Alliance)
Stop TB Working group Representatives	
Chakaya Jeremiah	DEWG / KAPTLD
Kamp Netty	ACSM Subgroup/KNCV
Representative	New Diagnostics Working Group/GLI
Community/Patient Representative	
Gordon Case	World Care Council
Regional advisers (Ex-officio)	
RA AFRO	WHO
RA AMRO	WHO
RA EMRO	WHO
RA EURO	WHO
RA SEARO	WHO
RA WPRO	WHO
Ad-Hoc members	
Kamble Puri Shaloo	WEF
Malmborg Rasmus	LHL
Secretariat	
Uplekar Mukund	WHO
Lonnroth Knut	WHO
Dias Hannah Monica	WHO

(iii) Is membership up to date?
Yes, the new PPM core group was constituted in January 2011

(iv) Secretariat hosted in: WHO Stop TB Department (TBS)

(v) Frequency of working group meetings:
a) Full working group: Annually if funding allows
b) Core group: The core group meets twice a year, teleconferences are held every quarter.

(vi) Terms of reference:
- To actively promote engagement of all public, private, voluntary and corporate health care providers in TB control in line with ISTC, the Stop TB Strategy and the Global Plan to Stop TB.
- To that purpose, discuss and provide guidance on developing global, regional, country-specific strategies aimed at involving all care providers in implementation of TB control activities, including DOTS expansion, MDR/XDR TB management, and TB/HIV collaborative activities.
- To offer a platform to share ideas and experiences related to PPM implementation and development
- To assist in development and implementation of a research agenda related to PPM.
- To identify resources to support PPM related documentation and research and assist in global coordination for technical assistance related to PPM.
- To assist the development of tools for PPM planning and implementation at the country level
- To assist in developing training material, tools and programmes and advocacy strategies on PPM
- To review progress in PPM implementation on global, regional and country level.
- To promote widely PPM as a comprehensive approach to engage all health care providers in TB control, as well as for delivery of other public health interventions and for general strengthening of the capacity of health systems to utilize the full potential of available health care providers.

(vii) Resources for biennium 2010-2011:
a) Approved budget: None
b) Provided (as of January 2011): 0 USD from TBP. Funding was mobilized through other resources (247,988 USD through TBCAP APA5 was sought exceptionally for a PPM Subgroup meeting). No funding has been provided for 2011
c) Estimated in-kind contributions 2010-2011: None

(viii) Country focus: All low and middle income countries with special attention to the 22 TB HBCs

(ix) Priorities in 2010-2011:

- To contribute to the goal of universal access to high quality diagnostic and treatment services through appropriate engagement of public, private, voluntary and corporate care providers, healthcare facilities and laboratories
- To strengthen health systems through systematic engagement of all providers
- To promote best practices for implementation and scale-up of activities for engagement of all providers by providing guidance and tools for global, regional, country-specific policies, strategies and plans
- To promote the rational use of anti-TB drugs and new diagnostic tools in the private sector
- To ensure that the current and/or potential role of the private sector is taken into account in the activities of all components of the Stop TB Strategy.

(x) Main achievements since establishment:

Since the establishment of the PPM Subgroup,

- A number of PPM initiatives have been launched, piloted and scaled up in countries. Data published in the Global TB report of 2010 from 15 countries (including nine high-TB burden countries) in 2010, demonstrated the major contribution that PPM has made to case notifications (table). In these 15 countries, the contribution of PPM initiatives typically ranges from between about one fifth to one third of total notifications, in the geographical areas in which PPM has been implemented. This has been accompanied by maintenance of high rates of treatment success.

Table : Contribution of PPM to TB case notification in selected countries

Country	Types of non-NTP care providers engaged	Coverage	Number of cases notified per year[6]	Contribution to total notifications (%)
Angola	Diverse public and private providers	Countrywide	4591	12%
Cambodia	Pharmacies, private clinics and hospitals	Countrywide	6550	17%
China	General public hospitals	Countrywide	337 286	37%
Ghana	Diverse public and private providers	Countrywide	2124	15%
India	Diverse public, private and NGO providers	14 large cities (50 million population)	12450	36% of new smear-positive cases
Indonesia	Public and private hospitals	Countrywide	38362	13%
Islamic Republic of Iran	Diverse public and private providers	Countrywide	2514	25%

[6] Data for 2009 except where specified

Kazakhstan	Prison health services	Countrywide	1515	8%
Myanmar	Private practitioners through the professional medical association	26 townships (6.4 million population)	8526 (2008)	21%
Nepal	Diverse public and private providers	Countrywide	2519	8%
Nigeria	Private clinics and hospitals	Countrywide	29418	34%
Pakistan	Private practitioners, NGOs and hospitals	Countrywide	43162	14%
Philippines	Private clinics and hospitals	30 million population	3994	28% of new smear-positive cases
Tanzania	Private and NGO hospitals	Countrywide	11492	19%

- Various key tools and guidance documents such as the PPM guidance document and the tool for National Situation Assessment have been developed and translated into French and Spanish. The PPM toolkit- a compilation of tools on the basic aspects of PPM implementation, as well as on engaging specific types of care providers was launched in Berlin on 11 November 2010.
- Consultant training courses and regional PPM workshops were organized.
- The International Standards for TB Care, now in its second edition, has been widely distributed, translated into 12 languages, utilized by many national TB control programs, and endorsed by a large number of national and international organizations.

All of the above have created a strong foundation for scaling up engagement of all providers, as called for in the Global Strategy to Stop TB.

(xi) 3-5 main (expected) outputs in 2010-2011:

- White paper on revitalizing the PPM Subgroup
- Updated evidence based guidance on scaling up PPM to engage all care providers
- Status paper on utilization of Gene Xpert within the private sector
- A situation assessment tool to initiate PPM for MDR-TB
- Guidelines on TB control in workplaces

(xii) Advocacy activities:

a) Description of WG's advocacy activities for 2011

- Promotion and dissemination of the PPM toolkit and related video
- Dissemination of e-updates on the work of the subgroup
- Promotion of PPM in various conferences such as the Union Conference
- Updating the PPM Subgroup and WHO PPM websites

b) Main targets of advocacy

- National TB programmes
- Non-NTP care providers
- Regional Offices
- Partners
- Donors

c) Key advocacy challenges

- Documenting results and analysing the impact
- Influencing national programmes and providers to work with each other
- Funding

d) Upcoming advocacy opportunities

- Union Conference in Lille
- World TB Day
- FIP Conference in India

(xiii) Main challenges and opportunities:

- Creating a sense of urgency and priority to expand PPM to increase case detection
- Increased coordination with other groups to address the engagement of all care providers in all elements of the Stop TB Strategy especially in the prevention and management of MDR-TB
- Lack of resources and commitment to regulating the private drug market
- Collaboration with private sector in the roll out of new diagnostics

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:

- In key areas, the PPM core group has requested working groups to nominate focal points to join the core group
- Ensure representation of PPM core group members in other Partnership working groups on a regular basis
- Develop joint work plans addressing engagement of private providers in the various strategic components such as MDR-TB, TB/HIV, new TB drugs and new TB Diagnostics
- Develop joint products such as practical tools and guidance.

1f. Subgroup on TB & Poverty:

(i) Established in: The Union Conference in 2004 and officially endorsed as a subgroup by the DEWG in 2005.

(ii) Core group members and affiliation

Karam Shah	WHO Afghanistan	Chair
Parvaiz Tufail	National Group of TB People, Pakistan	Co Chair, Community Representative
Gillian Mann	Liverpool School of Tropical Medicine, UK	
Bertie Squire	Liverpool School of Tropical Medicine, UK	
Rachael Thomson	Liverpool School of Tropical Medicine, UK	
Vishnu Kamineni	The Union	
Karen Bissell	The Union	
Verena Mauch	KNCV Tuberculosis Foundation	
Maarten Van Cleeff	KNCV Tuberculosis Foundation	
Peter Gondrie	KNCV Tuberculosis Foundation	
Faruque Ahmed	BRAC, Bangladesh	
Jeremiah Chakaya	Centre for Respiratory Diseases Research, Kenya Medical Research Institute	
Giorgio Roscigno	FIND	
Kimberley Barker	Indigenous Peoples Association	
Knut Lonnroth	WHO	

(iii) Is membership up to date? Yes

(iv) Secretariat hosted in: The Union South-East Asia office, New Delhi, India

(v) Frequency of working group meetings:

a) **Full working group:** DEWG meets annually adjacent to World Lung Conference. The DEWG secretariat coordinates meetings from time to time.

b) **Core group:** For the smooth functioning of the subgroup, the secretariat coordinates a minimum of 4 quarterly teleconferences. The purpose of these teleconferences is to track progress on the work plan, objectives assigned to different focal organizations, address issues faced by the core group members and

share information related to poverty-centric activities carried out by the core group members. In addition to teleconferences the secretariat also conducts a face-to-face meeting of the core team during the World Lung Conference.

(vi) Terms of reference:

To enable the Stop TB Partnership to achieve its global targets and contribute to its poverty related mission statements:

a. To ensure that every TB suspect/patient has easy and equitable access to effective diagnosis, treatment and cure.
b. To reduce the inequitable social and economic toll of TB.
c. Coordination to promote poverty-centric activities: To promote dialogue and coordination among Core Team members, facilitate and support implementation of the subgroup action plan (mainly through teleconferences).
d. Initiate and sustain interest in high-burden, low-income and developing countries: To promote involvement of NTP managers, particularly those belonging to the high-burden countries and other developing countries.
e. Build and enhance the secretariat's financial capacities: To assist the TB & Poverty Subgroup in securing additional financial and other support as required.
f. To document and disseminate progress against the TB & Poverty Subgroup's vision, mission and outputs.
g. To sustain the smooth functioning of the Subgroup through:
    - Renewal of the TB & Poverty Core Team membership and the democratic election of key officers in line with the STOP-TB Partnership policy and principles.
    - Handover of the secretariat responsibilities to another institution in due course as advised by the Core Team.

(vii) Resources for biennium 2010-2011:

a) Budget proposed to be approved: 125,000 USD

b) Provided (as of January 2011): 50,000 USD till December 2010 with NCE till March 2011

c) Estimated in-kind contributions 2010-2011: 50,000 USD from The Union

(viii) Country focus: 22 TB HBCs

- Afghanistan
- Bangladesh
- Brazil
- Cambodia
- China
- DRC
- Ethiopia
- India
- Indonesia
- Kenya
- Mozambique
- Myanmar
- Nigeria
- Pakistan
- Philippines
- Russian Federation
- South Africa
- Thailand
- Uganda
- UR Tanzania
- Viet Nam
- Zimbabwe

(ix) Priorities in 2010-2011:

1. Coordination to promote poverty-centric activities: To promote dialogue and coordination among Core Team members, facilitate and support implementation of the subgroup action plan (mainly through teleconferences).
2. To document and disseminate progress against the TB & Poverty Subgroup's vision, mission and outputs.
3. To sustain the smooth functioning of the Subgroup through:
    - Renewal of the TB & Poverty Core Team membership and the democratic election of key officers in line with the STOP-TB Partnership policy and principles.
    - Handover of the secretariat responsibilities to another institution in due course as advised by the Core Team.

(x) Main achievements during Aug – Dec 2010:

1. **Coordination to promote poverty-centric activities**

   The Secretariat facilitated a series of teleconferences with the core group members to obtain updates from the core team members against subgroup action plans, and among others to finalize the agenda of the face-to-face meeting of the core group at the World Lung Conference in Berlin. The secretariat was responsible for coordination and organization of the face-to-face meeting in Berlin where several issues including progress updates and revitalization of the core group were discussed. The face-to-face meeting allowed dissemination of information including workshop updates on the SEA regional consultative TB and poverty workshop.

2. **Documentation and dissemination of progress against the TB & Poverty Subgroup's vision mission and outputs**

   A key activity of the Secretariat has been to monitor and document the progress of the Subgroup's action plan and to disseminate this information. The year 2010 witnessed progress against this action plan by a wide range of partners and there is a strong sense that the Subgroup is achieving its objectives across a range of activities from advocacy and support to research. Members with multiple representations also contributed towards promoting the Subgroup's activities through participation in other Stop TB Partnership Working Groups like the New Diagnostics Working Group and the INAT subgroup of the DEWG.

3. **Sustaining the smooth functioning of the Subgroup**

   The renewal of the TB & Poverty Core Team membership and the democratic election of key officers in line with the Stop TB Partnership policy and principles were discussed at length during the Union World Conference at Berlin. The core team deliberated and agreed that the team should be a blend of experience and youth. The secretariat proposes for the core group members to define selection criteria during the revitalization process (for example Organizational focal point core group members representing in not more than 2 working groups). This will allow cross-fertilization as well as ensure having committed members joining the core team. It was agreed that the core group membership should not exceed 15 members and also attempt to strive and include members from non-health sectors such as the World Bank etc. A detailed

plan for the renewal with timelines is to be finalized in consultation with the core group members during the teleconference in 1st Quarter 2011.

4. **Regional consultative workshop in South-East Asian region**: While there were no committed funds for addressing objective 2 aimed at initiating and sustain interest in high-burden, low-income and developing countries within the allocated budget under the Union-TBP agreement; The Union raised financial resources to organize a regional consultative meeting to promote TB and poverty at the south-east Asian regional level. Thirty participants including NTP manager from India and representatives from the high burden countries like Nepal and Thailand along with State TB programme managers from poorest Indian States such as Bihar, Jharkhand, Madhya Pradesh, Chhattisgarh, Uttarakhand and other states with identified poverty pockets like Tamil Nadu, Haryana and Chandigarh shared their experiences and innovations aimed at addressing poverty in TB Control within the scope of Universal access. Representatives from World Bank, World Vision India, National Partnership Secretariat for TB Care & Control in India, GFATM Round 9 TB project and the media also shared their views and participated during the workshop. The event was well covered in the media and worldwide web by CNS and Asia Tribune. (Link: http://www.citizen-news.org/2010/12/cns-coverage-from-tb-and-poverty-sub.html)

5. **TB and Poverty presence at Biennial Conference of the Irish Forum for Global Health at Dublin**: The IFGH meet was organized by IFGH with support from Combat Diseases of Poverty Consortium (CDPC), Irish Aid and National University of Ireland Maynooth (NUIM) Ireland on 29-30 November 2010. The secretariat facilitated development of communication material - TB and Poverty Flyer and power point presentations for poverty related information sharing and dissemination at the biennial conference of the Irish Forum for Global Health at Dublin. The secretariat coordinated to ensure core team nomination (LSTM representative) as well as media representation (Citizen's News service) participated in the biennial conference to promote TB and poverty. Rachel Thomson from LSTM said that there is a need to combat TB by addressing the barriers faced due to poverty such as infrastructural, housing, employment, educational and nutritional deficiencies. She added that one of the major steps forward in addressing poverty and TB will be to put health on the poverty agenda and poverty on the health agenda.

6. **Promote advocacy efforts at regional level:** The secretariat coordinated with The Union conference committee and organized a TB and Poverty sensitization workshop at the African regional conference on 2nd March 2011. 30 participants from various African countries shared their experiences of poverty-centric approaches in their respective TB Control Programmes.

(xi) 3-5 main (expected) outputs in 2010-2011:

a) To establish a new Subgroup Secretariat in a low-income country that organises communication, dissemination and meetings for the Subgroup (completed)

b) To actively promote the explicit acceptance that diagnosis of smear positive TB disease is an international public good and should be provided free of charge for universal access in all health systems (ongoing)
c) To identify additional and feasible entry points for TB control interventions addressing prevention and specifically social determinants of TB (ongoing)
d) To promote implementation of the TBCAP patient-centered approach (Tool to Estimate Patients' Costs, QUOTE TB Light Tool, TB/HIV Literacy toolkit, Patients' Charter and Practical Guide to Improve Quality TB Patient Care) and indicators that NTPs can use to assess equity in access in relation to geographical, social/cultural, health system or economic barriers (ongoing)
e) To ensure that the needs of the poor are met as new tools are developed and implemented, including work with Introducing New Approaches and Tools Working Group (INAT) and Treat TB (ongoing)

(xii) Advocacy activities:

a) Description of WG's advocacy activities for 2010

1. Systematic review of interventions for addressing socioeconomic-related conditions as part of TB treatment:
    - The systematic review and a draft report were finalized.
    - Plans for publishing and dissemination are being developed, including a possible WHO policy brief.
    - The review of impact data has been accepted for publication in IJTLD, in a theme issue on ethics and social determinants of TB (see below).
    - The review of the implementation challenges is under consideration for a second publication.
    - Findings were presented at The Union conference in Berlin in the Symposium on social determinants
    - The review will serve as a basis for an expert meeting on socioeconomic interventions for improved TB control, planned for 2011
2. Several members of the core group contributed to the development of a theme issue for IJTLD on ethics and social determinants of TB. The issue will be published in 2011.

b) Main targets of advocacy

- Addressing and promoting concepts related to poverty in tuberculosis control programs
- Increasing involvement of the stakeholders
- Recommendations to the programs for improving access of poor to TB services

c) Key advocacy challenges

- Budget Constraints
- Bringing stakeholders on a common platform
- Putting poverty on health agendas of countries

d) Upcoming advocacy opportunities

Engagement of practitioners, NGOs and other stakeholders, including representatives of poor women and men, tribal or indigenous populations to promote the access of the poor to TB services: At the time of reporting and over the period Aug-Dec 2010, the secretariat is examining poverty centric approaches within the scope of Global funded Round 9 Tuberculosis grant in India that is being implemented across 21 states in a project target population of 600 million in India (including 174 million women and 199 million children). The objective is to explore poverty action and research possibilities within the scope of project that specifically targets ACSM interventions in 250 million people living in poor and backward districts (includes 50 million tribal/indigenous populations, and 40 million people in urban slums). The civil society interventions in the project implemented by principal recipient – Union south-east Asia office provides a unique opportunity to the secretariat to examine synergies, engage NGO and public sector stakeholders to promote access of the poor to TB services at country level. The secretariat perceives this project offers potential engagement opportunities for the core team members to develop tools and guidelines for poverty.

(xiii) Main challenges and opportunities

- Organizing Teleconferences and face-to-face meetings
- Obtaining updates on agreed objectives
- Working on sub-optimal funds

The race towards achieving Goals of MDGs has put poverty on the health agenda of diseases Programmes. There is an excellent opportunity to advocate for addressing the need of the poor and marginalized in the TB control programmes.

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:

- Adequate and assured funding for the smooth functioning of the TB & Poverty Secretariat
- With PPM Group of the DEWG:
  - To collaborate with the subgroup on developing global, regional, country-specific policies, strategies and plans to involve all care providers in implementation of TB control activities.
  - To facilitate in the development of country specific tools and training materials for PPM planning and implementation
- With TB Infection Control Subgroup
  - To collaborate with representatives of workers, patients, visitors, and other stakeholders in airborne infection control in agencies dealing with refugees, internally displaced persons and prisons.

2. TB/HIV Working Group

(i) Established in: 2001 to accelerate the implementation of collaborative TB/HIV activities to reduce the global burden of HIV related TB through effective collaboration between National TB and AIDS Control programs and other stakeholders, and through generation of evidence based policy and program guidance in order to achieve the global TB/HIV targets set for 2010-2015 in The Global Plan to Stop TB.

(ii) TB/HIV core group members and affiliation

Name	Affiliation	Membership type
Dr Diana Havlir	Prof of Medicine, Chief HIV/AIDS Division and Positive Health Program, University of California, San Francisco, USA	Chair and individual member
Dr Bess Miller	Centers for Disease Control and Prevention (CDC) Global AIDS Program (GAP), Atlanta, USA	Chair, Subgroup on Infection Control and Institutional Member
Dr Richard Chaisson	Consortium to Respond Effectively to the AIDS and TB Epidemic (CREATE) & Johns Hopkins University Center for TB Research	Institutional Member
In the process of rotational replacement	Family Health International (FHI)	Institutional Member
Dr Christine Lubinski	Infection Diseases Society of America (IDSA) Center for Global Health Policy, Arlington, USA	Institutional Member
Bertrand Audoin	International AIDS Society (IAS), Executive Director, Geneva, Switzerland	Institutional Member
Dr Riitta Dlodlo	The International Union Against Tuberculosis and Lung Disease, HIV Programme Coordinator, Zimbabwe	Institutional Member
Dr Jeroen van Gorkom	KNCV Tuberculosis Foundation, The Netherlands	Institutional Member
In the process of rotational replacement	National Institute of Allergy & Infectious Diseases (NIAID), National Institute for Health (NIH), Bethesda, USA	Institutional Member
Mr William Coggin	Office of the US Global AIDS Coordinator (OGAC), Washington DC, USA	Institutional Member

Mr Javid Syed	Treatment Action Group, (TAG) New York, USA	Institutional Member
Dr Alasdair Reid	UNAIDS, Geneva, Switzerland	Institutional Member
Dr Amy Bloom	USAID, Washington DC, USA	Institutional Member
In the process of rotational replacement	World Bank, Washington DC, USA	Institutional Member
Ms Gracia Violeta Ross Quiroga	Bolivian Network of PLHWA (REDBOL), La Paz, Bolivia	Community Representative
Mr Francis Apina	Network of Men Living with HIV/AIDS in Kenya (NETMA), Nairobi, Kenya	Community Representative
Dr Yibeltal Assefa	National HIV/AIDS Prevention and Control office, MOH, Addis Ababa, Ethiopia	National AIDS Programme
Dr B.B. Rewari	National AIDS Control Organisation, Department of AIDS Control, MOHFW, New Delhi, India	National AIDS Programme
Dr Mean Chhi Vun	National Center for HIV/AIDS Dermatology and STD, Ministry of Health, Cambodia	National AIDS Programme
Dr Joseph Sitienei	National TB Control Programme Manager, National Leprosy and TB Control Programme, Ministry of Health, Nairobi, Kenya	National TB Programme
Dr Helen Ayles	Zambart Project, University of Zambia, Lusaka, Zambia	Individual member
Dr Robert Makombe	BOTUSA Partnership, Gaborone, Botswana	Individual member
Dr John Nkengasong	CDC	GLI liaison

(iii) Is membership up to date? Yes. The TB/HIV Working Group has a total of 311 actively registered members (as of March 10, 2011) representing a broad spectrum HIV and TB expertise. The Working Group Secretariat keep members of the Working Group informed of latest progress and consults on strategic issues as deemed necessary through electronic communication, including email updates and regular newsletters. The Core Group, which is the strategic decision making part of the Working Group, has two categories of membership: standing institutional and rotating individual members representing AIDS and TB programme managers, community representatives and scientists and researchers. The Terms of Reference of the Working Group, which has been revised in 2008 and set out the six year priorities of the Working Group (2008-2013) including election and selection of members. The Working Group have a liaison member with the Global Laboratory Initiative.

(iv) Secretariat hosted in: The Stop TB Department of WHO in collaboration with the HIV/AIDS Department hosts the Secretariat of the Working Group.

(v) Frequency of working group meetings: The last annual Working Group meeting was held in 2004. Since 2007 the Working Group is conducting regional meetings that are tailored to the regional specific needs to catalyse implementation and nationwide scale-up of collaborative TB/HIV activities. The Core Group of the Working Group meets once a year through a face to face meeting and also through ad hoc electronic media as deemed necessary.

(vi) Terms of reference/functions: The terms of reference of the Working Group were revised in 2007 through the full participation of members of the Working Group and other stakeholders to conduct the following functions between 2008-2013.

- Document and promote the exchange of best practices and experiences among members and other stakeholders in order to catalyse implementation.
- Advise on the development and revision of evidence based policy and program guidance to address the intersecting epidemics of the two diseases.
- Promote and encourage TB/HIV research in building a critical evidence base and ensuring the delivery of quality services.
- Increase the global and national visibility of TB/HIV though advocacy and the mainstreaming of collaborative TB/HIV activities in HIV and TB efforts including research, care and treatment programs, funding mechanisms and monitoring and evaluation.
- Build effective collaboration between TB and HIV/AIDS programs and communities and engaging all health providers in implementing TB/HIV activities in countries and communities with a high burden of HIV related TB.

By the end of 2013, the Working Group will again revisit its performance and will revise its functions

(vii) Resources for biennium 2010-2011:

a) Approved budget: USD300,000 from Stop TB Partnership Secretariat (USD250,000 is for the TB/HIV WG and USD50,000 is for the Infection Control sub-group)

b) Provided (as of January 2011): USD150,000 (out of which USD125,000 for the TB/HIV Working Group and USD25,000 for the Infection Control sub-Group) was received from the Partnership Secretariat .

c) Estimated in-kind contributions 2010-2011: The TOR of the WG defines that partner organisations should also contribute financially and in kind for the activities of the Working Group. In this regard in 2010, more than half of the participants of the regional meetings were covered by other sources. Organisational members of the Core Group (USAID,CDC, CREATE and KNCV) contributed in sharing the cost of the activities of the Working Group in 2010.

(viii) Country focus: Although the Working Group promotes the implementation of collaborative TB/HIV activities in all countries, it has 63 priority countries that account for 97% of the global TB/HIV burden and hence need intensified action.

Priority countries of the TB/HIV Working Group of the Stop TB Partnership	
AFRO Angola Benin Botswana Burkina Faso Burundi Cameroon Central African Republic Chad Congo Cote d'Ivoire Democratic Republic of the Congo Equatorial Guinea Eritrea Ethiopia Gabon Ghana Guinea Guinea-Bissau Kenya Lesotho Liberia Madagascar Malawi Mali Mozambique Namibia Niger Nigeria Rwanda Sierra Leone South Africa Swaziland Togo Uganda United Republic of Tanzania Zambia Zimbabwe	**AMRO** Bahamas Barbados Belize Brazil Dominican Republic Guatemala Guyana Haiti Honduras Jamaica Panama Suriname Trinidad and Tobago **EMRO** Djibouti Somalia Sudan **EURO** Estonia Russian Federation Ukraine **SEARO** India Indonesia Myanmar Thailand **WPRO** Cambodia China Viet Nam

(ix) Priorities in 2010-2011:

- Nationwide scale-up of collaborative TB/HIV activities in all regions with particular emphasis on the scaling up of the Three Is for HIV TB in sub-Saharan Africa.
- Intensified action to promote integrated delivery of HIV and TB services including among maternal and child health services.
- Provide evidence based policy and programme guidance including defining and promoting TB/HIV research priorities and encourage their uptake particularly by HIV researchers
- Promote increased access to collaborative TB/HIV activities for most at risk populations such as prisoners and injecting and other drug user particularly in Eastern Europe and Central Asia.
- Increase and maintain the visibility of TB among HIV stakeholders and events.
- Enhance the involvement of civil society in the global TB/HIV response through capacity building.

(x) Main achievements since establishment: The Working Group has been instrumental in coordinating the global TB/HIV response through the provision of evidence based policy and programme guidance which has resulted in the following key achievements:

- Massive scale up of collaborative TB/HIV activities in all the regions. Between 2001 and 2009 the number of TB patients tested for HIV increase from nearly 1000 in 2001 to 1.7 million in 2009, representing over 2000 fold increase in scale up.
- Similarly TB screening among people living with HIV has increased from nearly 2000 in 2003 to 1.7 million people living with HIV in 2009, representing more than a 1000 fold increase. Isoniazid preventive therapy was scaled up from about 4000 in 2002 to 85,000 in 2010 representing about 20 fold increase.
- TB/HIV has been mainstreamed into key HIV stakeholders including UNAIDS, International AIDS Society and PEPFAR.

(xi) 3-5 main (expected) outputs in 2010-2011:

- Provide and coordinate forum for catalysing the nationwide scale-up of collaborative TB/HIV activities in all regions with particular emphasis on Eastern Europe and Central Asia (Core group meeting in Almaty, Kazakhstan May 2010 and Vienna Workshop July 2010), and the scaling up of the Three Is for HIV/TB in sub-Saharan Africa (March 2011).
- Higher visibility of TB was maintained among key AIDS and TB events and stakeholders including the international AIDS Conference (IAS 2010), at the Conference of Retrovirus and opportunistic infections (CROI 2010, CROI 2011) and UNGASS 2011 where TB/HIV will be integrated into the UN high level meeting (June 2011).
- Simplified guidelines on TB screening and IPT and document with prioritized TB/HIV research document with full engagement of members of the Working Group developed.
- Increase capacity of civil society representatives and activists to promote increased access to collaborative TB/HIV activities for most at risk populations including

prisoners and drug users (Liverpool workshop in June 2010 in collaboration with the International Harm Reduction Association and Vienna workshop in collaboration with UNAIDS)

(xii) Advocacy activities:

a) Description of WG's advocacy activities for 2011: Advocacy to garner political and programme support for scaling up the implementation of collaborative TB/HIV activities is one of its key functions. The TB/HIV Working Group Secretariat in close consultation with the Core Group defines its advocacy priorities every year. The following are the key advocacy objectives of the Working Group for 2011:

- o Maintain the global, regional and national visibility of TB especially among HIV stakeholders, including program mangers, policy makers and researchers.
- o Advocate for nationwide scale up of collaborative TB/HIV activities in all regions to reduce HIV associated mortality by half by 2015 (Global Plan target).
- o Address the structural barriers of implementation of collaborative TB/HIV activities in Eastern Europe and Central Asia to ensure patient centred care.
- o Enhance the uptake of TB/HIV research priorities especially by HIV and TB researchers.
- o Promote the importance of TB among women and enhance the integration of TB and HIV services including into maternal and child health services.

b) Main targets of advocacy: The advocacy of the Working Group targets all TB and HIV stakeholders including global and national programme managers and policy makers, implementers and researchers. Funding and other technical agencies working on TB and AIDS are also targeted for the advocacy. UNAIDS co-sponsors are particularly targeted to enhance the implementation of the UNAIDS strategy which has now TB as one of the ten key areas.

c) Key advocacy challenges: The lack of commitment of some key organisations who should take more leadership role of global TB/HIV advocacy is a concern. Similarly lack of access of funding for civil society and community representatives who could carry out effective advocacy efforts is a major bottleneck for TB/HIV advocacy both at global and national level.

d) Upcoming advocacy opportunities

- International Harm Reduction Association Conference, Beirut
- High Level Meeting, UNGASS, June 2011
- IAS 2011
- World Aids Day
- ICASA 2011

(xiii) Main challenges and opportunities:

Opportunities:

- The renewed global commitment for effectiveness and integration offers an opportunity to integrate TB and HIV services.

- Examples of rapid scale up of collaborative TB/HIV activities in some outstanding countries like South Africa and India help to further catalyse nationwide scale up in many regions.
- The improving diagnostic pipeline of TB (e.g. Xpert TB)

Challenges:

- Most at risk groups in low burden countries are particularly vulnerable when donors are looking for more impact from their funding and when our resources are limited.
- The convergence of MDR/XDR TB with HIV and limited response especially those countries where the two epidemics overlap.

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups: The TB/HIV Working Group have been working closely with most Working Groups especially the Global Laboratory Initiative, the New Diagnostic Working Group and MDR through its meetings. The GLI has a liaison officer sitting as an observer in the TB/HIV Core Group.

2a. Subgroup on Infection Control

(i) Established in: November 2006

(ii) Core group members and affiliation

Dr Bess Miller	Division of Global HIV/AIDS, CDC Atlanta, GA, USA	Chair
Dr Paul Jensen	CDC, Atlanta, USA	
Ms Grace E. Egos	The Philippines	Country Representative
Dr Nii Nortey Hanson - Nortey	Focal Point for TB/HIV Collaboration, National TB Control Programme, Ghana	Country representative
Mr Javid Syed	TB/HIV Project Director, Treatment Action Group, NY, USA	Community representative
Dr Jeroen Van Gorkum	KNCV Tuberculosis Foundation, The Hague, The Netherlands	
Dr Edward A. Nardell	Harvard School of Public Health, Boston, USA	
Ms Cheri Vincent	Global Health Bureau, Office of Health and Infectious Diseases, USAID, Washington DC, USA	
Dr Martin Yagui Moscoso	Peruvian Society of Epidemiology, Lima, Peru	
Dr Alasdair Reid	UNAIDS, Geneva, Switzerland	

(iii) Is membership up to date?
We are in the process of renewal/rotation of core members, which should start at the next annual meeting. We would like to add expertise in general Infection Control, in Occupational Health, and to increase representation from high burden countries.

Dr. Jeroen Van Gorkum from KNCV has rotated off and Dr. Max Meis, KNCV has been added.Dr. Reuben Granich is liaison from WHO HIV Dept.

(iv) Secretariat hosted in: WHO Stop TB Department (TBS)

(v) Frequency of working group meetings:
a) Full working group: Once/year – face to face at Union Annual Meeting
b) Core group: Once/year face to face (the subgroup has had intermittent, infrequent teleconference calls)

(vi) Terms of Reference

The goal of the TB Infection Control subgroup is to develop, test, monitor, evaluate, advocate and support implementation of policy, tools and procedures to promote effective TB infection control in health care and congregate settings.

Terms of reference TB infection control subgroup:

1. To advise the WHO on the development of policies, strategies, research priorities, and guidelines for implementing effective tuberculosis infection control practices with emphasis on MDR- TB, XDR-TB, and TB/HIV, based on available knowledge, latest evidence, and practical field experience.

2. To build strategic partnerships for effective TB infection control with other Stop TB Partnership working groups, especially MDR-TB, and DOTS Expansion, with WHO Departments (HIV, CDS), occupational health groups, the scientific community, health care providers, and representatives of workers, patients, visitors, and others in the community directly and indirectly affected by TB transmission.

3. To build capacity at the country level for infection control implementation, including advocating for the training of international and national technical consultants in TB infection control, and facilitating their availability to provide technical assistance for the scale-up of TB infection control activities.

4. To prioritize the protection of health care workers, particularly PLHIV, by ensuring that global occupational health and safety programs understand the negative impact of TB transmission on health care workers, and that they advocate for TB infection control in the workplace.

5. To assist WHO and partners to develop and implement ways to monitor the implementation of infection control measures at the country level, including the development and testing of performance indicators to identify implementation and efficacy issues that may require additional attention.

6. To estimate the costs of implementing infection control activities, and advocate for resource mobilization, while monitoring the inclusion of specific funding for infection control in project proposals and funding opportunities.

7. To strengthen the working relationships and collaboration with the scientific community, health care providers, and representatives of workers, patients, visitors, and other stakeholders in airborne infection control in health care and congregate settings, e.g., agencies dealing with refugees, internally displaced persons, prisons, nursing homes, and military barracks.

(vii) Resources for biennium 2010-2011:
a) Approved budget: USD 50,000 is for the Infection Control sub-WG, as part of the 300,000 allocated to TB/HIV WG.
b) Provided (as of January 2011): 25,000 USD from the Stop TB Partnership plus 55,796 USD (including 13% PSC) from USAID TBCAP APA5 (Oct '09 - Sept '10)
c) Estimated in-kind contributions 2010-2011: In 2010, organisational members of the Core sub-WG (USAID,CDC, and KNCV) participated in the Core sub-WG meeting with their own funds. In addition, several members of the Core sub-WG applied in 2010-2011 for future activities (see below xi) to other sources of funding, especially to TB CARE.

(viii) Country focus: TB Infection Control, as a cross-cutting topic, is focusing on both the 63 TB/HIV Priority Countries and on the 27 MDR-TB High burden countries (76 countries altogether).

- Angola
- Armenia
- Azerbaijan
- Bahamas
- Bangladesh
- Barbados
- Belarus
- Belize
- Botswana
- Brazil
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Central African Republic
- Chad
- China
- Côte d'Ivoire
- Dijbouti
- DRC
- Dominican Republic
- Equatorial Guinea
- Eritrea
- Estonia
- Ethiopia
- Gabon
- Georgia
- Ghana
- Guatemala
- Guinea
- Guinea-Bissau
- Guayana
- Haiti
- Honduras
- India
- Indonesia
- Jamaica
- Kazakhstan
- Kenya
- Kyrgyzstan
- Latvia
- Lesotho
- Liberia
- Lithuania
- Madagascar
- Malawi
- Mali
- Mozambique
- Myanmar
- Namibia
- Niger
- Nigeria
- Pakistan
- Panama
- Philippines
- Republic of Moldova
- Russian Federation
- Rwanda
- Sierra Leone
- Somalia
- South Africa
- Sudan
- Suriname
- Swaziland
- Tajikistan
- Thailand
- Togo
- Trinidad and Tobago
- Uganda
- Ukraine
- UR Tanzania
- Uzbekistan
- Viet Nam
- Zambia
- Zimbabwe

(ix) Priorities in 2010-2011:

- Focus on TB in health care workers (surveillance, occupational care model) – Use as indicator for TB infection control
- Demonstrate scale up of IC in countries and share best practices of TB IC
- Scale up training of health care workers on TB IC

- Develop health facility design and renovation case study book
- Network with General Infection control leadership (e.g., IPC Global Network)

(x) Main achievements since establishment:

- Collaborated on development of 2009 WHO Policy on TB Infection Control
- Participated in Beijing MDR TB meeting – and got TB infection control included in Call to Action and on Workplans of high MDR TB burden countries
- Developed TB Infection Control Advocacy Strategy document (April 2010)
- Initiated/supported regional and country training courses on IC for more than 1300 participants (2007-2009)
- Developed TB IC Implementation Framework and Human resources development strategy (November 2010)
- Collaborated to modelling cost analysis of TB IC activities implementations (used for estimate the budget necessary for TB-IC; incorporated in the Global Plan to Stop TB - 2011-2015).

(xi) 3-5 main (expected) outputs in 2010-2011:
Some of future deliverables agreed upon in the last Core sub-WG meeting (in November 2010) were further elaborated by several Core sub-WG members, and submitted to funding request, mostly as part of TB CARE. Therefore, if these proposals will be accepted, we can expect by end of 2011 the following outcomes:

- Development of tools to measure TB incidence and prevalence in Health Care Workers
- Development of a Core Package of IC interventions
- Performance of Training and Mentoring for Technical Assistance on TB IC
- Finalising the Health facility design and renovation case study book.

(xii) Advocacy activities:
a) Description of WG's advocacy activities for 2011
In 2010, an Advocacy strategy for adoption and dissemination of the WHO policy on TB infection control in health-care facilities, congregate settings and households, has been published and disseminated.

In 2011, as mentioned above (xi), a proposal has been send to TB CARE in order to support the development of a Core Package of IC interventions. The objective of this project is to develop, through consensus, a core TB-IC package that is likely to be effective, marketable, implementable and measureable in various regions of the world. This core TB-IC package should be then part of future campaigns.

b) Main targets of advocacy
They will be discussed during the consensus meeting for the deliverable described above (xii, a).

c) Key advocacy challenges
To be determined in the upcoming consensus meeting.

d) Upcoming advocacy opportunities

(xiii) Main challenges and opportunities:

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:
TB-IC is, by definition, a cross-cutting issue. Therefore, the fields of activities include Health System Strengthening, TB/HIV, MDR-TB, Lab bio-safety, and also other fields such as non-TB Infection Control and Occupational Health.

Representatives of these other disciplines are also invited to the annual meeting of the Core subgroup, and we would like also to enhance our participation to other working groups and subgroups meetings.

Actually, the current chair of the TB-IC sub-WG is also a member of the TB/HIV WG. We are suggesting to:

- Identify TB IC subgroup member(s) to liaise with several Stop TB partnership working groups, including DOTS Expansion, MDR TB, and Global Lab Initiative. Participate in these working group meetings.
- Include ex officio members from other working groups (noted above) on TB IC subgroup, to participate in our meetings.
- Consider holding meeting of Chairs and secretariat of all working groups and subgroups – to promote networking, cross-fertilization
- Consider having workgroups and subgroups present at Coordinating Board Meetings (could have several highlighted at each meeting)

3. MDR-TB Working Group

(i) Established in: In 1999, WHO launched the working group on "DOTS-Plus for MDR-TB". In 2006, this working group was renamed "the Stop TB Working Group on MDR-TB".

(ii) MDR-TB Core group members and affiliation

Dr Aamir Khan	Director, MDR-TB Control Program, The Indus Hospital, Karachi, Pakistan	Chair
Dr Amy Bloom	USAID	
Dr Patrizia Carlevaro	Eli Lilly	
Dr Carole Mitnick	University of Harvard	
Dr Paula Fujiwara	The Union	
Dr Chuck Daley	American Thoracic Society	
Dr Michael Kimerling	The Gates Foundation, Seattle, USA	
Dr Catharina Van Weezenbeek	Regional Adviser TB, WPRO, Manilla, The Philippines	
Gloria Nwagboniwe	Nigeria	Community representative
Alam Shabab	India	Community representative
Dr Paul Thorn	UK	Vice-Chair
Vacant since December		Country representatives
Vacant since December		Country representatives

(iii) Is membership up to date? Yes

(iv) Secretariat hosted in: WHO Stop TB Department (TBC)

(v) Frequency of working group meetings:
a) Full working group: Every 18 months, on average.
b) Core group: In-person meetings every four months, and teleconferences in between on ad-hoc basis.

(vi) Terms of reference

- Assisting in implementation of programmatic drug-resistant TB management of as part of the Stop TB Strategy.
- Promoting worldwide universal access to effective diagnosis and appropriate treatment of MDR-TB by 2015.
- Promoting the creation of a healthy and competitive global market of quality assured second-line anti-TB drugs.
- Ensuring the use of second-line anti-TB drugs according to WHO guidelines to prevent amplification of resistance and emergence of XDR-TB.

- Promoting the introduction of new diagnostics, new anti-TB drugs, and new vaccines through research and cooperation with other Working Groups.
- Developing and promoting the implementation of a research agenda that supports the scale-up of management of MDR-TB and the development of new tools.
- Mobilizing sufficient resources dedicated to the above goals and all aspects of MDR-TB management.
- Conceptualizing, developing, testing, monitoring, evaluating, advocating and supporting implementation of tools, and procedures to promote effective MDR-TB prevention and care, according to WHO policies.

(vii) Resources for biennium 2010-2011:
a) Approved budget: 250,000 USD
b) Provided (as of January 2011): 250,000 USD
c) Estimated in-kind contributions 2010-2011:

(viii) Country focus: 27 MDR-TB Priority Countries
- China
- India
- Russian Federation
- Pakistan
- Bangladesh
- South Africa
- Ukraine
- Indonesia
- Philippines
- Nigeria
- Uzbekistan
- DRC
- Kazakhstan
- Viet Nam
- Ethiopia
- Myanmar
- Tajikistan
- Azerbaijan
- Republic of Moldova
- Kyrgyzstan
- Belarus
- Georgia
- Bulgaria
- Lithuania
- Armenia
- Latvia
- Estonia

(ix) Priorities in 2010-2011:

- Support the development and implementation of a new framework for coordinating and delivering advice to partners and support to countries for scale-up of programmatic management of MDR-TB.

(x) Main achievements since establishment:

- Inclusion of programmatic management of MDR-TB in the Stop TB strategy
- Advice to WHO for producing and regularly updating the guidelines for the programmatic management of MDR-TB
- Development of ambitious plans for scale up of programmatic management of MDR-TB in the Global Plan to Stop TB 2006-2015; including the revised plan 2011-2015

(xi) 3-5 main (expected) outputs in 2010-2011:

- Successful implementation of new framework for coordinating and delivering advice to partners and support to countries for scale-up of programmatic management of MDR-TB

(xii) Advocacy activities:

a) Description of WG's advocacy activities for 2011

Pending to be agreed

b) Main targets of advocacy

Pending to be agreed

c) Key advocacy challenges

Pending to be agreed

d) Upcoming advocacy opportunities

Pending to be agreed

(xiii) Main challenges and opportunities:

Pending to be agreed

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:

Pending to be agreed

3a. Green Light Committee

(i) Established in: 2000

(ii) Core group members and affiliation

Name (principal member listed first.)	Affiliation	Function in the working group
Charles Daley Richard Menzis	American Thoracic Society	Member
Domingo Palmero Ximena Gonzalo	Hospital Francisco J. Muñiz, Argentina	Member
Amir Khan Hamidah Hussain	Indus Hospital	Member
Jose Caminero Arnaud Trebucq	International Union Against Tuberculosis and Lung Disease	Member
Agnes Gebhard Jacques van den Broek	KNCV Tuberculosis Foundation	Member
Francis Varaine Myriam Henkins	Médecins sans Frontières	Member
Salmaan Keshavjee	Partners In Health	Member
Vaira Leimane	State Agency for TB & Lung Disease - Latvia	Member
Wieslaw Jakubowiak Fraser Wares	WHO	Member

(iii) Is membership up to date? Yes

(iv) Secretariat hosted in: WHO Stop TB Department (TBC)

(v) Frequency of working group meetings: In person almost every two months.

(vi) Terms of reference:
Under revision.

(vii) Resources for biennium 2010-2011:
a) Approved budget: USD
b) Provided (as of January 2011): USD
c) Estimated in-kind contributions 2010-2011:

(viii) Country focus: 27 MDR-TB Priority Countries
- China
- India

- Russian Federation
- Pakistan
- Bangladesh
- South Africa
- Ukraine
- Indonesia
- Philippines
- Nigeria
- Uzbekistan
- DRC
- Kazakhstan
- Viet Nam
- Ethiopia
- Myanmar
- Tajikistan
- Azerbaijan
- Republic of Moldova
- Kyrgyzstan
- Belarus
- Georgia
- Bulgaria
- Lithuania
- Armenia
- Latvia
- Estonia

(ix) Priorities in 2010-2011:

(x) Main achievements since establishment:

(xi) 3-5 main (expected) outputs in 2010-2011:

(xii) Advocacy activities:
a) Description of WG's advocacy activities for 2011

b) Main targets of advocacy

c) Key advocacy challenges

d) Upcoming advocacy opportunities

(xiii) Main challenges and opportunities:

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:

3b. Research subgroup

(i) Established in: September 2006

(ii) Core group members and affiliation

Name	Affiliation	Function in the working group
Frank Cobelens	AMC CPCD Foundation	Member (former Chair)
Mark Harrington	Treatment Action Group (TAG)	Member
Einar Heldal	Norwegian Lung Association	Member
Christian Lienhardt	WHO Stop TB/STOP TB Partnership	Member
Michael Eli Kimerling	Gates Foundation	Member
Carole Mitnick	Department of Social Medicine - Harvard Medical School	Chair
Laura J. Podewils	US Centers for Diseases Control and Prevention	Member
Rajeswari Ramachandran	Tuberculosis Research Centre	Member
Hans Rieder	The Union	Member
Christine Sizemore	US National Institute of Allergy & Infectious Diseases	Member
Matteo Zignol	WHO Stop TB	Secretariat

Composition of the Scientific Subgroup

The Subgroup will be comprised of six institutional participants of the Working Group on voluntary basis. They will serve for a period of two years with the possibility of renewal at the end of the term. WHO could provide the secretariat functions.

A chair will be selected by consensus of the participants of the Scientific Subgroup, in principle for the duration of the term of the membership. The chair will preside over the meetings of the Scientific Subgroup.

(iii) Is membership up to date?

Yes

(iv) Secretariat hosted in: At the moment in WHO but it will be soon moved to another body.

(v) Frequency of working group meetings: Teleconferences every 2 months and annual face-to-face meeting

a) Full working group: NA

b) Core group: NA

(vi) Terms of reference:

Background

The Working Group on MDR-TB (MDR-TB WG) is an inter-institutional working group involving institutions/agencies and experts active in the management of Multidrug-Resistant Tuberculosis (MDR-TB). The Working Group is established to assist in producing policy recommendations for Member States on the management of MDR-TB, based on the assessment of the feasibility, effectiveness and cost-effectiveness data generated by pilot projects implemented by the agencies/institutions participating in the Working Group, or by the World Health Organization (WHO); to coordinate and monitor the implementation of internationally comparable pilot projects for the management of MDR-TB; to establish a system that allows WHO Member States to have access to high-quality second-line drugs at reduced prices and, at the same time, prevents misuse of such drugs; to review progress achieved in countries managing MDR-TB through the Green Light Committee (GLC); and to identify resources to fund and implement MDR-TB control and to assist with global coordination of the initiative.

The MDR-TB WG has indicated in its fifth meeting in Atlanta the need to revitalize the scientific component of the Working Group. Many research questions remain to be answered in order scale-up the management of drug resistant tuberculosis (DR-TB) in resource-constrained countries, according to the Global Plan to Stop TB 2006-2015. Further research evidence on MDR-TB management will enable WHO to update the recently published "Guidelines for the programmatic management of drug-resistant tuberculosis". To prioritize, promote, coordinate and steer research activities in the field of DR-TB the Research Subgroup of the MDR-TB WG is established.

Objectives of the Research subgroup

1. To develop and maintain updated a research agenda on DR-TB and promote its development.
2. To develop a modus operandi of the subgroup describing all operating procedures related to work of the subgroup.
3. To keep update a system to track the research initiatives conducted by the members of the DR-TB WG and create a forum to exchange data, experiences, and information on the epidemiology, diagnosis and management of DR-TB.
4. To assist the GLC in the scientific analysis of the evidence that supports the advice to WHO on policy for the programmatic management of DR-TB.
5. To promote research collaborations between the agencies/institutions participating in the MDR-TB WG and between the GLC-approved projects.
6. To strengthen working relationships with the scientific community involved in MDR-TB research and particularly with the Working Groups on New TB Diagnostics, New TB Drugs and New TB Vaccines of the STOP TB Partnership.
7. To assist GLC-approved projects in developing and implementing operational research plans on MDR-TB management.
8. To promote resource mobilization for research activities on MDR-TB.
9. To steer the research on MDR-TB by reviewing and commenting on major publications on MDR-TB in peer reviewed journals.

(vii) Resources for biennium 2010-2011:
a) Approved budget: USD 160,000 (USD 60,000 in 2010; USD 100,000 in 2011)
b) Provided (as of January 2011): USD 60,000
c) Estimated in-kind contributions 2010-2011: USD 350,000

(viii) Country focus: 27 MDR-TB Priority Countries

- China
- India
- Russian Federation
- Pakistan
- Bangladesh
- South Africa
- Ukraine
- Indonesia
- Philippines
- Nigeria
- Uzbekistan
- DRC
- Kazakhstan
- Viet Nam
- Ethiopia
- Myanmar
- Tajikistan
- Azerbaijan
- Republic of Moldova
- Kyrgyzstan
- Belarus
- Georgia
- Bulgaria
- Lithuania
- Armenia
- Latvia
- Estonia

(ix) Priorities in 2010-2011:

Maintaining a website to coordinate activities of the subgroup and share information
Support to RESIST-TB Secretariat
Contribution to OR plan Research Movement
Analysis report or protocol review
Workshop for templates' development for operational research
Scientific symposium at Union Conference and subgroup meeting

Coordinating activities
Secured funding for international travels
Support countries to submit OR components to the GF call for proposals
Review and comment on major publications on MDR-TB in peer reviewed journals on ad-hoc basis
Scientific symposium and subgroup meeting
Overall coordination implementation of new structure, integration of new members

(x) Main achievements since establishment:
- Revised prioritized MDR-TB research agenda
- Symposia at the International Union Conferences
- Establishment of RESIST TB
- Workshops on MDR-TB clinical trials and DR-TB epidemiologic research

(xi) 3-5 main (expected) outputs in 2010-2011:
- Symposium at the International Union Conference
- Workshop on operational research in DR-TB control
- New structure of the subgroup with larger participation

(xii) Advocacy activities:
a) Description of WG's advocacy activities for 2011
See MDR-TB WG

b) Main targets of advocacy
See MDR-TB WG

c) Key advocacy challenges
See MDR-TB WG

d) Upcoming advocacy opportunities
See MDR-TB WG

(xiii) Main challenges and opportunities:
- Lack of funds for 2011
- WHO won't be able to act as Secretariat from 2011 due to lack of staff
- Need of a financial mechanism to the subgroup not relying on WHO

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:
- Need to have the Partners more engaged
- Need to have more support from the Partnership Secretariat

3c. Subgroup on Drug Management (non active since 2009)

4. Global Laboratory Initiative

(i) Established in: October 2008 (before that there was a DEWG subgroup on laboratory capacity strengthening which was established in November 2002)

(ii) GLI Core group members and affiliation

Dr Rick O'Brien	FIND, Based in USA	Chair
Dr Tom Shinnick	CDC, Atlanta, USA	Vice-Chair
Ms Maria Alice Da Silva Telles	National Reference Laboratory, Brazil	
Dr Satoshi Mitarai	National Reference Laboratory, Japan	
Dr John Ridderhof	CDC, Atlanta, USA	
Dr Rumina Hasan	Aga Khan University, Pakistan	
Dr Dick van Soolingen	RIVM, The Netherlands	
Dr Armand Van Deun	The Union, Belgium	
Dr John Nkengasong	CDC /PEPFAR	
Dr Amy Piatek	USAID	
Dr Sabine Rusch-Gerdes	SRL, Borstel	Chair SRLN sub-Group
Vacant	GLI partner	
Vacant	GLI partner	
Vacant	NTP manager	
Dr Karin Weyer	WHO	
Dr Chris Gilpin	WHO	Secretariat
Dr Vijay K. Gupta	India	Community Representative
Mr Nelson Otwoma	Kenya	Community Representative

(iii) Is membership up to date? Yes

(iv) Secretariat hosted in: WHO Stop TB Department (TBL)

(v) Frequency of working group meetings:
a) Full working group: Annual meeting
b) Core group: Monthly teleconference calls and two face-to face meeting each year

(vi) Terms of reference
Terms of reference for the GLI and its secretariat include the following:

- Provide strategic and technical global guidance on strengthening TB laboratory systems, including guidelines for development of evidence-based laboratory policies, norms and standards for existing and future TB diagnostic tests;

- Maintain the GLI Secretariat and facilitate coordination of GLI partner technical assistance;

- Promote communication and coordination among Stop TB Partnership Working Groups and across WHO Departments on laboratory strengthening-related issues;

- Provide monitoring and evaluation support and global analysis on progress in laboratory systems strengthening;

- Promote strengthening of laboratory systems through supporting TB advocacy activities, resource mapping and coordinated resource mobilization.

(vii) Resources for biennium 2010-2011:
a) Approved budget: 250,000 USD
b) Provided (as of January 2011): 125,000 USD plus 63,676 USD (including 13% PSC) for GLI Secretariat from USAID TBCAP APA5 (Oct '09 - Sept '10)

c) Estimated in-kind contributions 2010-2011: This is difficult to estimate but some partners, e.g. CDC, have provided significant in-kind contributions for GLI activities. TBL Stop TB WHO provides in-kind secretariat support to the GLI working group and maintains an updates the GLI website. Staff costs 61,650 USD: 15% P5 staff (36,900 USD), 15% P3 staff (24,750 USD)

(viii) Country focus: 27

- Bangladesh
- DRC
- Ethiopia
- India
- Indonesia
- Kenya
- Myanmar
- Uganda
- UR Tanzania
- Viet Nam
- Cameroon
- Côte d'Ivoire
- Djibouti
- Haiti
- Lesotho
- Swaziland
- Zambia
- Azerbaijan
- Belarus
- Georgia
- Kazakhstan
- Kyrgyzstan
- Moldova
- Tajikistan
- Uzbekistan
- Peru
- Senegal

(ix) Priorities in 2010-2011:

- WHO co-ordination of GLI partners to support roll-out of the Xpert MTB/RIF test under programmatic conditions to generate evidence for widespread implementation and scale-up
- Expanding the TB Supranational Reference Laboratory Network with coordination of in-country technical assistance
- Interface design with other laboratory networks to ensure appropriate integration

- Standardized laboratory quality assurance for rapid molecular diagnostics including the Xpert MTB/RIF test
- A roadmap for national level TB reference laboratories and networks to meet international standards for laboratory accreditation.

(x) Main achievements since establishment:

1. Working with TBCAP provided key multi-cosponsored tools that included:
    - Comprehensive training package (workshop in a box-WIB) for TB culture and DST methods;
    - a training WIB for country implementation of external quality assessment for AFB smear microscopy which includes preliminary guidance for fluorescence microscopy; guidance and specifications for purchasing high quality reliable equipment;
    - Standard Operating Procedures (SOPs) for critical TB test methods and processes; and management information systems (MIS) that includes data collection and spreadsheet software for a variety of laboratory processes.
2. Developed a roadmap for implementation of TB diagnostics at the country level that provides guidance on strengthening policy and infrastructure for TB diagnosis in the framework of an integrated national laboratory system and strategic plan.
3. Developed draft bio-safety guidance based on a risk assessment of different TB laboratory processes. A technical manual has been prepared for performing first- and second-line DST. The document is undergoing final peer review.
4. The establishment of four time-limited technical working groups focused on key priority areas for the laboratory strengthening efforts of the GLI:
    - Technical working group on laboratory accreditation
    - Technical working group on TB laboratory biosafety
    - Technical working group on unresolved issues relating to drug susceptibility testing
    - Technical working group on integrated laboratory networks

(xi) 3-5 main (expected) outputs in 2010-2011:

1. Led a Global Consultation on Xpert MTB/RIF (endorsed by WHO in December 2010) to develop consensus interim testing algorithms, patient management approaches, and key data elements needed to guide Xpert MTB/RIF roll-out and gather programmatic and operational evidence for widespread scale-up;

2. Completed Laboratory assessments for 19 of the 27 recipient countries under the EXPAND-TB project. This included a needs assessment and gap analyses, upgrades and renovation of laboratory infrastructure, training of staff, diagnostic

policy reform, technology transfer and country validation of new technologies. Six countries in this GLI/UNITAID/FIND/WHO/GDF project are now routinely diagnosing MDR-TB patients – clearly demonstrating the feasibility of rapid scale-up of the numbers of patients detected once laboratories have been validated;

3. Developed and conducted a training workshop for TB laboratory and non-laboratory consultants in the skills required to assist countries to develop integrated laboratory plans for Global Fund applications that would ensure that appropriate TB laboratory services were available and adequately funded. Structured feedback was provided to 12 countries requesting GLI input, nine of which were successfully awarded Round 10 Global Fund grants;

4. Conducted a Global Consultation of the TB Supranational Reference Laboratory Network (SRLN) that resulted in revised (and expanded) terms of reference, agreed eligibility and exclusion criteria for new and existing SRLs, a policy for formally linking SRLs and national laboratories, and a new funding strategy to support the SRLN in provision of technical assistance to countries. As a result, all 27 MDR-TB priority countries are now formally linked to the SRLN and several countries in the EXPAND-TB Project are receiving SRLN technical support;

5. The GLI laboratory tool set has been expanded to include a Roadmap for TB Laboratory Strengthening within the context of national strategic laboratory plans, a WHO Framework for Implementing New TB Diagnostics (supported by WHO policy guidance on several new TB diagnostics), and a Technical Manual for first- and second-line drug susceptibility testing.

(xii) Advocacy activities:

a) Description of WG's advocacy activities for 2011

Support is needed from the Stop TB partnership for the development of a comprehensive advocacy strategy for the GLI**.** There is currently insufficient, time, resources and expertise with the GLI for advocacy activities.

b) Main targets of advocacy

USAID, DFID, CIDA, JATA, GFATM

c) Key advocacy challenges

The main challenges for advocacy are lack of resources both financial and human. The GLI secretariat is already overburdened with the co-ordination of the GLI working group activities.

d) Upcoming advocacy opportunities

The roll-out of the Xpert MTB/RIF assay will represent an important advocacy opportunity. The impact of Xpert MTB/RIF roll-out will a key topic at various forums during 2011. The latter includes World TB day, The Union World Conference on Lung Health and the annual GLI Partners meeting.

(xiii) Main challenges and opportunities:
There is a strong willingness of donors to invest in the roll-out of the Xpert MTB/RIF which represents both an opportunity and challenge for the co-ordination of GLI partner efforts to build evidence systematically through standardised data collection to enable scale-up and widespread implementation of this important technology.

Additionally, the roll-out of the Xpert MTB/RIF represents an opportunity for integration with other laboratory strengthening efforts and especially for HIV/TB diagnostic services. This will create demand for additional resources and staffing if effective integration of these diagnostic services is to be ensured.

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:
Strong co-ordination already exists between the GLI and the other working groups in the Stop TB partnership. GLI liaisons have been designated to participate in the Core Group and Working Group meetings of the other implementation Working Groups. Reciprocal arrangements are in place for participation of liaisons from the other Working Groups at GLI meetings.

4a. TB Supranational Reference Laboratory Network (SRLN) sub-Group GLI

(i) Established in: 2010

(ii) Core group members and affiliation

Name	Affiliation	Function in the working group
Dr Sabine Rusch-Gerdes	SRL Borstel	Chair SRLN

(iii) Is membership up to date? Membership comprises the heads of 29 TB Supranational Reference Laboratories

(iv) Secretariat hosted in: WHO Stop TB Department (TBL)

(v) Frequency of working group meetings:
a) Full working group: Annual meeting (depending on availability of funds)
b) Core group: Ad hoc based on activities in the 4 time limited technical Working groups of the GLI.

(vi) Terms of reference:

1. Liaise with Global Laboratory Initiative (GLI) technical partners, National TB Reference Laboratories (NRLs) and National TB Programmes (NTPs) to facilitate implementation of WHO policy guidance on TB diagnostics and laboratory norms and standards.
2. Support the integration of quality TB diagnostic services with national laboratory strategic laboratory plans incorporating cross cutting laboratory issues including supply management, specimen transport and referral and human resource development.
3. Advocate for TB laboratory worker protection with use of current WHO TB bio-safety recommendations.
4. Support development of M&E indicators starting with a good data management system
5. Provide guidance on quality management systems for a process towards NRLs achieving accreditation.

(vii) Resources for biennium 2010-2011:
a) Approved budget: USD
b) Provided (as of January 2011): USD
c) Estimated in-kind contributions 2010-2011: TBL Stop TB WHO provides in-kind secretariat support to the SRLN sub-group GLI working group and co-ordinates the in-country technical assistance provided through the network. Staff costs 61,650 USD : 15% P5 staff (36,900 USD), 15% P3 staff (24,750 USD)

(viii) Country focus: 27 High MDR-TB Countries

- Bangladesh
- DRC
- Ethiopia
- India
- Indonesia
- Kenya
- Myanmar
- Uganda
- UR Tanzania
- Viet Nam
- Cameroon
- Côte d'Ivoire
- Djibouti
- Haiti
- Lesotho
- Swaziland
- Zambia
- Azerbaijan
- Belarus
- Georgia
- Kazakhstan
- Kyrgyzstan
- Moldova
- Tajikistan
- Uzbekistan
- Peru
- Senegal

(ix) Priorities in 2010-2011:

1. Expansion of the SRL network with the creation of new candidate SRLs which can support national reference laboratories in their region;
2. Interface design with other laboratory networks to ensure appropriate integration
3. Support the roll-out of a standardized laboratory quality assurance for rapid molecular diagnostics including the Xpert MTB/RIF test
4. Development of a roadmap for national level TB reference laboratories and networks to meet international standards for laboratory accreditation.

(x) Main achievements since establishment:

1. All 27 MDR-TB priority countries are now formally linked to the SRLN and several countries in the EXPAND-TB Project are receiving SRLN technical support;

(xi) 3-5 main (expected) outputs in 2010-2011:

1. Revised (and expanded) terms of reference, agreed eligibility and exclusion criteria for new and existing SRLs;

2. Conducted a mapping exercise on the existing linkages between SRLs and national laboratories;

3. Established a mechanism to create formal links between SRLs and national laboratories, and a new funding strategy to support the SRLN in provision of technical assistance to countries.

(xii) Advocacy activities:
a) Description of WG's advocacy activities for 2011

b) Main targets of advocacy

c) Key advocacy challenges

d) Upcoming advocacy opportunities

(xiii) Main challenges and opportunities:

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:
Excellent coordination and collaboration exists between the SRLN subgroup of GLI. The SRLN is an essential technical resource of the GLI and the Chair of the SRLN sub-Group is a member of the GLI Core Group.

5. Working Group on New Diagnostics

(i) Established in: 2001

(ii) Core group members and affiliation

Dr Giorgio Roscigno	FIND, Geneva, Switzerland	Co-Chair
Dr Madhukar Pai	McGill University, Canada	Co-Chair
Dr Arend Kolk	University of Amsterdam, The Netherlands	Academia
Dr Mark Perkins	FIND, Geneva, Switzerland	Diagnostic developer
Dr Jean-François de Lavison	EDMA, Belgium	Diagnostic manufacturer
Thokozile Phiri-Nkhoma	Lilongwe, Malawi	Patient community
Mayowa Joel	Lagos, Nigeria	Patient community
Dr Christian Lienhardt	Stop TB Partnership, Geneva, Swizterland	WHO Stop TB Partnership
Dr Anne Detjen	TREAT TB, New York, USA	The Union
Dr Rumina Hasan	Aga Khan University, Karachi, Pakistan	Global Laboratory Initiative
Dr Charles Sandy	NTP Manager, Zimbabwe	National TB Programme

(iii) Is membership up to date? Updated

(iv) Secretariat hosted in: Geneva, Switzerland, with FIND (since November 2010)

(v) Frequency of working group meetings:
a) Full working group: Once a year
b) Core group: One face-to-face meeting per year and three to four teleconferences
c) Subgroup Chairs: One face-to-face meeting per year and three to four teleconferences

(vi) Terms of reference Current version will be revised, following new organization of the working group.

(vii) Resources for biennium 2010-2011
a) Approved budget: 250,000 USD
b) Provided (as of January 2011):125,000 USD
Note: the NDWG budget is not yet with the new Secretariat at FIND and precise figures as to awards until January 2011 are not available
c) Estimated in-kind contributions 2010-2011:
No global figure is available, but in-kind contributions include working time of members, travel costs, telecommunication costs and use of premises and equipment, which are provided by members' institutions. In addition, FIND is covering 50% of the costs for staffing the Secretariat function.

(viii) Country focus (if any): Global approach as to geographical focus

(ix) Priorities in 2010-2011:
- Restructuring of the working group;
- Improving communication at all levels within the working group;
- Increasing cooperation with other working groups;
- Technical work within Subgroups (see below).

(x) Main achievements since establishment:
- Endorsement by WHO of several diagnostic technologies, including the Xpert MTB/RIF test, LED-fluorescence and front-loaded microscopy, line probe assays for MDR-TB diagnosis;
- Publication with participation by all Subgroups of a scientific blueprint, "Pathways to better diagnostics for tuberculosis: a blueprint for the development of TB diagnostics';
- Update of the diagnostics research and development component of the Global Plan to Stop TB 20011–2015 and development of a logical framework for activities;
- Contribution to definition of WHO policy guidance on use of various diagnostic tools, including commercial serological tests and IGRAs, same-day-diagnosis by microscopy, LED microscopy, non-commercial culture and DST for MDR-TB, liquid culture and rapid species identification for culture and DST;
- Implementation of diagnostics for MDR-TB in high-burden MDR-TB countries, through an initiative of UNITAID, the Global Laboratory Initiative, the Global Drug Facility and the Foundation for Innovative New Diagnostics;
- Collaboration with other Working Groups and with the Retooling Task Force to facilitate the adoption, introduction and implementation of new tools and approaches, in particular with the publication of "New laboratory diagnostic tools for TB control";
- Publication of a number of meta-analyses and systematic reviews of different diagnostic tests, based on evidence of the performance of TB diagnostics.

(xi): 3-5 main (expected) outputs in 2010-2011
- Implementation of the new organization (elections, terms of reference, standard operating procedures, information to members);
- Revamping of website, with new design, content revision and expansion and enhanced interactivity;
- Creation of a Newsletter (first issue on 1st February 2011);
- Organization of the Annual Meeting with entire membership and back-to-back with Working Group on New Drugs, in order to have areas of overlap;
- Organization of a joint symposium on New Tools for TB, together with the Working Groups on New Drugs and New Vaccines and with the Research Movement;
- Technical outputs by Subgroups (see below).

(xii) Advocacy activities:
a) Description of WG's advocacy activities for 2011
The Subgroup on Community, Poverty and Advocacy has been defined within the new structure as an evolution of the past Poverty and TB Diagnostics Subgroup. The coordinator of this extended subgroup will be elected in March 2011 and a new action

plan, also including the advocacy perspective, will be defined afterwards.

b) Main targets of advocacy

c) Key advocacy challenges

d) Upcoming advocacy opportunities

(xiii) Main challenges and opportunities:

Challenges

- The new Secretariat has no access to the working group budget, which represents a problem for day-to-day operations, work to be initiated by Subgroups and credibility of the new Secretariat.
- The past Secretariat had regular problems in having timely access to the working group budget.

Opportunities

- The new structure of the working group represents an opportunity for improving functioning, defining more efficient procedures and reactivating Subgroups;
- The new communications tools represent an opportunity for higher interaction with the entire working group and for active contributions by members.

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:

In addition to joint initiatives, as described above, occasional meetings of working groups chairs and secretariats would be helpful in order to strengthen coordination and to identify opportunities for collaboration at subgroups level.

Note on restructuring:

The New Diagnostics Working Group has been created in 2001, in order to support the Stop TB Partnership's goals, in particular by providing a coordination and communication platform to facilitate common work towards the development and adoption of new diagnostic tools for tuberculosis.

Past organization

Until 2010, the organization of the New Diagnostics Working Group has been the following (also shown in organization chart in Figure 5.1):

- Two Co-Chairs,
- A Secretariat hosted by TDR until November 2010 (now hosted by FIND),
- A Core Group with representatives of various constituencies, including the Stop TB Partnership, the Union, academia, diagnostics developers, the patients community and the GLI,
- Nine Subgroups, each one having two Co-Chairs and covering the various areas in which the Working Group has been engaged:

o Optimizing smear microscopy
o Culture-based diagnostics and DST
o Nucleic acid amplification tests (NAAT) for diagnosis and resistance testing
o Diagnostics for latent TB infection (LTBI)
o Point of care diagnostics for TB
o Evidence synthesis for TB diagnostics
o TB diagnostics and poverty
o TB diagnostics and HIV
o Diagnostics and paediatric TB

Meetings of the New Diagnostics Working Group have taken place on the following basis:

- Regular ad hoc meetings of Co-Chairs and Secretariat,
- Three to four teleconferences per year of Core Group, including Co-Chairs and Secretariat,
- Three to four teleconferences per year of all the Subgroup Chairs, including Co-Chairs and Secretariat,
- One face-to-face meeting per year organized at the Union World Conference, including Co-Chairs, Secretariat, Core Group and Subgroup Chairs,
- One Annual Meeting of the entire New Diagnostics Working Group organized at the Union World Conferences and attended by 250 to 300 participants.

New structure

In order to ensure higher efficiency and to better respond to the new objectives of the Global Plan to Stop TB 2011-2015, the New Diagnostics Working Group has been recently reorganized.

The restructuring process started in 2010 mainly aimed at reducing the number of the existing Subgroups, in order to:

- have a more efficient management of the working group and promote active Subgroups,
- improve allocation of the limited budget available,
- align the working group structure with the focus on deliverables still pending in the diagnostics pipeline.

In line with the most recent priorities in diagnostics development, the new structure includes the following three technical platforms:

- Point Of Care Diagnosis
- Drug Susceptibility Testing
- Diagnostics for Latent TB Infection

The following three additional Subgroups cover cross-cutting themes:

- Paediatric TB
- Evidence Synthesis and Policy
- Community, Poverty and Advocacy

The six Subgroups have been organized in a matrix structure (Figure 5.2), which ensures higher interaction between the Subgroups and ideal representation of the cross-cutting issues with the technical Subgroups.

Although the TB/HIV problem is no longer covered by a specific Subgroup, this major issue will be addressed by all the Subgroups.

In order to improve coordination and intercommunication within the working group, the new organization also involves an expanded Core Group, which, in addition to the current members, will include direct representation of the Subgroup Coordinators. The election of Subgroup Coordinators will take place in March 2011.

N.B. Due to the restructuring currently taking place, the responses from the NDWG and its subgroups (below) are not complete. The NDWG is planning the election of the Subgroup coordinators for the last week of March 2011 and the ballot is being set up with the online voting tool of the Stop TB Partnership.

Figure 5.1

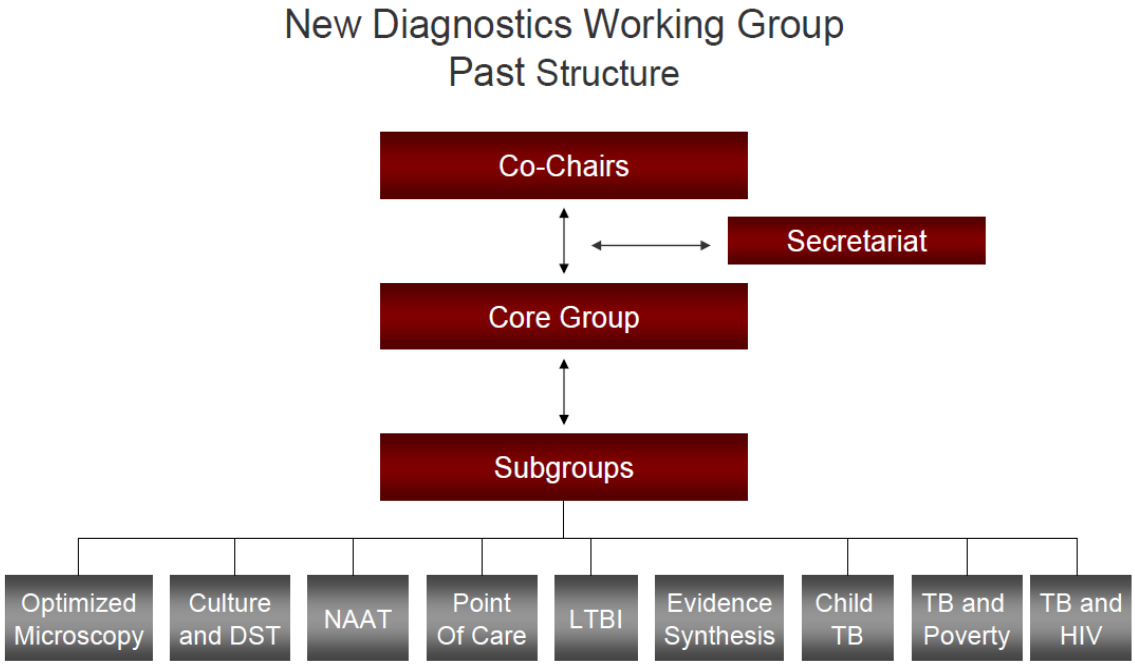
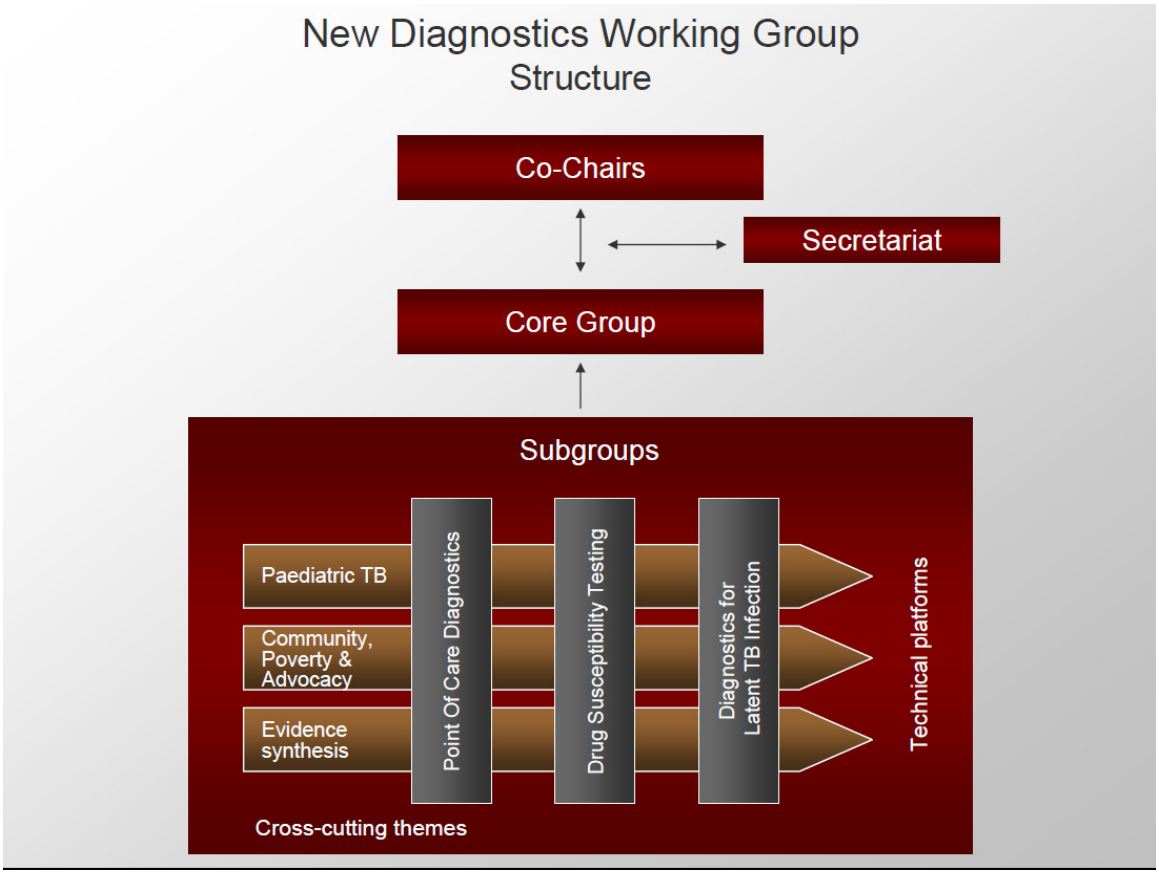

New Diagnostics Working Group
Past Structure
Co-Chairs
Secretariat
Core Group
Subgroups
Optimized Microscopy
Culture and DST
NAAT
Point Of Care
LTBI
Evidence Synthesis
Child TB
TB and Poverty
TB and HIV

Figure 5.2


New Diagnostics Working Group
Structure
Co-Chairs
Secretariat
Core Group
Subgroups
Paediatric TB
Community, Poverty & Advocacy
Evidence synthesis
Point Of Care Diagnostics
Drug Susceptibility Testing
Diagnostics for Latent TB Infection
Technical platforms
Cross-cutting themes

5a. Subgroup on Optimizing TB smear microscopy

Subgroup has been discontinued (see Overview)

5b. Subgroup on Culture-based diagnostics and resistance

Subgroup is maintained (see Overview) and will be named Drug Susceptibility Testing

(i) Established in: 2007

(ii) Core group members and affiliation

Dr David Moore	Faculty of Infectious and Tropical Diseases, Department of Clinica Research. LSHTM, UK Universiddad Peruana Cayetano Heredia, Peru	Co-chair
Dr Nicolas Durier	Consultant, Thailand	Co-chair

(iii) Is membership up to date? Will be updated based on new WG structure

(iv) Secretariat hosted in: With WG Secretariat at FIND, Geneva

(v) Frequency of working group meetings: see above
a) Full working group:
b) Core group:

(vi) Terms of reference see above

(vii) Resources for biennium 2010-2011
a) Approved budget: 22,000 US$
b) Provided (as of January 2011): None yet
c) Estimated in-kind contributions 2010-2011: working time of the co-chairs (3-4 hours per week) and the subgroup members involved in activities that are under way.

(viii) Country focus (if any): Asia and Africa regions as a whole.

(ix) Priorities in 2010-2011:
Establish 2 pilot regional training centers (1 based in India for countries/labs in Asia, 1 based in Uganda for countries/labs in Africa) on new non-commercial culture/DST methods endorsed by the WHO (MODS, NRA, CRI)

(x) Main achievements since establishment:
2009-2010:
- Submitted an activity proposal with a funding request of 22,000 USD. Proposal was approved.
- Initiated a summary technical brief of all existing culture and DST methods.

- Completed and posted on the "tbevidence" website a complete bibliography of abstracts or full-length articles on culture and DST methods. Over 280 resource publications have been made publically available. See:
http://www.tbevidence.org/rescentre/sop/tbcultures.htm
- Started to establish SOPs on new-non commercial culture/DST methods

2010-2011 :
- Submitted an ambitious activity proposal with a funding request of 41,0000 US$. Proposal was technically approved in whole, but available approved funding is only of 22,000 USD.
- Signed TOR/agreements with 2 member institutes to establish regional training centers on MODS, NRA, CRI.

(xi): 3-5 main (expected) outputs in 2010-2011

- Establish the training services in the 2 selected institutes.
- Offer the 1st regional training course in each of the centers.
- Establish a group of investigators to plan/design a head-to-head field comparison study of new non-commercial culture/DST methods.

(xii) Advocacy activities:
a) Description of WG's advocacy activities for 2011
Use of MODS, NRA, CRI

b) Main targets of advocacy
NRLs, NTPs, donors, TA partners

c) Key advocacy challenges
Little echo truly by the WHO and STP on the "WHO-endorsement" of these methods, which offer important potential to rapidly increase case detection and detection of DRTB. Competing attention placed almost exclusively on new molecular test (Xpert TB), which despite being a great instrument, is not all that is needed!!!!! Expert Recommendations recognize that culture based DST remain needed!

d) Upcoming advocacy opportunities
The Union meetings.
NDWG website

(xiii) Main challenges and opportunities:
Time necessary to conduct meaningful activities.
Limited funding.

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:
Subgroup co-chairs get more direct interaction with the NDWG core-group.

5c. Subgroup on Nucleic-acid amplification techniques for diagnosis

Subgroup has been discontinued (see Overview)

5d. Subgroup on Diagnostics for Latent TB infection

Subgroup is maintained (see Overview)

(i) Established in: 2007

(ii) Core group members and affiliation

Dr Keertan Dheda	University of Cape Town, South Africa	Co-chair
Dr Philip Hill	University of Otago, New Zealand	Co-chair

(iii) Is membership up to date? Will be updated based on new working group structure.

(iv) Secretariat hosted in: With the Working Group secretariat at FIND in Geneva, Switzerland

(v) Frequency of working group meetings:
a) Full working group: 1x year and as required
b) Core group: 2x year and as required

(vi) Terms of reference

(vii) Resources for biennium 2010-2011
a) Approved budget: ? (Need: USD 50,000)
b) Provided (as of January 2011): ?
c) Estimated in-kind contributions 2010-2011: USD 6,000

(viii) Country focus (if any): High Burden Countries

(ix) Priorities in 2010-2011:
(i) Teaching and training: The NDWG for LTBI together with several stakeholders including the NDWG members, ATS, IUTALD, ERS etc will facilitate seminars and courses on LTBI and Diagnostics. An example is the course organised by Dr M Pai at McGill in July 2011 on Diagnostic Research Methods. Suggestions will be sought from members. In addition to standard methodologies, there will be a focus on Bayesian approaches to diagnosis.
(ii) Capacity building: Training for researchers in developing countries will be an important component. FIND will be engaged to enhance relevant infrastructural and laboratory support in its projects being undertaken in high burden settings. See advocacy below.
iii) Advocacy: This will be done in conjunction with the other subgroups. The aim will be to elevate the profile of LTBI-related research by driving RFPs by major funding

agencies e.g. NIH, EU, EDCTP, UK MRC etc to fund TB-related research. This will be done in a collective fashion with the Stop TB Partnership one obvious focal point.

(x) Main achievements since establishment:
(i) Teaching and training: In the past 2 years courses were held in South Africa and Canada.
(ii) Capacity building and advocacy: Networking meetings were held with members to drive advocacy for LTBI diagnosis and treatment. A grant was secured from WHO-TDR to enable a student from SA to attend training with Madhu Pai in McGill. The student will focus on meta-analysis of data related to LTBI diagnosis.

(xi): 3-5 main (expected) outputs in 2010-2011

a. student-led meta-analyses of TB and LTBI-related diagnostics.
b. Networking meetings and electronic communications facilitating such.
c. Advocacy to funding bodies to promote relevant RFPs. Other advocacy efforts in synchrony with the Stop Tb Partnership.
d. Other activities endorsed my members and the working group.

(xii) Advocacy activities: As outlined above under (ix)
a) Description of WG's advocacy activities for 2011
On hold.
b) Main targets of advocacy
On hold.
c) Key advocacy challenges
On hold.
d) Upcoming advocacy opportunities
Outlined above under (ix).

(xiii) Main challenges and opportunities:

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:
Need more regular meetings and direction from sub-group chairs. Efforts need coordination.

5e. Subgroup on Point-of-care diagnostics for TB

Subgroup is maintained (see Overview)

(i) Established in:

(ii) Core group members and affiliation

Dr Ruth McNerney	London School of Hygiene and Tropical Medicine, UK	Co-Chair
Dr Catherina Boehme	FIND, Geneva, Switzerland	Co-chair

(iii) Is membership up to date?

(iv) Secretariat hosted in:

(v) Frequency of working group meetings:
a) Full working group:
b) Core group:

(vi) Terms of reference

(vii) Resources for biennium 2010-2011
a) Approved budget:
b) Provided (as of January 2011):
c) Estimated in-kind contributions 2010-2011:

(viii) Country focus (if any):

(ix) Priorities in 2010-2011:

(x) Main achievements since establishment:

(xi): 3-5 main (expected) outputs in 2010-2011

(xii) Advocacy activities:
a) Description of WG's advocacy activities for 2011

b) Main targets of advocacy

c) Key advocacy challenges

d) Upcoming advocacy opportunities

(xiii) Main challenges and opportunities:

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:

5f. Subgroup on Evidence Synthesis for TB diagnostics

Subgroup is maintained as cross-cutting theme (see Overview) and will be named Evidence Synthesis and Policy

(i) Established in: 2007

(ii) Core group members and affiliation

Dr Rick O'Brien	FIND, Geneva, Switzerland	Co-chair
Dr Karen Steingart	University of Washington, Seattle, USA	Co-chair

(iii) Is membership up to date? Will be updated based on new WG structure

(iv) Secretariat hosted in: With WG Secretariat at FIND, Geneva

(v) Frequency of working group meetings: See overview
a) Full working group:
b) Core group:

(vi) Terms of reference General, see overview
Project specific: APW 200296448

(vii) Resources for biennium 2010-2011
a) Approved budget: 15,000 USD
b) Provided (as of January 2011): On 3 Dec 2010 KS received 3750 USD
c) Estimated in-kind contributions 2010-2011: 10,000 USD

(viii) Country focus (if any):
India

(ix) Priorities in 2010-2011:
1.Translation of at least 10 systematic reviews on TB diagnostics into 'Plain Language summaries'. Purpose of summaries is to enable TB patients, advocates, and others to make choices about health and advocate for policies based on the best available evidence. The reviews need to be 'translated' into understandable language for people to use them.
2. **Economic and epidemiologic costs of TB serological testing in India**, This will be a dynamic epidemic model that also incorporates costs and cost-effectiveness estimates, using parameters from the literature. We will use this model to compare total costs, TB diagnoses made, inappropriate treatments for TB, and morbidity/mortality among TB suspects under alternative diagnostic algorithms, including one in which serological testing is replaced by sputum smear microscopy, sputum smear plus TB culture, or rapid molecular testing (i.e., Xpert MTB/RIF, either with or without sputum smear), throughout India.

(x) Main achievements since establishment:
1. Evidence-based TB diagnosis website www.tbevidence.org/ 33,356 total visits from 179 different countries since inception to 10 March 2011(xi): 3-5 main (expected) outputs in 2010-2011.
2. Develop plain language summary template with input from community members. Participating community members have been identified.
3. Develop and post 10-15 plain language summaries on www.tbevidence.org/
4. Economic and epidemiologic costs of TB serological testing in India – report

(xii) Advocacy activities:
a) Description of WG's advocacy activities for 2011
Plain language summaries – this is a project that lends itself to participation by the wider community. Effective and evidence-based information lays the groundwork for advocacy.

b) Main targets of advocacy
TB patients and community activists, also health care providers, scientists, policy makers, and funders
c) Key advocacy challenges
A well thought out strategy. Time and money. The plain language summaries could be translated in to languages other than English.
d) Upcoming advocacy opportunities
Union World Conference on Lung Health, 2011 –opportunity to get feedback on plain language summaries.

(xiii) Main challenges and opportunities: Limited financial resources and limited opportunities for face-to-face meetings.

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:
Alessandra Varga has been invaluable in facilitating communication with other Subgroup chairs.

5g. Subgroup on TB diagnostics and Poverty

Subgroup is maintained as cross-cutting theme (see Overview) and will also include Community and Advocacy

(i) Established in:

(ii) Core group members and affiliation

Dr Bertie Squire	Liverpool School of Tropical Medicine, UK	Co-chair
Dr Gilliain Mann	Liverpool School of Tropical Medicine	Co-chair

(iii) Is membership up to date?

(iv) Secretariat hosted in:

(v) Frequency of working group meetings:
a) Full working group:
b) Core group:

(vi) Terms of reference

(vii) Resources for biennium 2010-2011
a) Approved budget:
b) Provided (as of January 2011):
c) Estimated in-kind contributions 2010-2011:

(viii) Country focus (if any):

(ix) Priorities in 2010-2011:

(x) Main achievements since establishment:

(xi): 3-5 main (expected) outputs in 2010-2011

(xii) Advocacy activities:
a) Description of WG's advocacy activities for 2011

b) Main targets of advocacy

c) Key advocacy challenges

d) Upcoming advocacy opportunities

(xiii) Main challenges and opportunities:

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:

5h. Subgroup on TB diagnostics and HIV

Subgroup has been discontinued (see Overview)

5i. Subgroup on Diagnostics and paediatric TB

Subgroup is maintained as cross-cutting theme (see Overview)

(i) Established in: 2009

(ii) Core group members and affiliation

Prof. Anneke Hesseling	Desmond Tutu TB Centre, Stellenbosch University, Cape Town, South Africa	Co-chair and core groups representative
Prof. Steve Graham	The Royal Children's Hospital, Melbourne, Australia	Co-chair

(iii) Is membership up to date? Yes, there are over 50 members from over 20 countries

(iv) Secretariat hosted in: With Working Group Secretariat at FIND, Geneva

(v) Frequency of working group meetings:
a) Full working group: once a year – linked to IUATLD, and DEWG Childhood TB Subgroup meetings
b) Core group: three times a year – during 2009 and 2010: linked to IUATLD, DEWG Childhood Tb Subgroup and TDR meetings

(vi) Terms of reference in original submitted document (October 2009; see below)

Note: Original Application proposal submitted and initiated by sub group co-chairs: Anneke Hesseling and Steve Graham (No formal Request for Applications was launched)

The applications detailed below pertains to the 2010 cycle and was intended to support relevant activities matching the NDWG Strategic Plan as outlined in our sub group activities for 2010.

Dates of contract*:* January 2010 through December 2010 (funding may be disbursed in 2009 based on funding availability and the ongoing activities already initiated by the subgroup during 2009)

PI and institutions: Anneke C. Hesseling and Stephen Graham, co-chairs: Desmond Tutu TB Centre, Stellenbosch University, South Africa and Centre for Global Child Health, Melbourne, Australia
Note: the contract will be with the Desmond Tutu TB Centre, Stellenbosch University, South Africa, as agreed by the co-chairs.

Listing of main activities: year 1
- Establishing and maintaining a representative membership: June 2009-ongoing

- Launching of Official NDWG child subgroup in Cancun with presentation during the NDWG session: December 2009
- Establish links with other ongoing initiatives and subgroups including Childhood TB Subgroup of WHO STOP TB DEWG, IUATLD, TB CAP, TREAT-TB and WHO TDR: Sept 2009-ongoing
- Engage with and inform the WHO Global Plan Update for Research on drugs, diagnostics and vaccine components to include paediatric TB: Sept 2009-ongoing
- Engage and involve paediatric TB diagnostic researchers to present data on novel research findings of TB diagnostics in children through attendance of regional or international TB meetings: December 2009-ongoing
- Prepare for a child TB diagnostic meeting during 2010 (linked to Berlin Union Global Lung Health meeting in October)
- Establish a NDWG Childhood Subgroup website that is linked to the larger NDWG, WHO Stop TB, Union and DEWG Childhood TB Subgroup websites: December 2009
- Write NDWG consensus paper on diagnostic challenges and needs in childhood TB: September 2010
- Engage with advocacy groups for diagnostics relevant to children- e.g. TAG, MSF: Sept 2009-ongoing
- Engage with funding agencies to mobilize resources for TB diagnostic studies in children: October 2009-ongoing
- Generate a pragmatic scientific and operational framework for the conduct of diagnostic testing in children. Such a framework will highlight paediatric-specific issues and will include aspects of operational research. Such a document will be relevant to improved surveillance and the implementation of trials on TB vaccines and drugs in children (years 1 and 2): October 2010
- Map out current research paediatric TB diagnostic research activities in the field and pilot studies that may benefit from seed funding (years 1 and 2): June 2010

Budget is requested for the following specific activities (total available budget for year 1: $15,000):

- Engage and involve paediatric TB diagnostic researchers to present data on novel research findings of TB diagnostics in children through attendance of regional or international TB meetings: **Travel budget: $7,000**
- Establish a NDWG Childhood Subgroup website – linked to the larger NDWG, WHO Stop TB, Union and DEWG Childhood TB Subgroup websites: **Technical consultancy for website development and maintenance: $4,000**
- Communication between working group members including teleconferencing: **$500,00**
- Preparation of a Child TB satellite diagnostics meeting linked to the Berlin Union meeting, 2010: **$3500,00**

Total budget requested: *$15,000*

Please note that seed funding for promising preliminary studies and funding of technical consultants to develop guidelines for diagnostic testing is not possible with the current

budget allocation. We therefore request that if additional funds become available, the subgroup be notified.

Institutional contact details:
Subcontractor: Stellenbosch University, Faculty of Health Sciences, (Incorporated by Act No. 13 of 1916, with Head Office at Victoria Street, Stellenbosch)
PI located at the Desmond Tutu TB Centre, Stellenbosch University, Tygerberg, South Africa
Grants management: Ms. Grace Bruintjies, Room 0063, Desmond Tutu TB Centre, Clinical Building, Faculty of Health Sciences.
Phone+ 27 21 9389173
Fax +27 21 93898179
Email: graceb@sun.ac.za or annekeh@sun.ac.za

(vii) Resources for biennium 2010-2011
a) Approved budget: $15 000
b) Provided (as of January 2011): No funding has been disbursed despite multiple submissions since 2009 of this approved budget.

c) Estimated in-kind contributions 2010-2011:
- The DTTC contributed $2000 towards development of a website
- Travel support to attend meetings (Hesseling and Graham) has been provided through academic investigator grants, DEWG Childhood TB Subgroup or support from the Union.
- Both co-chairs have institutional salary and administrative support

(viii) Country focus (if any):
We have purposefully maintained both a high-band lower burden country focus in order to represent the global paediatric population and their under-served diagnostic needs.

(ix) Priorities in 2010-2011:
1. Maintaining a representative global membership and regular communication
2. Maintain an active NDWG childhood subgroup website
3. Write draft guidelines for the conduct of paediatric TB diagnostic studies in collaboration with TDR (DEEP initiative ; 2-3 manuscripts in progress and 1 document r already published online)
4. Creating an open source web resource repository for standard operating procedures relevant to childhood TB diagnostic studies
5. Consult and collaborate on the WHO Research Roadmap for TB research priorities in children
6. Collaborate on the WHO Roadmap for Operational Research : childhood TB chapter
7. Collaborate with advocacy groups and NGOs to highlight diagnostic needs and research, funding for TB in children (notably TAG and MSF)
8. Participate in international meetings including childhood TB symposia and invited speaker opportunities including : Union Berlin 2010 childhood TB Clinical research symposium, ECDC Childhood TB meeting March 2011, NIH TRIUMPH meeting

June 2010, NIH HIV/TB diagnostic meeting June 2011, Union Child Lung health, Union Child TB Training Working Group and WHO DEWG Childhood Subgroup meeting, Union.

9. Disseminate funding and collaborative opportunities between members and other partners

(x) Main achievements since establishment:

Collaboration: Despite not receiving any funding to date, this group has been very active. Given the limited human resources in the field of paediatric TB diagnostic research, collaboration with other groups has been a hallmark of our activities.
Partners include: WHO TDR; IUATLD; MSF; NIH; DEWG Childhood TB Subgroup; TAG; and, Multiple academic partners.

Advocacy:

- the group has been actively involved in advocacy for childhood TB diagnostic research access using multiple opportunities
- Publication of a lay summary of the needs for paediatric TB diagnostic studies (web publication on WHO, TDR and other websites – see attached)
- Drafting and contributing to the « call for action document » from the March 2011 ECDC meeting as an advocacy tool for childhood TB research including diagnostic research ; this document will be disseminated online for sign-up and support.
- Childhood TB You Tube during Union Berlin meeting focusing on diagnostic needs of children
- NDWG childhood subgroup website
- Participation in numerous international meetings focusing on the needs for research in childhood TB diagnostics: childhood TB symposia and invited speaker opportunities including : Union Berlin 2010 childhood TB Clinical research symposium, ECDC Childhood TB meeting March 2011, NIH TRIUMPH meeting June 2010, NIH Childhood TB diagnostic meeting June 2011 and WHO DEWG Childhood Subgroup meeting, Union USAID Treat TB meetings.

Other key activities:

- We have established TOR, established and maintained a representative membership
- Participation in DEEP guidelines for conduct of paediatric TB diagnostic studies
- Participation in the Stop TB Partnership WHO Research Roadmap for TB research priorities in children

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(xi): 3-5 main (expected) outputs in 2010-2011

1. Development of an open web source repository of clinical and lab SOPs for the conduct for paediatric TB diagnostic studies
2. Publication of 2-3 papers in collaboration with TDR on guidance (roadmap) for paediatric TB diagnostic studies (DEEP guidelines) – to be published in an open access journal

3. Participation in the Union 2011 Lille meeting through several symposia; participation in the June 2011 NIAID NIH Diagnostic Workshop to generate a paediatric TB research roadmap
4. Active engagement with TB advocacy groups to mobilize awareness and funding for paediatric diagnostic studies at all levels.

(xii) Advocacy activities:

(a) Description of WG's advocacy activities for 2011

- Participation in the Childhood TB ECDC meeting in Stockholm (Graham, Hesseling, Wingfield, Gie, Marais, Cuevas)
- Participation in the Union 2011 Lille meeting through several symposia; participation in the June 2011 NIAID NIH Diagnostic Workshop to generate a paediatric TB research roadmap
- Active engagement with TB advocacy groups including TAG to mobilize awareness and funding for paediatric diagnostic studies at all levels
- Drafting and contributing to the « Call for action document « from the March 2011 ECDC meeting as an advocacy tool for childhood TB research including diagnostic research ; this document will be disseminated online for sign-up and support to civil society, funders, researchers, industry, regulators and NTPs.
- Participating in dissemination proceedings of ECDC Childhood TB advocacy meeting in Stockholm, March 2011 with special focus on the diagnostic needs of children

(b) Main targets of advocacy

- Donors including USAID, BMGF, NIH
- Basic research groups
- NTPs
- NGOs and civil society

(c) Key advocacy challenges

Limited knowledge of paediatric TB among donors.
Perceived low priority of childhood TB.
Limited engagement with paediatric TB community “up front” for development of new diagnostics.
Small number of paediatric TB experts with adequate contents expertise to advocate strategically.
An important principle we have been focusing on is to highlight on the unique needs of children for TB diagnostics, while including them in the overall larger TB research and program agenda.

(d) Upcoming advocacy opportunities

“Call for Action for Paediatric TB ” : global dissemination and sign-up activities linked to World TB Day
Meetings with US federal government representatives, Capitol Hill: Washington DC March 2011-03-19
NIH TB/HIV diagnostic meeting: June 201

IUATLD 2011 meeting, Lille: WHO symposium planned on maternal and child health including diagnostic challenges and 3 symposia on child lung health and tuberculosis

(xiii) Main challenges and opportunities:
There is enthusiasm and support for childhood TB research; challenges remain access to funding for high-quality clinical and operational diagnostic research.
There is an urgent need to include children in biomarker studies and call for applications – this needs to be communicated to donors.
The Childhood TB Subgroup has further not received any funding to date and have supported its activities through collateral funding.

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:
Ongoing collaboration with the following groups is envisaged

- DEWG Childhood TB Group
- IUATLD Childhood TB Training Group
- TDR MSF and other partners

Participation of the Childhood TB Subgroup in the core group with regular communication would be tremendously helpful; the childhood TB subgroup has been somewhat isolated.

6. Working Group on New Drugs

(i) Established in: 2001

(ii) Core group members and affiliation*

William Bishai	Center for Tuberculosis Research, Johns Hopkins University, Baltimore, MD, USA	Co-chair
Mel Spigelman	Global Alliance for TB Drug Development, New York, NY, USA	Co-chair
Christopher Locher	Vertex Pharmaceuticals Incorporated, Cambridge, MA, USA	Leader, Biology targets subgroup
Barbara Laughon	Office of the Director Division of Microbiology and Infectious Diseases, National Institute of Allergy & Infectious Diseases (NIH/NIAID), Bethesda, MD, USA	Leader, Candidates subgroup
Jacques Grosset	Center for Tuberculosis Research, Johns Hopkins University, Baltimore, MD, USA	Co-Leader, Critical Knowledge and tools subgroup
Gerhard Walzl	Molecular Biology and Human Genetics, Faculty of Health Sciences, Stellenbosch University	Co-Leader, Critical Knowledge and tools subgroup
Christian Lienhardt	Stop TB Partnership Secretariat, WHO, Geneva, Switzerland	Leader, Clinical trials capacity subgroup
Wim Vandevelde	Chair, European AIDS Treatment Group, Brussels, Belgium	Community representative
Cherise Scott	Global Alliance for TB Drug Development, New York, NY, USA	Secretariat

*See attached Appendix A for full membership list

(iii) Is membership up to date? Yes [152 active members to date]

(iv) Secretariat hosted in:
Global Alliance for TB Drug Development
40 Wall Street, 24th Floor
New York, NY 10005, USA

(v) Frequency of working group meetings:
a) Full working group: annually
b) Core group: quarterly; more frequently as needed

(vi) Terms of reference

1 Rationale for the Stop TB Working Group on New Drugs (hereinafter the WGND)

Current short-course (6-month) combination therapy for tuberculosis (TB) is effective when administered reliably. However, TB control has long been hindered by the lengthy and complex treatment required by current drugs, and is further complicated by the disease's deadly interaction with HIV/AIDS and the rise of multidrug resistant (MDR-)

and extremely drug resistant (XDR-) TB. Treatment of most MDR-TB cases takes 18-24 months. Inconsistent treatment breeds drug-resistant strains that increasingly defy current medicines. Faster acting drugs are needed to shorten treatment duration, and new drugs that attack novel targets are needed to fight resistant strains of *M. tuberculosis*. In areas of high HIV/AIDS prevalence, new therapies are urgently needed to enable concurrent administration of TB and HIV treatments, avoiding dangerous drug-drug interactions that occur with the medicines available today. These innovative new therapeutics will be required if the Partnership is to achieve its targets in these regions. These factors underscore the urgent public health need for new TB therapies.

For the first time in 40 years, there is a coordinated portfolio of promising new compounds in the global TB drug pipeline, some of which have the potential to become the new cornerstone drugs of TB control. However, it is widely recognized that drug discovery and development in general is a slow process (8 to 12 years) and that, for TB drugs in particular, it is not possible to rely on traditional market forces for sustainability. Moreover, it must be acknowledged that drug candidate attrition throughout drug research and development (R&D) is a significant risk for sponsors in terms of both time and funds: Only about 10% of candidates that enter the clinical pipeline advance to registration, mostly due to safety concerns. Thus, a robust and sustained pipeline of new candidates and backup discovery programs is absolutely essential to success.

Since its inception, the WGND has served as a venue for interaction among partners working in all stages of TB drug R&D, to increase efficiencies and decrease risk for the process as a whole. One of the lessons learned since the introduction of the existing anti-TB drugs is that continued multi-year worldwide commitment, research and vigilance to ensure a consistent pipeline of new antimicrobials will be required to eradicate TB in the 21st century. Thus, there is a need to sustain the critical collaborations between public and private partners, which have leveraged the scientific and clinical knowledge of industry, the public health sector, and world-wide academic laboratories, to build the current portfolio. With its diverse membership, including representatives of all these constituencies, as well as regulators and those in a position to provide funding and support, the WGND remains a unique mechanism for doing so.

Further, the WGND recognizes that affordability, adoption and access to new drugs and regimens are intimately linked to the manufacture and production of medicines, alone or in combination, and to the adoption of such therapies as international standards. It is therefore imperative for those involved in R&D to work closely with members involved in international health agencies and in-country work to understand these needs, thereby ensuring rapid, successful introduction and adoption of the new regimens in the field. The WGND is in a position to promote coordination of all relevant stakeholders in TB drug development, including researchers working on new tools, and public health stakeholders involved in TB control.

2 Objective of the WGND

The objective of the WGND is the development of new drugs and new drug regimens for TB, through:

- Identifying validated drug targets for persistent bacilli and latent disease;
- Ascertaining mechanisms of action of drugs in the global portfolio to generate complementary or even synergistic combinations effective against *M.tb;*
- Developing a sustainable portfolio of new drug candidates that meet the drug profile criteria;
- Developing animal models that can predict compound activity and side effects;
- Building clinical trial sites and initiating and conducting clinical trials that meet regulatory requirements and highest ethical standards.
- Developing biomarkers, surrogate endpoints and testing programs to speed future clinical development programs and validated surrogate markers that are broadly adopted by TB drug developers, and
- Establishing harmonized regulatory guidelines, including fast-track approval for TB drug developers.

The pillars of the WGND strategy support the WGND's objective and include:

- Provision of data on global anti-TB drug R&D efforts;
- Provision of expert opinion and advice to WGND members, other individuals and institutions;
- Execution of projects determined by the WGND and WGND subgroups (see section 3.4 for current subgroups) to be key to successful TB drug R&D;
- Input into core publications and public policy recommendations developed by the Partnership;
- International coordination of activities listed above and effective collaboration with the other Stop TB Partnership WGs, partners and other relevant institutions.

These processes require commitment of all partners to common goals and coordination of stakeholder actions.

3 The structure of the Working Group on New Drugs

3.1 Governance

The WGND is one of the 7 working groups that report to the Stop TB Partnership Coordinating Board.

3.2 Composition (membership)

The WGND membership rests with individuals, not institutions. Thus, the WGND has no "lead agency" and is not dominated by any institution or group of institutions. The WGND is composed of diverse interested stakeholders in TB drug development, including those working in TB drug R&D, regulators, public health workers, funders, community representatives, advocates and policy-makers. Members represent the private and public sectors and come from diverse geographical locations.

Membership is based on the following basic criteria:

- The two prime qualifications for membership are
  - (i) a shared understanding of the mission and goals of the WGND;
  - (ii) the ability to engage in activities to achieve those goals, playing an advisory role and/or executing projects;

- Members are expected to attend an annual meeting, either in person or by teleconference for those without access to travel support;
- Members of the WGND employed by large institutions are expected to support Secretariat and WGND activities through financial or staff support, and by hosting meetings of the WGND, Core Group (CG), or ad hoc/subgroups;
- Specific individuals may be invited to participate in meetings based on their potential contribution to the activities of the WGND.

3.2.1 Co-Chairs

The WGND is equally Co-Chaired by (1) an appointed representative of TB Alliance and (2) an elected representative of a WGND member institution other than TB Alliance. The elected Co-Chair will serve a term of three years, eligible for renewal and is elected by the body of the WGND as described in section 4.3. As the institution of the appointed Co-Chair, TB Alliance commits to providing the majority of non-Partnership funding for WGND operations, in addition to housing the WGND Secretariat. The Co-Chairs of the WGND are jointly and equally responsible for chairing the WGND meeting and meetings of the CG. The Co-Chairs also represent the WGND on the Coordinating Board of the Stop TB Partnership, although it is noted that the WGND has only one voting seat on the Board. The Co-Chairs may therefore alternate attendance and voting at Board meetings, or attend together and vote after reaching consensus with one Co-Chair casting the vote while the other attends in an observational capacity. The Co-Chairs act as the chief liaisons between the Partnership and the WGND. If neither Co-Chair is available to perform their duties, the CG will designate a representative of the CG or the WGND Secretariat.

The joint functions of the Co-Chairs are defined as follows:

- Oversee the WGND and its associated subgroups and task forces; and monitor implementation of the recommendations of the WGND;
- Lead and coordinate the WGND in an effective response to the challenges of TB drug development;
- Ensure the availability of resources, both financial and human, needed to effectively achieve the WGND objectives;
- Foster coordination, dynamic interaction and exchange among all members of the WGND and its subgroups, as well as other members of the Stop TB Partnership;
- Assume joint responsibility with the WGND Secretariat in ensuring implementation of the recommendations of the WGND and the CG;
- Amplify the collective voice and engage the expertise of the entire WGND.

3.2.2 Core Group (CG)

The CG provides leadership and sets the strategic direction for the work of the WGND. The CG is designed to facilitate and accelerate decision-making, and to act as a catalyst to effective implementation of the Global Plan to Stop TB 2006-2015. While meeting these objectives first and foremost, every effort will be made to ensure that the CG is reflective of the WGND membership.

The CG is composed of the Co-Chairs, the Leaders of the WGND subgroups, and one WGND community representative. Although the main drivers of candidate selection will be competencies, motivation, and availability to do the required work, efforts should be made to ensure regional equity and institutional representation. Each Subgroup will elect its own Subgroup Leader and those Subgroup Leaders will become members of the CG. The community representative on the CG will be selected by the community representatives. Members will serve for three years with the possibility of renewal at the end of each term. Additional participants with requisite experience can be co-opted for individual meetings after discussion with the Co-Chairs and Secretariat.

The CG members form the coordinating centre of the WGND. Therefore CG members have to be able and willing to devote time to the activities related to the TOR listed below (see code of conduct referred to in paragraph 4.5).

The TOR of the CG include:

- To assist with preparatory work for the (annual) WGND meeting;
- To assist the Co-Chairs in determining and addressing strategic and operational issues.
- To initiate, oversee and manage the activities of the subgroups and ad-hoc task forces of the WGND;
- To closely collaborate with and consult the other Stop TB WGs on crosscutting issues;

3.2.3 Secretariat

The Secretariat is staffed by one Full Time Employee, employed specifically and solely to carry out the Terms of Reference below. The Secretariat may be housed at and paid by TB Alliance or an alternate institution when practicable and preferred. The housing and salary arrangement is determined by the Co-Chairs and CG at the beginning of each three year term. The Secretariat is answerable to the Co-Chairs and to the WGND. The Secretariat works in close collaboration with and follows guidance from the CG. However, initiative for action can come from either the CG and or the Secretariat, but should always include the other.

The TOR of the Secretariat are:
Work with CG to implement the strategic direction of the WGND and develop action items;

- Proposing new actions to the CG (through the Co-Chairs, copying all CG members);
- Assuring that the WGND functions in an accountable and transparent manner;
- Tracking the implementation of the recommendations of the CG;
- Applying for, reporting on and managing resources provided by the Stop TB Partnership for the functioning of the WGND;
- Translating input of WGND members into Partnership and other documents and initiatives;
- Producing reports and other documents requested by the Partnership;
- Organizing the meetings of the WGND and the CG;

- Preparing the agenda and relevant documents for these meetings (in consultation with the Co-Chairs and relevant members of the CG and other subgroups);
- Producing and distributing meeting reports;
- Updating membership information;
- Promoting year-round engagement of members by e.g. maintaining an up-to-date website and producing periodic newsletters and reports.
- Facilitating effective communications within the WGND and between the WGND and other individuals and bodies.
- Supporting the Co-Chairs by providing presentations, briefings etc.

3.2.4 Subgroups and Task Forces

Subgroups will be established with specific objectives to address particular scientific issues. Membership, achievements, and TOR/rationale for the subgroups will be reviewed at the annual WGND meeting. Subgroups will be dissolved once objectives have been accomplished or by consensus of the Core Group (CG) and the members of the subgroup. Proposed initial subgroups include the Biology/Targets subgroup, Candidates subgroup, Critical Knowledge and Tools subgroup and Clinical Trials Capacity subgroup.

Objectives, scope of work, priorities and activities of each subgroup were developed by the subgroups at the Annual Meeting October 17, 2008 in Paris and during subsequent email exchanges and teleconferences that occurred in the first quarter of 2009.

Task Forces are set up for a limited period of time to address a specific issue. The terms of reference of the Task Forces are developed by the CG and include a time-frame and expected outcomes.

4 Procedural questions

The way of working of the WGND aims for full transparency and maximal input from members, especially those who are active in subgroups and task forces or ad-hoc subgroups.

4.1 Meetings of the WGND

- The WGND will meet at least once each year;
- One meeting per year will be held at the location and time of the IUATLD World Conference; locations of additional meetings will rotate among regions to the greatest extent possible;
- The annual meeting will be a forum structured to develop actions that support the rationale and objective of the WGND (see paragraphs 1 and 2);
- The annual meeting will serve to:
    - Review progress in implementing recommendations and progress towards Global Plan targets and indicators;
    - Discuss and endorse decisions proposed by the CG or subgroups;
    - Discuss and endorse policy documents;
    - Report on the activities of the subgroups/ad-hoc committees;
    - Consolidate and increase partners' commitment to the mission and goals of the WGND;

- Exchange information;
- Identify problems and new challenges, and formulate appropriate responses;
- Endorse future strategic directions, activities, and policies.

4.2 Decision making process

The members of the WGND shall have 1 vote per individual WGND member. The decisions regarding both substantive and procedural questions shall be taken by majority vote, either by a show of hands during the WG meeting, or through the use of electronic voting, managed by the Secretariat.

4.3 Election of Elected Co-Chair

The elected Co-Chair of the WGND is elected from within the members of the WGND and will serve a term of three years, eligible for renewal.

The following procedure will be observed for the election process:

- The election process shall be transparent and open to all members of the WGND.
- The election process shall be administered by the Secretariat through secret ballot using the electronic voting tool, in accordance with paragraph 4.2 above.
- After discussion with the CG, the Secretariat will determine the date of elections.
- The Secretariat will send out a notification to all WGND members one month prior to the scheduled election date, soliciting nominations for the post of Co-Chair. The elected Co-Chair must be external to TB Alliance. Following instructions on the use of the electronic voting tool, the members of the WGND will provide nominations within two weeks time.
- Each member of the WGND will have the right to nominate one person for Co-Chair and may self-nominate;
- During the 3rd week after opening of nominations, the Secretariat will create a shortlist of a maximum of three candidates, based on the highest number of nominations and confirmation of candidate interest. The Secretariat will obtain confirmation from the nominees that the nomination is accepted and that the nominee is willing to run for election.
- The shortlisted candidates will submit their statements of motivation to the Secretariat within the 4^{th} week after opening of nominations.
- The Secretariat will post the names of the shortlisted candidates together with their statements of motivation on the electronic voting system and will send out a notification to all WGND members announcing the opening of the election process on the agreed upon election date. If feasible, candidates will be invited to present themselves to WGND members via teleconference in advance of the election date.
- The members of the WGND will have 5 working days to cast their votes.
- Following the election, the Secretariat will contact all candidates to announce the results. Should two candidates receive the same number of votes, efforts will be made to solicit further votes and a re-count will be conducted.
- Should the elected Co-Chair wish to withdraw from their position at any point after having accepted the post, a new election shall be organized.

4.4 Application for the membership on the WG

Applications for the membership of the WGND should be made in writing and addressed to the WGND Secretariat. A short statement of motivation in compliance with the provisions under paragraph 3.2 is recommended for all applicants, as is the provision of a bio-sketch or CV. The Secretariat will submit the application to the CG for review and notify the applicant of the decision of the CG within 10 working days. Pending the formation of a CG, the Secretariat will approve all applications submitted with the recommendation of any current WGND member.

4.5 The modus operandi of the CG

The modus operandi of the CG is as follows:

- The CG will meet face-to-face at least twice each year, with travel support provided by the WGND operating budget. It is noted that such travel support for 8 individuals could amount to $25,000 or more, so attention should be paid to the location of the meeting and efforts should be made to secure a venue at low or no cost. Ideally, CG meetings should be hosted by a CG member's organization;
- The CG will have at least one teleconference each trimester, with the agenda prepared by the Co-Chairs of the WGND and the WGND Secretariat.
- The agenda and all relevant documents for meetings will be prepared by the Secretariat in consultation with the Co-Chairs;
- Decisions will be based on consensus. However, if consensus can not be reached, the majority vote will apply, and the results of any such vote will be reported at the annual WGND meeting;
- The CG will address the following in its meetings:
    - Progress in implementing WGND and CG meeting recommendations, including activities of subgroups and task forces;
    - Strategic issues and provision of advice and recommendations to the WGND and its members;
    - Analysis of the external environment, identification of opportunities and challenges;
    - The long-term view required for setting future directions;
    - Revision of the current document should the necessity emerge;
    - The agenda for the annual WGND meeting.

Code of conduct of the CG members:

The purpose of the Code of Conduct is to provide guidance to the members of the CG on how to conduct themselves when participating in the activities of the CG. Members have a general duty to act in the interest of the WG and, in particular, its rationale, objective, and mode of operation as defined in this document.

As a general rule, members of the CG are expected to participate in and actively contribute to the activities of the CG. Members who are unable to attend more than two consecutive meetings, either in person or teleconference, may be asked by the Co-Chairs, in consultation with the Secretariat, to relinquish their membership. The same applies to those members who do not actively contribute to the activities of the CG. This includes

participation in special ad hoc groups, representation of the CG in selected activities, and in executing special tasks delineated by the CG.

4.6 Financial Support

The Co-Chairs are jointly responsible for ensuring the availability of resources, both human and financial, needed for execution of WGND activities over and above those funded by the operating budget. The WGND operating budget is used to finance:

- Convening of face-to-face and teleconference meetings;
- Travel support for CG meetings;
- Participation of the Co-Chairs or their delegate in Partnership Coordinating Board meetings;
- Publication development/printing costs;
- Staffing the Secretariat function (unless a Full Time Employee is donated, along with overhead, by a member institution).

The WGND operating budget comprises financing from the Stop TB Partnership in addition to significant funding from members, in a cost-sharing arrangement. As the institution of the appointed Co-Chair, TB Alliance commits to financing the majority of the non-Partnership component of this budget. The WGND operating budget is managed by the Secretariat. The Stop TB Partnership component can be (a) awarded as a grant to, transferred to and dispersed by TB Alliance, acting on behalf of the WGND, if the WGND Secretariat is housed at TB Alliance or (b) transferred directly to the WGND Secretariat, if the Secretariat is housed within WHO.

(vii) Resources for biennium 2010-2011:

a) Approved budget: 250,000 USD

b) Provided (as of January 2011): 62,500 USD (another 62,500 USD to be sent upon receipt of 2010 Financial Report)

c) Estimated in-kind contributions:

- 204,000 USD from TB Alliance as well as access to facilities, experts on staff, e-mail and phone services, vendors, office supplies and other logistical services
- 50-65% discount from Darby Communications for website development and maintenance including blog, event capture of major meetings, video/audio interviews, and administration of online tools; estimated value of 115,000-140,555 USD worth of services for 2010-2011
- 40-50 hours of pro bono time from BLISS PR firm per 6 month contract
- Advertising space on Google home page during World TB Day 2009 with over 500,000 impressions/hits from March 24 to April 17 with a value that exceeds the Working Group's ability to determine but is estimated to be upward of $500,000 USD or more.
- 5-10 hours per month per core team member for Working Group activities
- Free access to meeting facilities due to affiliation of core team members

(viii) Country focus (if any): Global focus

(ix) Priorities in 2010-2011:

- Advocacy and public relations for new TB drugs
- Development of new online resources for the TB drug development community
- Facilitation of information sharing among the various stakeholders including academia, governments, foundations, industry, and effected communities
- Creation of collaborative networks within the scientific and the TB drug development community
- Integration of Working Group activities with those of the Critical Path to TB Drug Regimens (CPTR)

(x) Main achievements since establishment:

- The Working Group on New Drugs has supported continually through its activities the advancement of the global pipeline of TB drugs. For the first time in 40 years, there is a coordinated portfolio of promising new compounds, some of which have the potential to become the cornerstone drugs of TB control and contribute to the elimination of TB in the future. There are currently 11 compounds in clinical testing with two compounds in Phase III and two compounds in late stage development for MDR TB. This achievement is the result of critical collaborations between public and private partners.
- Strategic planning discussions in 2004/2005 resulted in the adoption of a ground-breaking new approach to drug development: early combination-testing of drug candidates to minimize delay in registering new TB regimens. This new approach has influenced the formation of initiatives such as the Critical Path to TB Drug Regimens (CPTR).
- Several key meetings and fora have been sponsored by the Working Group on New Drugs.
    - In an effort to initiate discussion of regulatory issues in developing drugs for TB, the Working Group co-sponsored the Open Forum Conference Series which has thus far consisted of four meetings to date held in Washington D.C., USA; London, United Kingdom; Delhi, India; and Addis Ababa, Ethiopia.
    - In 2009, the Working Group sponsored a workshop on paediatric TB drug development in Washington, DC, as well as, a workshop on establishing communication between TB trial groups in Cancún during the Union World Conference.
    - In 2007, the Working Group established an MDR/XDR Task Force, which helped to develop a research agenda for improving outcomes of treatment of MDR/TB and XDR/TB; to identify the most efficient path to new drug regimens for MDR/TB and XDR-TB; to integrate animal and preclinical research with clinical trials design; and to stimulate funding for clinical trials of MDR- and XDR-TB treatment.
    - In 2004, the working group helped to organize a roundtable (Drug-Resistant TB – A Global Crisis) at the Council on Foreign Relations hosted by Pulitzer Prize-winning journalist, Laurie Garrett to bring attention to the release of new WHO figures on MDR-TB.

- Since its inception, there has been an annual meeting for Working Group membership sponsored at the Union World Conference. Representatives from the private and public sectors gave presentations and updates on the latest development in TB drug development.
- The Working Group has actively participated in the Stop TB Partners' Forum meetings providing updates on recent advances in TB drug development.

- Advocacy and public relations activities of the Working Group have substantially increased from its founding.
  - In 2008/2009, the Working Group launched a new website with greater utility and opportunity to make available information and resources of interest to its membership and the broader drug development community
  - As part of the new website, a dynamic Global TB Drugs Pipeline was developed that presents information on active projects and compounds in development. Organizations submit and update the projects they own to enable the Pipeline to present the most accurate and current information possible.
  - In 2009, the Working Group engaged Google to place free of charge to the partnership a promotion for World TB Day on their home page, as well as, to provide public-service TV air time for a tuberculosis awareness ad which significantly increased public awareness of the global tuberculosis crisis. It received over 500,000 hits/visits from March 24 to April 17.
  - In 2009 and 2010, the working group engaged BLISS PR firm to develop a strategy for direct promotion, blog and social media campaigns
  - During scientific conferences, the Working Group has set up booths, distributed materials, and actively recruited members.
- The Working Group has contributed to, as well as, released publications to support its mission.
  - In 2004, the publication *Tuberuclosis: Scientific Blueprint for TB Drug Development* initially released in 2001 was reprinted.
  - In 2006, the *Strategic Plan for the Stop TB Partnership Working Group on New TB Drugs* was released.
  - The Working Group made a significant contribution to the *Global Plan to Stop TB 2006-2015*
  - The Working Group made a significant contribution to the TB Drug section of the revised *Global Plan to Stop TB 2011-2015* placing considerable efforts into developing the New TB Drugs Strategic Framework.

(xi) 3-5 main (expected) outputs in 2010-2011:

- Increased support of the advancement of the global pipeline of TB drugs. The community is on the verge of the first new TB drug to be introduced into the standard care regimen in over 40 years. Interactions among working group members have resulted in an collaborative agreement for the drug candidate TMC207 for susceptible TB, advances in combination therapy testing in vitro and in animal models, completion of three phase II NCE (new chemical entity)

clinical trials with two of the three trials targeting MDR TB, and the completion of a phase III trial for latent TB. Phase IIb data will be available in 2011 on a novel regimen with potential to cure both drug susceptible and MDR TB in less than 6 months.

- Sponsorship and hosting of several meetings and workshops to include:
  - Annual Working Group Meeting held at the Union World Conferences to engage membership and to provide updates on the advancements in TB drug development
  - Joint symposium at the Union conference between the three New Tools Working Groups
  - Workshop on pyrazinamide and its derivatives to advance research in the field and overall drug development
  - Workshop on clinical trial capacity to coordinate different efforts across the field and develop plan to secure more resources in this area
  - Workshop series on target identification and immune mechanisms to advance research in the field and overall drug development
- Creation of more resource tools available online to the community including:
  - TB R&D Matters Blog which presents a variety of news, reviews, and information happening in the world related to tuberculosis; the posting include both written articles, video interviews and podcast interviews
  - Improvements in the Online Global TB Drug Pipeline that ensures the community continues to find value in the information presented on the pipeline
  - The addition of a Biologics/Immunotherapeutics Pipeline that will provide information to the community of developments in this field
  - The addition of a target/compound database specific for tuberculosis to aid researchers in early discovery for TB drugs
  - Improvement and expansion of the resource listings in various categories available for TB
- Publications:
  - Major contribution to the TB Drug section of the revised *Global Plan to Stop TB 2011-2015* placing considerable efforts into developing the New TB Drugs Strategic Framework.
  - Revised *Strategic Plan for the Stop TB Partnership Working Group on New Drugs*
  - Revised *Scientific Blueprint for TB Drug Development*

(xii) Advocacy activities:

a) Description of WG's advocacy activities for 2011

- Participation and contribution to advocacy groups and events including the Global Health Council TB Roundtable, the World TB Events in Washington, DC, High Level Missions in conjunction with Coordinating Board Meeting, Critical Path to TB Drug Regimens (CPTR)
- Social media campaign through Linkedin Group, Facebook, Jumo, and Twitter
- Publishing of articles and interviews on the Working Group's TB R&D Blog
- Guest-publishing of articles on science and health blogs such as *Science Speaks:*

HIV & TB News
- Publishing of the *Strategic Plan* document for the Working Group
- Equipping of Working Group members with materials to distribute during scientific conferences to colleagues
- Promotion of online resources and improvements to the Working Group's website
- Seeking opportunities to sponsor and partner on events and specific projects with other working groups and with groups such as the CPTR (i.e., clinical trial site landscape)

b) Main targets of advocacy
- U.S. Governmental Agencies
- Grant-making foundations and organizations that fund research and development for infectious diseases
- Consortiums and organizations who have significant resources for research and development for infectious diseases
- American and European youth
- General public

c) Key advocacy challenges
- Lack of obvious cohesive strategy from Stop TB Partnership
- Developing messages that resonate with targeted groups
- Identifying the most effective media to focus advocacy efforts

d) Upcoming advocacy opportunities
- World TB Day
- High Level Missions in conjunction with Coordinating Board Meeting
- World Health Day
- Scientific conferences [American Thoracic Society, Gordon Research Conference -- TB Drug Development, 4th International Workshop on Clinical Pharmacology of Tuberculosis Drugs, 51th Interscience Conference on Antimicrobial Agents and Chemotherapy
- 42nd Union World Conference on Lung Health
- Guest blog post in *Science Speaks: HIV & TB News*
- Partnership with the CPTR

(xiii) Main challenges and opportunities:
- **Challenges**
  - Competing priorities for governments and funding agencies
  - Political and economic climate limiting commitment to global health
  - Limited funding committed to research for TB and specifically for TB drug development
  - Inadequate support from the Stop TB Partnership
- **Opportunities**
  - Engaging higher proportion of membership to actively participate in activities

- Partnering with other working groups, initiatives, and organizations to combine efforts on specific projects

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:

- Indentifying areas of cross-over (i.e., incorporation of diagnostics with clinical trials, issues around paediatrics) and working with relevant groups/subgroups around these areas whether initiating projects/meetings or combining efforts and resources
- Having a forum to share strategies, announcements, and information to help with coordination between groups
- Proactive effort to share news and information from other groups with membership and public (the Working Group on New Drugs does this actively through its website and e-mail communication with membership)
- Holding joint conferences and/or meetings covering common topics of interest (The Working Group on New Drugs is working with the Working Groups on New Diagnostics and New Vaccines to hold a joint symposium at the Union World Conference in 2011).

6a. Biology Targets Subgroup

(i) Established in: 2008

(ii) Subgroup members and affiliation

Last Name	First Name	Country	Affiliation	Function In Working Group
Barrio	Belén	France	Sanofi-Aventis R&D	Member
Bishai	William	United States	Johns Hopkins School of Medicine	Co-Chair
Bordon-Pallier	Florence	France	Sanofi-Aventis	Member
Cho	Sang Nae	South Korea	Yonsei University College of Medicine	Member
Chopra	Sidharth	United States	SRI International	Member
Dick	Thomas	United States	Novartis Institute for Tropical Diseases	Member
Duncan	Ken	United States	Bill & Melinda Gates Foundation	Member
Freundlich	Joel	United States	Texas A&M University	Member
Frincke	James	United States	Hollis Eden Pharmaceuticals	Member
Furr	Barry	United States	Astrazeneca	Member
Harrington	Mark	United States	Treatment Action Group	Member
Hipskind	Philip	United States	Eli Lilly and Company; Lilly Research Laboratories	Member
Husson	Robert	United States	Children's Hospital Boston/Harvard Medical School	Member
Lamichhane	Gyanu	United States	Johns Hopkins University	Member
Locher	Christopher	United States	Vertex Pharmaceuticals	Subgroup Leader
Lowrie	Doug	United Kingdom	Cardiff University	Member
Ma	Zhenkun	United States	TB Alliance	Member
McCammon	Maggie	United States	University of Michigan	Member
Mitchison	Dennis	United Kingdom	St Georges. University of London	Member
Okada	Masaji	Japan	Clinical Research Center, National Hospital Organization Kinki-Chuo Chest Medical Center	Member
Old	Iain	Switzerland	SCIPROM - Scientific Project Management	Member
Orme	Ian	United States	Colorado State University	Member
O'Toole	Ronan	New Zealand	Victoria University of Wellington	Member
Parish	Tanya	United Kingdom	Infectious Disease Research Institute	Member

Rao	Kanury	India	International Centre for Genetic Engineering & Biotechnology	Member
Rook	Graham	United Kingdom	Centre for Infectious Diseases and International Health (CIDIH), University College London	Member
Sassetti	Christopher	United States	University of Massachusetts Medical School	Member
Schnappinger	Dirk	United States	Weill Cornell Medical College	Member
Shadiack	Annette	United States	TB Alliance	Member
Sherman	David	United States	Seattle Biomedical Research Institute	Member
Tsodikov	Oleg	United States	University of Michigan	Member
Vandal	Omar	United States	Bill and Melinda Gates Foundation	Member
Wallis	Robert	United States	Pfizer Inc	Member
Zeldis	Jerome	United States	Celgene	Member
Zhang	Xuelian	China	Fudan University	Member

(iii) Is membership up to date? Yes

(iv) Secretariat hosted in:
Global Alliance for TB Drug Development
40 Wall Street, 24th Floor
New York, NY 10005, USA

(v) Frequency of subgroup meetings:
a) Full subgroup: at least annually but often two or three times a year
b) Core group: Not applicable

(vi) Terms of reference:
Objectives:
The primary purpose of the Biology/Targets subgroup is to exchange and to distil information to improve decision making for target selection and treatment strategies of Mtb and to help build a global vision for TB drug development. By promoting the transparency of multiple organizations, the subgroup will provide centralized, relatively open-access website to drive innovation, create opportunities for global synergy, and to facilitate recommendations in a timely manner. This process will be driven by:

- Maintaining an active subgroup that meets regularly by having telephone conference calls and face to face meetings to define specific time-bound goals and action items
    - Facilitate data sharing and information gathering and regularly updating a member-accessible subgroup calendar
    - Generating a master list of Mtb targets and/or group projects (i.e. database of all known drug targets, including the status of research activities) and

maintaining the succinct master list, including group projects that are no longer active (and why) as well as projects under priority consideration
    - Define parameters for selection of specific targets, propose targets from specific pathways learned from Mtb biology, define metrics for drug-ability of targets and prioritize targets that are most likely to shorten therapy, target persistent, latency, as well as MDR/XDR isolates, and work in synergy with drug candidates and existing drugs
- Identifying challenges and unmet needs in new targets and Mtb biology
    - Solicit ongoing feedback on specific biological/target that are not being adequately addressed including operational challenges
    - Promote understanding of Mtb and human immunologic and metabolic relationships to map out new strategies for Mtb drug therapeutics and to seek new ways of optimizing the contribution of the immune system.
    - Identifying resources and opportunities for funding to support progression of Mtb targets
- Providing a foundation in the overall WGND strategy and in the global Mtb community
    - Define resources available to facilitate target based drug discovery and improving compound penetration of Mtb for efficacy
    - Increase visibility and help drive global policy development
    - Provide clear direction and illustrate opportunities by drafting white papers, presentations and review articles to inspire interest and to accelerate drug discovery

(vii) Resources for biennium 2010-2011:
a) Approved budget: 15,000 USD [part of total budget listed in 6.vii]
b) Provided (as of January 2011): 7,500 [part of total budget listed in 6.vii]
c) Estimated in-kind contributions 2010-2011:
- Access to facilities, experts on staff, e-mail and phone services, vendors, and office supplies from TB Alliance
- 50-65% from Darby Communications for website development and maintenance including blog, event capture of major meetings, video/audio interviews, and administration of online tools
- 5-10 hours per month of subgroup leader for subgroup activities
- Free access to meeting facilities due to affiliation of core team members

(viii) Country focus/priority Countries (if any): Global focus

(ix) Priorities in 2010-2011:
- Advocacy and public relations for new TB drugs
- Development of new online resources for the TB drug development community
- Facilitation of information sharing among the various stakeholders including academia, governments, foundations, industry, and effected communities
- Creation of collaborative networks within the scientific and the TB drug development community

- Integration of Working Group activities with those of the Critical Path to TB Drug Regimens (CPTR)

(x) Main achievements since establishment:

- In 2009, each of the subgroups of the Working Group instituted terms of reference for the subgroup

(xi) 3-5 main (expected) outputs in 2010-2011:

- Creation a global network of scientists, existing databases and websites to make recommendations of targets of high interest, Repository for compounds from screening campaigns
- Completion of a survey to private companies compiling information on screening programs and targets for tuberculosis
- Development of a database housing targets of high interest and repository of compounds from screening campaigns
- Workshop series on target identification and immune mechanisms to advance research in the field and overall drug development

(xii) Advocacy activities:

a) Description of WG's advocacy activities for 2011

- Participation and contribution to advocacy groups and events including the Global Health Council TB Roundtable, the World TB Events in Washington, DC, High Level Missions in conjunction with Coordinating Board Meeting, Critical Path to TB Drug Regimens (CPTR)
- Social media campaign through Linkedin Group, Facebook, Jumo, and Twitter
- Publishing of articles and interviews on the Working Group's TB R&D Blog
- Guest-publishing of articles on science and health blogs such as *Science Speaks: HIV & TB News*
- Publishing of the *Strategic Plan* document for the Working Group
- Equipping of Working Group members with materials to distribute during scientific conferences to colleagues
- Promotion of online resources and improvements to the Working Group's website
- Seeking opportunities to sponsor and partner on events and specific projects with other working groups and with groups such as the CPTR (i.e., clinical trial site landscape)

b) Main targets of advocacy

- U.S. Governmental Agencies
- Grant-making foundations and organizations that fund research and development for infectious diseases
- Consortiums and organizations who have significant resources for research and development for infectious diseases
- American and European youth
- General public

c) Key advocacy challenges

- Lack of obvious cohesive strategy from Stop TB Partnership
- Developing messages that resonate with targeted groups
- Identifying the most effective media to focus advocacy efforts

d) Upcoming advocacy opportunities

- World TB Day
- High Level Missions in conjunction with Coordinating Board Meeting
- World Health Day
- Scientific conferences [American Thoracic Society, Gordon Research Conference -- TB Drug Development, 4th International Workshop on Clinical Pharmacology of Tuberculosis Drugs, 51th Interscience Conference on Antimicrobial Agents and Chemotherapy
- 42nd Union World Conference on Lung Health
- Guest blog post in *Science Speaks: HIV & TB News*
- Partnership with the CPTR

(xiii) Main challenges and opportunities:

- **Challenges**
  - Competing priorities for governments and funding agencies
  - Political and economic climate limiting commitment to global health
  - Limited funding committed to research for TB and specifically for TB drug development
  - Inadequate support from the Stop TB Partnership
- **Opportunities**
  - Engaging higher proportion of membership to actively participate in activities
  - Partnering with other working groups, initiatives, and organizations to combine efforts on specific projects

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:

- Indentifying areas of cross-over (i.e., incorporation of diagnostics with clinical trials, issues around paediatrics) and working with relevant groups/subgroups around these areas whether initiating projects/meetings or combining efforts and resources
- Having a forum to share strategies, announcements, and information to help with coordination between groups
- Proactive effort to share news and information from other groups with membership and public (the Working Group on New Drugs does this actively through its website and e-mail communication with membership)
- Holding joint conferences and/or meetings covering common topics of interest (The Working Group on New Drugs is working with the Working Groups on New Diagnostics and New Vaccines to hold a joint symposium at the Union World Conference in 2011).

6b. Candidates Subgroup

(i) Established in: 2008

(ii) Subgroup members and affiliation

Last Name	First Name	Country	Affiliation	Function in Working Group
Andries	Koen	Belgium	Tibotec	Member
Beconi	Maria	United States	TB Alliance	Member
Chopra	Sidharth	United States	SRI International	Member
Clayden	Polly	United Kingdom	HIV i-Base	Member
Cole	Stewart	Switzerland	Ecole Polytechnique Fédérale de Lausanne (EPFL)	Member
Cynamon	Michael	United States	VAMC, SUNY, Upstate Medical University	Member
Demers	Brigitte	France, Metropolitan	sanofi-aventis	Member
Duncan	Ken	United States	Bill & Melinda Gates Foundation	Member
Freundlich	Joel	United States	Texas A&M University	Member
Ginsberg	Ann	United States	TB Alliance	Member
Gumbo	Tawanda	United States	University of Texas Southwestern Medical Center at Dallas	Member
Heinrich	Norbert	Germany	Universtiy of Munich / PanACEA	Member
Hipskind	Philip	United States	Eli Lilly and Company; Lilly Research Laboratories	Member
Hoelscher	Michael	Germany	Ludwig-Maximilians-University	Member
Husson	Robert	United States	Children's Hospital Boston/Harvard Medical School	Member
Jabes	Daniela	Italy	NeED Parma	Member
Kamboj	Rajender	India	Lupin Limited	Member
Kawakubo	Hiromu	Japan	Asahi Kasei Chemicals Corporation	Member
Laughon	Barbara	United States	National Institute of Allergy and Infectious Diseases, NIH, DHHS	Subgroup Leader
McCammon	Maggie	United States	University of Michigan	Member
Moser	Heinz	United States	Achaogen	Member
Nacy	Carol	United States	Sequella, Inc.	Member
Old	Iain	Switzerland	New Medicines For Tuberculosis	Member
O'Toole	Ronan	New Zealand	Victoria University of Wellington	Member

Pan	Martin	Spain	GlaxoSmithKline R&D, Diseases of the Developing World Medicines Development Campus	Member
Pavan	Fernando	Brazil	São Paulo State University, UNESP, Brazil	Member
Phyu	Sabai	Singapore	Novartis Institute for Tropical Diseases	Member
Protopopova	Marina	United States	Sequella, Inc.	Member
Rouse	Doris	United States	RTI International	Member
Syed	Javid	United States	Treatment Action Group	Member
Thomson	John	United States	Vertex Pharmaceuticals	Member
Vandevelde	Wim	Portugal	European AIDS Treatment Group (EATG)	Member
Vernon	Andrew	United States	U.S. Centers for Disease Control and Prevention	Member
Zhang	Xuelian	China	Fudan University	Member

(iii) Is membership up to date? Yes

(iv) Secretariat hosted in:
Global Alliance for TB Drug Development
40 Wall Street, 24th Floor
New York, NY 10005, USA

((v) Frequency of subgroup meetings:
a) Full subgroup: at least annually but often two or three times a year
b) Core group: Not applicable

(vi) Terms of reference:
3.2.4.2 Candidates subgroup (Preliminary draft kindly provided by Ken Duncan)

Objectives:
The Candidates Sub-group aims to promote research and collaboration that will result in the creation of affordable, high-quality candidate drugs for the treatment of TB. Its objectives are:

- Monitor and evaluate the pipeline of TB drug candidates;
- Identify gaps and resource needs to potential funders;
- Stimulate research on new TB drug leads;
- Increasing access to technical assistance to facilitate optimization and testing of new drug candidates;

- Promote co-ordination and collaboration amongst drug developers to ensure that optimal combinations of new drugs are identified;
- Create improved information sharing mechanisms on TB drug discovery/development across the research community.

The Candidates Sub-group is a component of the New Drugs group that serves as a technical advisory body to the Stop TB Partnership and WHO. Its primary tasks are:

- Gather information relating to the progress of potential drug candidates and evaluating the likelihood of technical success;
- Assess the landscape of drug development to identify gaps and gather the necessary evidence to advocate for increased resources;
- Identify sources of technical assistance to ensure projects are optimally resourced;
- Maintain active coordination and communication with the entire WGND and especially with other subgroups;
- Inform Stop TB partnership of its findings;
- Share information on candidates with the TB research community.

Members: The Candidates Sub-group is comprised of representatives from institutions with specific expertise in drug discovery and pre-clinical development, and which have active research programs. Its membership rests with individuals, not institutions.

((vii) Resources for biennium 2010-2011:
a) Approved budget: 15,000 USD [part of total budget listed in 6.vii]
b) Provided (as of January 2011): 7,500 [part of total budget listed in 6.vii]
c) Estimated in-kind contributions 2010-2011:

- Access to facilities, experts on staff, e-mail and phone services, vendors, and office supplies from TB Alliance
- 50-65% from Darby Communications for website development and maintenance including blog, event capture of major meetings, video/audio interviews, and administration of online tools
- 5-10 hours per month of subgroup leader for subgroup activities
- Free access to meeting facilities due to affiliation of core team members

(viii) Country focus/priority Countries (if any): Global focus

(ix) Priorities in 2010-2011:

- Advocacy and public relations for new TB drugs
- Development of new online resources for the TB drug development community
- Facilitation of information sharing among the various stakeholders including academia, governments, foundations, industry, and effected communities
- Creation of collaborative networks within the scientific and the TB drug development community

(x) Main achievements since establishment:

- In 2009, each of the subgroups of the Working Group instituted terms of reference for the subgroup

(xi) 3-5 main (expected) outputs in 2010-2011:

- Management and improvements to online Global TB Drugs Pipeline
- Development of the online Clinical Trial Landscape tool that will be a searchable and filterable database that provides information on 1) trial sites that are currently doing TB drug clinical trials 2) trial sites that have the capability and are interested in conducting TB drug clinical trials

(xii) Advocacy activities:

a) Description of WG's advocacy activities for 2011

- Participation and contribution to advocacy groups and events including the Global Health Council TB Roundtable, the World TB Events in Washington, DC, High Level Missions in conjunction with Coordinating Board Meeting, Critical Path to TB Drug Regimens (CPTR)
- Social media campaign through Linkedin Group, Facebook, Jumo, and Twitter
- Publishing of articles and interviews on the Working Group's TB R&D Blog
- Guest-publishing of articles on science and health blogs such as *Science Speaks: HIV & TB News*
- Publishing of the *Strategic Plan* document for the Working Group
- Equipping of Working Group members with materials to distribute during scientific conferences to colleagues
- Promotion of online resources and improvements to the Working Group's website
- Seeking opportunities to sponsor and partner on events and specific projects with other working groups and with groups such as the CPTR (i.e., clinical trial site landscape)

b) Main targets of advocacy

- U.S. Governmental Agencies
- Grant-making foundations and organizations that fund research and development for infectious diseases
- Consortiums and organizations who have significant resources for research and development for infectious diseases
- American and European youth
- General public

c) Key advocacy challenges

- Lack of obvious cohesive strategy from Stop TB Partnership
- Developing messages that resonate with targeted groups
- Identifying the most effective media to focus advocacy efforts

d) Upcoming advocacy opportunities

- World TB Day

- High Level Missions in conjunction with Coordinating Board Meeting
- World Health Day
- Scientific conferences [American Thoracic Society, Gordon Research Conference -- TB Drug Development, 4th International Workshop on Clinical Pharmacology of Tuberculosis Drugs, 51th Interscience Conference on Antimicrobial Agents and Chemotherapy
- 42nd Union World Conference on Lung Health
- Guest blog post in *Science Speaks: HIV & TB News*
- Partnership with the CPTR

(xiii) Main challenges and opportunities:

- **Challenges**
  - Competing priorities for governments and funding agencies
  - Political and economic climate limiting commitment to global health
  - Limited funding committed to research for TB and specifically for TB drug development
  - Inadequate support from the Stop TB Partnership
- **Opportunities**
  - Engaging higher proportion of membership to actively participate in activities
  - Partnering with other working groups, initiatives, and organizations to combine efforts on specific projects

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:

- Indentifying areas of cross-over (i.e., incorporation of diagnostics with clinical trials, issues around paediatrics) and working with relevant groups/subgroups around these areas whether initiating projects/meetings or combining efforts and resources
- Having a forum to share strategies, announcements, and information to help with coordination between groups
- Proactive effort to share news and information from other groups with membership and public (the Working Group on New Drugs does this actively through its website and e-mail communication with membership)
- Holding joint conferences and/or meetings covering common topics of interest (The Working Group on New Drugs is working with the Working Groups on New Diagnostics and New Vaccines to hold a joint symposium at the Union World Conference in 2011).

6c. Critical Knowledge and Tools Subgroup

(i) Established in: 2008

(ii) Subgroup members and affiliation

Last Name	First Name	Country	Affiliation	Function in Working Group
Beconi	Maria	United States	TB Alliance	Member
Chopra	Sidharth	United States	SRI International	Member
Dadzie	Kobina Bosumtwi	Ghana	wiljok Childaid and health organization	Member
de Groote	Mary Ann	United States	Colorado State University	Member
Demers	Brigitte	France, Metropolitan	sanofi-aventis	Member
Doi	Noroi	Japan	Japan Anti-Tuberculosis Association; Research Institute of Tuberculosis	Member
Dukes Hamilton	Carol	United States	Family Health International	Member
Einck	Leo	United States	Sequella, Inc.	Member
Farooq	Muhammad	Pakistan	Govt of Pakistan	Member
Fourie	Bernard	South Africa	Medicine in Need (Mend)	Member
Freundlich	Joel	United States	Texas A&M University	Member
Gheuens	Jan	United States	Bill & Melinda Gates Foundation	Member
Ginsberg	Ann	United States	TB Alliance	Member
Grosset	Jacques	United States	Johns Hopkins University School of Medicine	Subgroup Leader
Gumbo	Tawanda	United States	University of Texas Southwestern Medical Center at Dallas	Member
Hipskind	Philip	United States	Eli Lilly and Company; Lilly Research Laboratories	Member
Jindani	Amina	United Kingdom	St. George's, University of London	Member
Kasprowicz	Victoria	South Africa	K-RITH (KwaZulu-Natal Research Institute for Tuberculosis and HIV)	Member
Khan	Ahmadul	Bangladesh	Ahmadul Hasan Khan	Member
Laughon	Barbara	United States	National Institute of Allergy and Infectious Diseases, NIH, DHHS	Member (Subgroup Leader of Candidates)
Lenaerts	Anne	United States	Colorado State	Member

			University	
Locher	Christopher	United States	Vertex Pharmaceuticals	Member (Subgroup Leader of Biology/Targets)
Lomtadze	Nino	Georgia	National Center for Tuberculosis and Lung Diseases	Member
McCammon	Maggie	United States	University of Michigan	Member
Moser	Heinz	United States	Achaogen	Member
Pan	Martin	Spain	GlaxoSmithKline R&D, Diseases of the Developing World Medicines Development Campus	Member
Parida	Shreemanta	Germany	Max Planck Institute for Infection Biology	Member
Semete	Boitumelo	South Africa	Council of Scientific Industrial Research (CSIR) in South Africa	Member
Swai	Hulda	South Africa	Council of Scientific Industrial Research (CSIR) in South Africa	Member
TETO	Fondacaro	Democratic Republic Of Congo (Zaire)	Programme National de lutte contre la Tuberculose	Member
Walzl	Gerhard	South Africa	Stellenbosch University	Subgroup Leader
Williams	Sharon	United States	National Institute for Allergy and Infectious Diseases, NIH	Member
Wingfield	Claire	United States	Treatment Action Group	Member

(iii) Is membership up to date? Yes

(iv) Secretariat hosted in:
Global Alliance for TB Drug Development
40 Wall Street, 24th Floor
New York, NY 10005, USA

(v) Frequency of subgroup meetings:
a) Full subgroup: at least annually but often two or three times a year
b) Core group: Not applicable

(vi) Terms of reference:
Objectives:
This subgroup aims to promote the development of knowledge critical to evaluating the most promising new TB drug candidates for entry into clinical trials. Moreover, this subgroup aims to promote the development of tools that will support the discovery, testing, or improvement of new TB drugs or treatment strategies that can ultimately be combined into novel TB regimens that correspond to the WGND aims. Its objectives are:

- To identify gaps in current knowledge and tools that are needed to support new drug development. As the subgroup is not able to address these gaps itself, its main objective will be to recognize the areas of need, to identify organizations capable of implementing the necessary actions and to identify appropriate funding sources to enable such implementation.
- To promote and support:
    - Compiling knowledge required at the interface of **preclinical and clinical development**, in particular the data required by multiple regulatory authorities;
    - The establishment of **animal models** for TB treatment evaluation, including animal models of combination drug therapy; Shorten the evaluation of drug candidates in animal models by advocating and facilitating the use of reporter strains, QC-PCR methods and devising new methods for short term animal models.
    - Studies of **PK/PD of TB drugs** and drug candidates, particularly regarding bioavailability alone and in combination;
    - **Improvement of existing regimens and optimization of existing drugs**;
    - Research into **biomarkers for TB treatment outcome and drug efficacy** including research into imaging technologies to improve understanding of TB pathophysiology and treatment response, and preclinical biomarkers of toxicity, especially hepatotoxicity;
    - Research into **alternative drug delivery technologies**;
    - **Standardization of procedures related to all stages of TB drug research**, including clinical and laboratory standard operating procedures such as specimen handling and processing, data definition, study design, analytical methodologies and development of a critical path for candidate TB drugs to regulatory approvals in collaboration with the Clinical Trials Group.
    - **Development of new PK/PD methodologies** to assist in clinical trials of new TB drugs that are specifically tailored to different drug candidates or mechanisms of action and derive the rules to better select preclinical drug leads including studies of drug/drug interactions, between TB drugs and drug candidates and, for example, between TB drugs/drug candidates and ARVs
    - Research to assist in **validation of diagnostic technologies** in collaboration with the New Diagnostics Working Group
    - **Facilitate information sharing of centralized resources** such as biobanks, strain collections and reference isolates.
- To promote and support the implementation of validated tools for new drug development into clinical trials and eventually clinical practice when such tools are validated and become available.

Tasks:

The Critical Knowledge and Tools Subgroup serves as a technical advisory body to the WGND and the Stop TB Partnership. Its primary tasks are:

Organize subgroup **meetings** to promote the objectives as outlined above.
To review guidance's and requirements issued by regulatory authorities for new TB drug development, and promote the coordination of research efforts to develop new tools for new TB drug development through workshops and discussion forums;

- Regular teleconferences to ensure progress in pursuing subgroup objectives
- Annual subgroup meetings during appropriate conferences, including IUATLD meetings to align subgroup strategies to achieve its objectives
- To compile and share lessons learned in chemistry, manufacturing, safety and efficacy studies by developers of recent candidate TB drugs;
- To explore resources available to the pharmaceutical industry and the wider TB research community on toxicology and predictors of toxicities ;
- To study available knowledge on PK/PD of existing TB drugs and new candidates;
- To identify and share information on drug-drug interactions likely to exist in TB prevalent settings.
- **Information exchange**:
    - Establishment of a publicly accessible **Tools Subgroup website** to facilitate information exchange including meeting coordination and maintaining a calendar of events in the following areas :
        - Survey of the most important global activities in the field of tools for new TB drug development and generation of a member activity list. The information will be collected through a customized questionnaire that will be sent to major role players in the field.
        - Posting of links to key references relating to tools for new TB drug development.
        - Presentations from scientific conferences and meetings
        - Posting of clinical and laboratory standard operating procedures, study design and analytical methodologies for the testing of new TB drugs and evaluation of appropriate tools with a commentary on inferior methods or products.
        - The existence of this web site and the appropriate links will be advertised through fliers at conferences and emails to Stop TB Partnership group participants.
    - **Providing a liaison with other working groups and subgroups**, including New Diagnostics Working Group and Subgroups Biological Targets, New Drugs in Clinical Trials and Clinical Trial Sites. This interaction will be facilitated by core group members.
    - To **engage funding bodies and policy makers** to advance research into tools for drug development, including the establishment of biobanks that will allow the discovery and validation of biomarkers for TB treatment response; (Please note: this is a major initiative for collaboration with other Stop TB WGs as well)
- Production of **white papers, review articles, and power point presentations** to increase the visibility of advances in tools for the development of new TB drugs. This will include advising regulatory bodies, the pharmaceutical industry and the wider TB research community through publications, workshops and web based

communication about implementation of validated tools for new drug development when such tools become available.

Members: The Tools Subgroup comprises representatives with specific programmatic, clinical, advocacy, scientific, regulatory and managerial expertise. Its membership rests with individuals with specific areas of expertise relevant to tools for drug development.

(vii) Resources for biennium 2010-2011:
a) Approved budget: 15,000 USD [part of total budget listed in 6.vii]
b) Provided (as of January 2011): 7,500 [part of total budget listed in 6.vii]
c) Estimated in-kind contributions 2010-2011:

- Access to facilities, experts on staff, e-mail and phone services, vendors, and office supplies from TB Alliance
- 50-65% from Darby Communications for website development and maintenance including blog, event capture of major meetings, video/audio interviews, and administration of online tools
- 5-10 hours per month of subgroup leader for subgroup activities
- Free access to meeting facilities due to affiliation of core team members

(viii) Country focus/priority Countries (if any): Global focus

(ix) Priorities in 2010-2011:

- Advocacy and public relations for new TB drugs
- Development of new online resources for the TB drug development community
- Facilitation of information sharing among the various stakeholders including academia, governments, foundations, industry, and effected communities
- Creation of collaborative networks within the scientific and the TB drug development community

(x) Main achievements since establishment:

- In 2009, each of the subgroups of the Working Group instituted terms of reference for the subgroup

(xi) 3-5 main (expected) outputs in 2010-2011:

- Completion of a survey of available tools, organizations, databases, and other resources for TB drug development
- Comprehensive publicly accessible resource page with information on tools, contacts, and networks for TB drug development
- Workshop on pyrazinamide and its derivatives to advance research in the field and overall drug development

(xii) Advocacy activities:
a) Description of WG's advocacy activities for 2011

- Participation and contribution to advocacy groups and events including the Global Health Council TB Roundtable, the World TB Events in Washington, DC, High

Level Missions in conjunction with Coordinating Board Meeting, Critical Path to TB Drug Regimens (CPTR)
- Social media campaign through Linkedin Group, Facebook, Jumo, and Twitter
- Publishing of articles and interviews on the Working Group's TB R&D Blog
- Guest-publishing of articles on science and health blogs such as *Science Speaks: HIV & TB News*
- Publishing of the *Strategic Plan* document for the Working Group
- Equipping of Working Group members with materials to distribute during scientific conferences to colleagues
- Promotion of online resources and improvements to the Working Group's website
- Seeking opportunities to sponsor and partner on events and specific projects with other working groups and with groups such as the CPTR (i.e., clinical trial site landscape)

b) Main targets of advocacy
- U.S. Governmental Agencies
- Grant-making foundations and organizations that fund research and development for infectious diseases
- Consortiums and organizations who have significant resources for research and development for infectious diseases
- American and European youth
- General public

c) Key advocacy challenges
- Lack of obvious cohesive strategy from Stop TB Partnership
- Developing messages that resonate with targeted groups
- Identifying the most effective media to focus advocacy efforts

d) Upcoming advocacy opportunities
- World TB Day
- High Level Missions in conjunction with Coordinating Board Meeting
- World Health Day
- Scientific conferences [American Thoracic Society, Gordon Research Conference -- TB Drug Development, 4th International Workshop on Clinical Pharmacology of Tuberculosis Drugs, 51th Interscience Conference on Antimicrobial Agents and Chemotherapy
- 42nd Union World Conference on Lung Health
- Guest blog post in *Science Speaks: HIV & TB News*
- Partnership with the CPTR

(xiii) Main challenges and opportunities:
- **Challenges**
    - Competing priorities for governments and funding agencies
    - Political and economic climate limiting commitment to global health

    - Limited funding committed to research for TB and specifically for TB drug development
    - Inadequate support from the Stop TB Partnership
- **Opportunities**
    - Engaging higher proportion of membership to actively participate in activities
    - Partnering with other working groups, initiatives, and organizations to combine efforts on specific projects

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:

- Indentifying areas of cross-over (i.e., incorporation of diagnostics with clinical trials, issues around paediatrics) and working with relevant groups/subgroups around these areas whether initiating projects/meetings or combining efforts and resources
- Having a forum to share strategies, announcements, and information to help with coordination between groups
- Proactive effort to share news and information from other groups with membership and public (the Working Group on New Drugs does this actively through its website and e-mail communication with membership)
- Holding joint conferences and/or meetings covering common topics of interest (The Working Group on New Drugs is working with the Working Groups on New Diagnostics and New Vaccines to hold a joint symposium at the Union World Conference in 2011).

6d. Clinical Trials Capacity Subgroup

(i) Established in: 2008

(ii) Subgroup members and affiliation

Last Name	First Name	Country	Organization	Function in Working Group
Bao	Jing	United States	Henry M Jackson Foundation for the Advancement of Military Medicine at DAIDS/NIAID/NIH	Member
Cayla	Joan A.	Spain		Member
Chaisson	Richard	United States	Johns Hopkins University Center for TB Research	Member
Diacon	Andreas	South Africa	University of Stellenbosch	Member
Geiter	Lawrence	United States	Otsuka Pharmaceutical Company	Member
Gumbo	Tawanda	United States	University of Texas Southwestern Medical Center at Dallas	Member
Heinrich	Norbert	Germany	Universtiy of Munich / PanACEA	Member
Hoelscher	Michael	Germany	Ludwig-Maximilians-University	Member
Horwith	Gary	United States	Sequella, Inc.	Member
Kasprowicz	Victoria	South Africa	K-RITH (KwaZulu-Natal Research Institute for Tuberculosis and HIV)	Member
Khan	Ahmadul	Bangladesh	Ahmadul Hasan Khan	Member
Kutsyna	Galyna	Ukraine	Luhansk State Medical University	Member
Lienhardt	Christian	Senegal	WHO Stop TB Partnership Research Movement	Subgroup Leader
Lomtadze	Nino	Georgia	National Center for Tuberculosis and Lung Diseases	Member
McCammon	Maggie	United States	University of Michigan	Member
McNeeley	David	United States	Tibotec	Member
Mitnick	Carole	United States	Harvard Medical School	Member
Nacy	Carol	United States	Sequella, Inc.	Member
O'Brien	Rick	Switzerland	Foundation for Innovative New Diagnostics	Member
Ordway	Diane	United States	Colorado State University	Member
Otwoma	Nelson	Kenya	Positive Familes Network (+FN)	Member
Pappas	Frances	United States	TB Alliance	Member

Phyu	Sabai	Singapore	Novartis Institute for Tropical Diseases	Member
Shimao	Tado	Japan	JATA Research Institute of Tuberculosis (RIT)	Member
Solomonia	Nelly	Georgia	National Center for Tuberculosis and Lung Diseases	Member
Springsklee	Martin	United States	Bayer Healthcare	Member
Tauscher	Gail	United States	NIH, NIAID	Member
Teto	Fondacaro	Democratic Republic Of Congo (Zaire)	Programme National de lutte contre la Tuberculose	Member
Trapaidze	Tamari	Georgia	Welfare Foundation	Member
van Niekerk	Christo	South Africa	TB Alliance	Member
Vernon	Andrew	United States	U.S. Centers for Disease Control and Prevention	Member
Wandiga	Steve	Kenya	KEMRI/CDC	Member

(iii) Is membership up to date? Yes

(iv) Secretariat hosted in:
Global Alliance for TB Drug Development
40 Wall Street, 24th Floor
New York, NY 10005, USA

(v) Frequency of subgroup meetings:
a) Full subgroup: at least annually but often two or three times a year
b) Core group: Not applicable

(vi) Terms of reference:
This subgroup aims to identify, highlight and address issues in the clinical trials of TB drugs that correspond to the aims of the WGND. Its objectives are:

Objectives :
- Identify bottlenecks and roadblocks faced by those involved in TB drugs clinical trials;
- Work towards addressing regulatory issues in TB drug development and harmonization of clinical guidelines and IP rights;
- Convene seminars and workshops to bring together government officials, regulators, NTP managers and researchers to establish strong links and identify ways to improve regulatory and/or government institutional requirements;
- Address specific and often marginalized issues in TB clinical trials such as trials for pediatric TB;
- Identify clinical trial sites for carrying out clinical studies for TB drug development and making this information publicly available (to complement the 80 site assessment performed by the Global Alliance for TB Drug Development);

- Establish clinical site selection criteria which should at minimum include:
    - the full description of the site infrastructure (clinical, lab, data management, administrative, etc),
    - the ability to understand GCP/GLP,
    - the level of preparedness to undertake various trial phases,
    - how regulatory issues can be met,
    - the level of training to be conducted.
- Develop interventions that will advance and/or complete the site preparation process for dozens of sites to carry out trials for susceptible or drug-resistant TB. Interventions could include sponsorship of regional training at trail sites in synergy with FHI, USAID, TBCAP, EDCTP, World Bank, RESIST-TB.

Members: The Clinical Trials Capacity Subgroup comprises representatives with specific programmatic, clinical, scientific, managerial and advocacy expertise. Its membership rests with individuals with specific areas of expertise relevant to clinical trials for drug development.

(vii) Resources for biennium 2010-2011:
a) Approved budget: 15,000 USD [part of total budget listed in 6.vii]
b) Provided (as of January 2011): 7,500 [part of total budget listed in 6.vii]
c) Estimated in-kind contributions 2010-2011:
- Access to facilities, experts on staff, e-mail and phone services, vendors, and office supplies from TB Alliance
- 50-65% from Darby Communications for website development and maintenance including blog, event capture of major meetings, video/audio interviews, and administration of online tools
- 5-10 hours per month of subgroup leader for subgroup activities
- Free access to meeting facilities due to affiliation of core team members

(viii) Country focus/priority Countries (if any): Global focus

(ix) Priorities in 2010-2011:
- Advocacy and public relations for new TB drugs
- Development of new online resources for the TB drug development community
- Facilitation of information sharing among the various stakeholders including academia, governments, foundations, industry, and effected communities
- Creation of collaborative networks within the scientific and the TB drug development community

(x) Main achievements since establishment:
- In 2009, each of the subgroups of the Working Group instituted terms of reference for the subgroup

(xi) 3-5 main (expected) outputs in 2010-2011:
- Conduct of a workshop on clinical trial capacity to coordinate different efforts across the field and develop plan to secure more resources in this area

(xii) Advocacy activities:

a) Description of WG's advocacy activities for 2011

- Participation and contribution to advocacy groups and events including the Global Health Council TB Roundtable, the World TB Events in Washington, DC, High Level Missions in conjunction with Coordinating Board Meeting, Critical Path to TB Drug Regimens (CPTR)
- Social media campaign through Linkedin Group, Facebook, Jumo, and Twitter
- Publishing of articles and interviews on the Working Group's TB R&D Blog
- Guest-publishing of articles on science and health blogs such as *Science Speaks: HIV & TB News*
- Publishing of the *Strategic Plan* document for the Working Group
- Equipping of Working Group members with materials to distribute during scientific conferences to colleagues
- Promotion of online resources and improvements to the Working Group's website
- Seeking opportunities to sponsor and partner on events and specific projects with other working groups and with groups such as the CPTR (i.e., clinical trial site landscape)

b) Main targets of advocacy

- U.S. Governmental Agencies
- Grant-making foundations and organizations that fund research and development for infectious diseases
- Consortiums and organizations who have significant resources for research and development for infectious diseases
- American and European youth
- General public

c) Key advocacy challenges

- Lack of obvious cohesive strategy from Stop TB Partnership
- Developing messages that resonate with targeted groups
- Identifying the most effective media to focus advocacy efforts

d) Upcoming advocacy opportunities

- World TB Day
- High Level Missions in conjunction with Coordinating Board Meeting
- World Health Day
- Scientific conferences [American Thoracic Society, Gordon Research Conference -- TB Drug Development, 4th International Workshop on Clinical Pharmacology of Tuberculosis Drugs, 51th Interscience Conference on Antimicrobial Agents and Chemotherapy
- 42nd Union World Conference on Lung Health
- Guest blog post in *Science Speaks: HIV & TB News*
- Partnership with the CPTR

(xiii) Main challenges and opportunities:

- **Challenges**
  - Competing priorities for governments and funding agencies
  - Political and economic climate limiting commitment to global health
  - Limited funding committed to research for TB and specifically for TB drug development
  - Inadequate support from the Stop TB Partnership
- **Opportunities**
  - Engaging higher proportion of membership to actively participate in activities
  - Partnering with other working groups, initiatives, and organizations to combine efforts on specific projects

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:

- Indentifying areas of cross-over (i.e., incorporation of diagnostics with clinical trials, issues around paediatrics) and working with relevant groups/subgroups around these areas whether initiating projects/meetings or combining efforts and resources
- Having a forum to share strategies, announcements, and information to help with coordination between groups
- Proactive effort to share news and information from other groups with membership and public (the Working Group on New Drugs does this actively through its website and e-mail communication with membership)
- Holding joint conferences and/or meetings covering common topics of interest (The Working Group on New Drugs is working with the Working Groups on New Diagnostics and New Vaccines to hold a joint symposium at the Union World Conference in 2011).

Appendix A: Full Membership List for Working Group on New TB Drugs

Last Name	First Name	Country	Organization
Aboul-Fadl	Tarek	Saudia Arabia	King Saud University
Andries	Koen	Belgium	Tibotec
Balasubramanian	Venkataraman	India	AstraZeneca R&D India
Balganesh	Tanjore	India	AstraZeneca R&D India
Bao	Jing	United States	Henry M Jackson Foundation for the Advancement of Military Medicine at DAIDS/NIAID/NIH
Barrio	Belén	France	Sanofi-Aventis R&D
Beconi	Maria	United States	TB Alliance
Bishai	William	United States	Johns Hopkins School of Medicine
Blackburn	Jonathan	South Africa	University of Cape Town
Bloom	Amy	United States	United States Agency for International Development
Bordon-Pallier	Florence	France	sanofi-aventis
Cardona	Pere-Joan	Spain	Institut Germans Trias i Pujol (IGTP)
Casey	Allen	United States	Infectious Disease Research Institute
Cassell	Gail	United States	Eli Lilly and Company
Castro	Kenneth	United States	U.S. Centers for Disease Control and Prevention
Cayla	Joan A.	Spain	
Chaisson	Richard	United States	Johns Hopkins University Center for TB Research
Chamberlin	William	United States	Self - (Texas Tech University Health Sciences Center)
Cho	Sang Nae	South Korea	Yonsei University College of Medicine
Chopra	Sidharth	United States	SRI International
Cieren-Puiseux	Isabelle	France	sanofi-aventis
Clayden	Polly	United Kingdom	HIV i-Base
Cole	Stewart	Switzerland	Ecole Polytechnique Fédérale de Lausanne (EPFL)
Cynamon	Michael	United States	VAMC, SUNY, Upstate Medical University
dadzie	kobina bosumtwi	Ghana	wiljok Childaid and health organization
de Groote	Mary Ann	United States	Colorado State University
Demers	Brigitte	France, Metropolitan	sanofi-aventis
Diacon	Andreas	South Africa	University of Stellenbosch
Dick	Thomas	United States	Novartis Institute for Tropical Diseases
Dippel	Chris	United States	Peloton Partnering, SP
Doi	Noroi	Japan	Japan Anti-Tuberculosis Association; Research Institute of Tuberculosis
Dukes Hamilton	Carol	United States	Family Health International
Duncan	Ken	United States	Bill & Melinda Gates Foundation
Einck	Leo	United States	Sequella, Inc.
Farooq	Dr Muhammad	Pakistan	Govt of Pakistan
Fourie	Bernard	South Africa	Medicine in Need (Mend)
Franzblau	Scott	United States	Institute for Tuberculosis Research, University of Illinois at Chicago
Freire	Maria	United States	Lasker Foundation

Freundlich	Joel	United States	Texas A&M University
Frincke	James	United States	Hollis Eden Pharmaceuticals
Fujii	Jennifer	United States	Vertex Pharmaceuticals
Furr	Barry	United States	Astrazeneca
Gardiner	Elizabeth	United States	TB Alliance
Geiter	Lawrence	United States	Otsuka Pharmaceutical Company
Gharakhanian	Shahin	United States	Vertex Pharmaceuticals
Gheuens	Jan	United States	Bill & Melinda Gates Foundation
Ginsberg	Ann	United States	TB Alliance
Gómez de las Heras	Federico	Spain	GlaxoSmithKline
Grosset	Jacques	United States	Johns Hopkins University School of Medicine
Grossman	Trudy	United States	Vertex Pharmaceuticals
Grzemska	Malgosia	Switzerland	World Health Organization
Gumbo	Tawanda	United States	University of Texas Southwestern Medical Center at Dallas
Harrington	Mark	United States	Treatment Action Group
Heinrich	Norbert	Germany	Universtiy of Munich / PanACEA
Hipskind	Philip	United States	Eli Lilly and Company; Lilly Research Laboratories
Hoelscher	Michael	Germany	Ludwig-Maximilians-University
Horwith	Gary	United States	Sequella, Inc.
Husson	Robert	United States	Children's Hospital Boston/Harvard Medical School
Ignatius	Heather	United States	TB Alliance
Jabes	Daniela	Italy	NeED Parma
Jindani	Amina	United Kingdom	St. George's, University of London
Kamboj	Rajender	India	Lupin Limited
Kaneko	Takushi	United States	TB Alliance
Karakousis	Petros	United States	Johns Hopkins University
Kasprowicz	Victoria	South Africa	K-RITH (KwaZulu-Natal Research Institute for Tuberculosis and HIV)
Kawakubo	Hiromu	Japan	Asahi Kasei Chemicals Corporation
Kesicki	Edward	United States	Infectious Disease Research Institute
Khan	Ahmadul	Bangladesh	Ahmadul Hasan Khan
Kutsyna	Galyna	Ukraine	Luhansk State Medical University
Lamichhane	Gyanu	United States	Johns Hopkins University
Laughon	Barbara	United States	National Institute of Allergy and Infectious Diseases, NIH, DHHS
Leboulleux	Didier	France	sanofi-aventis
Lenaerts	Anne	United States	Colorado State University
Lienhardt	Christian	Senegal	WHO Stop TB Partnership Research Movement
Locher	Christopher	United States	Vertex Pharmaceuticals
Lomtadze	Nino	Georgia	National Center for Tuberculosis and Lung Diseases
Love	James	United States	Knowledge Ecology International (KEI)
Lowrie	Doug	United Kingdom	Cardiff University
Ma	Zhenkun	United States	TB Alliance
Makhene	Mamodikoe	United States	NIH
Makone	Albert	Zimbabwe	Community Working Group on Health

Mangura	Bonita	United States	New Jersey Medical School Global TB Institute at UMDNJ
Matlin	Stephen	Switzerland	Global Forum for Health Research
McCammon	Maggie	United States	University of Michigan
McNeeley	David	United States	Tibotec
Mitchison	Dennis	United Kingdom	St Georges. University of London
Mitnick	Carole	United States	Harvard Medical School
Moser	Heinz	United States	Achaogen
Mueller	Peter	United States	Vertex Pharmaceuticals
Muh	Ute	United States	Vertex Pharmaceuticals
Nacy	Carol	United States	Sequella, Inc.
Narayanan	P. R.	India	Tuberculosis Research Centre, Chennai (retired)
Nuermberger	Eric	United States	Johns Hopkins University
O'Brien	Rick	Switzerland	Foundation for Innovative New Diagnostics
Ojanen	Matti	United Kingdom	AstraZeneca PLC
Okada	Masaji	Japan	Clinical Research Center, National Hospital Organization Kinki-Chuo Chest Medical Center
Old	Iain	Switzerland	SCIPROM - Scientific Project Management
Onyebujoh	Philip	Switzerland	WHO/Special Programme for Research and Training in Tropical Diseases (TDR)
Ordway	Diane	United States	Colorado State University
Orme	Ian	United States	Colorado State University
O'Toole	Ronan	New Zealand	Victoria University of Wellington
Otwoma	Nelson	Kenya	Positive Familes Network (+FN)
Pan	Martin	Spain	GlaxoSmithKline R&D, Diseases of the Developing World Medicines Development Campus
Pando	Rogelio Hernandez	Mexico	National Institute of Medical Sciences and Nutrition, Mexico
Pappas	Frances	United States	TB Alliance
Parida	Shreemanta	Germany	Max Planck Institute for Infection Biology
Parish	Tanya	United Kingdom	Infectious Disease Research Institute
Pavan	Fernando	Brazil	São Paulo State University, UNESP, Brazil
Phyu	Sabai	Singapore	Novartis Institute for Tropical Diseases
Protopopova	Marina	United States	Sequella, Inc.
Rao	Kanury	India	International Centre for Genetic Engineering & Biotechnology
Raviglione	Mario	Switzerland	World Health Organization
Rex	John	United Kingdom	AstraZeneca R&D
Ridley	Robert	Switzerland	WHO/Special Programme for Research and Training in Tropical Diseases (TDR)
Rook	Graham	United Kingdom	Centre for Infectious Diseases and International Health (CIDIH), University College London
Rouse	Doris	United States	RTI International
Sassetti	Christopher	United States	University of Massachusetts Medical School
Schnappinger	Dirk	United States	Weill Cornell Medical College
Semete	Boitumelo	South Africa	Council of Scientific Industrial Research (CSIR) in South Africa

Shadiack	Annette	United States	TB Alliance
Sherman	David	United States	Seattle Biomedical Research Institute
Shimao	Tado	Japan	JATA Research Institute of Tuberculosis (RIT)
Siuta	Gerald	United States	TB Alliance
Sizemore	Christine	United States	National Institute of Allergy & Infectious Diseases (NIH)
Small	Peter	United States	Bill & Melinda Gates Foundation
Solomonia	Nelly	Georgia	National Center for Tuberculosis and Lung Diseases
Spigelman	Melvin	United States	TB Alliance
Springsklee	Martin	United States	Bayer Healthcare
Stover	Charles K.	United States	Pfizer Inc
Swai	Hulda	South Africa	Council of Scientific Industrial Research (CSIR) in South Africa
Syed	Javid	United States	Treatment Action Group
Tauscher	Gail	United States	NIH, NIAID
TETO	Fondacaro	Democratic Republic Of Congo (Zaire)	Programme National de lutte contre la Tuberculose
Thomson	John	United States	Vertex Pharmaceuticals
Trapaidze	Tamari	Georgia	Welfare Foundation
Tsodikov	Oleg	United States	University of Michigan
Upton	Anna	United States	TB Alliance
van Niekerk	Christo	South Africa	TB Alliance
Vandal	Omar	United States	Bill and Melinda Gates Foundation
Vandevelde	Wim	Portugal	European AIDS Treatment Group (EATG)
Vernon	Andrew	United States	U.S. Centers for Disease Control and Prevention
Waldman	Todd	United States	Easton Associates
Wallis	Robert	United States	Pfizer Inc
Walzl	Gerhard	South Africa	Stellenbosch University
Wandiga	Steve	Kenya	KEMRI/CDC
Wang	Tiansheng	United States	Vertex Pharmaceuticals
Wells	Charles	United States	Otsuka Pharmaceutical Company
Wells	William	United States	TB Alliance
Williams	Sharon	United States	National Institute for Allergy and Infectious Diseases, NIH
Wingfield	Claire	United States	Treatment Action Group
Zeldis	Jerome	United States	Celgene
Zhang	Xuelian	China	Fudan University

7. Working Group on New Vaccines

(i) Established in: 2001

(ii) Core group members and affiliation

Name	*Affiliation*	*Constituency*
Michael BRENNAN *Alternate: Lew BARKER*	Aeras	Aeras (standing member)
Uli FRUTH	WHO/IVB	WHO (Secretariat)
Lucy GHATI	NEPHAK	Community Representative
Michel GRECO	**Independent vaccine expert, Lyon, France**	**Chair**
Didier LAPIERRE	GSK Biologicals	Private sector
Hassan MAHOMED *Alternate: Willem HANEKOM*	South African Tuberculosis Vaccine Initiative/University of Cape Town	Clinical research sites
Robert NAKIBUMBA	TASO Uganda	Community Representative
Laura SHACKLETON	Bill & Melinda Gates Foundation	Foundations
Christine SIZEMORE	NIAID/NIH	Public Sector
Jelle THOLE	TuBerculosis Vaccine Initiative (TBVI)	TBVI (standing member)
Suzanne VERVER	KNCV Tuberculosis Foundation	NGOs/Technical Agencies

(iii) Is membership up to date?
Core Group membership is up-to-date.

(iv) Secretariat hosted in: the WHO Initiative for Vaccine Research, with additional support provided by Aeras.

(v) Frequency of working group meetings:

a) Full working group: Biannual
b) Core group: Teleconferences 6-8 times per year; in-person once per year

(vi) Goal and objectives –
The goal of the Working Group on New Vaccines is to facilitate development of new, more effective TB vaccines that will prevent all forms of tuberculosis in all age groups and will be safe for people living with HIV. To accomplish this goal, the Working Group on New Vaccines:

- Provides a forum for dialogue on issues relevant to research, development and advocacy for new vaccines to combat tuberculosis

- Facilitates coordinated activities to support the objectives and milestones outlined in the Global Plan to Stop TB
- Convenes stakeholders to discuss key issues related to vaccine development
- Serves as an objective source of information on TB vaccines and vaccine development; and
- Advocates for increased investment in and support for new TB vaccine development.

The Working Group supports the objectives for vaccine development as identified in the Global Plan to Stop TB 2011-2016, including:

Objective 1. To maintain a robust TB vaccine pipeline by supporting research and discovery

Objective 2. To conduct research to identify correlates of protection, and preclinical studies to assess new TB vaccine candidates

Objective 3. To ensure availability of vaccine production capacity by expanding manufacturing facilities for TB vaccines

Objective 4. To build capacity for large-scale clinical trials (Phase II, IIb and III) of TB vaccine candidates at field sites in TB endemic countries

Objective 5. To conduct clinical trials of TB vaccine candidates

Objective 6. To develop, delivery, regulatory and access strategies for new TB vaccines

Objective 7. To build support for TB vaccine development and uptake through advocacy, communications and resource mobilization.

Specific initiatives and activities to support these objectives in 2010-2011 include the convening of the 2nd Global Forum on TB Vaccines in Estonia in September 2010, facilitating meetings on the topics of economics and product profiles, issues in clinical research, and innovative approaches to new TB vaccine development, facilitating a research project on the use of functional assays at clinical trial sites, and supporting and participating in WHO-led efforts to strengthen vaccine regulatory capacity in developing countries. In the coming year, the Working Group will work with constituencies across the listed objectives to develop a *Blueprint for TB Vaccine Development*, which will serve to guide the field over the next decade. The Working Group also serves as a centralized mechanism for integrating these activities with the development of other new technologies for TB and vaccines for other diseases.

(vii) Resources for biennium 2010-2011:
a) Approved budget: 250,000 USD
b) Provided (as of January 2011):125,000 USD
c) Estimated in-kind contributions 2010-2011:

The members of the Vaccines Working Group provide support for a number of its activities. A non-exhaustive list of the financial and in-kind contributions that the Working Group has received or expects to receive in 2011 are listed below.

Financial support for Working Group activities for the time period is estimated to be approximately $600,000. This funding supports the following activities:

- Funding from Aeras and the US Food and Drug Administration to conduct research on functional assays for use in TB vaccine clinical trials
- Support from Aeras for Working Group operations and activities, including staff travel to Partnership meetings and Working Group and Task Force teleconferences
- Financial sponsorship to support the Second Global Forum on TB Vaccines was received from Aeras, the Bill & Melinda Gates Foundation, TBVI, Crucell, Emergent BioSolutions, GSK Biologicals, KNCV Tuberculosis Foundation and Sanofi-Pasteur
- Financial support was also received from NIH to sponsor participants from endemic countries to attend the Second Global Forum on TB Vaccines

In addition, Working Group members provide in-kind support primarily through the contribution of staff time to Working Group activities, estimated to be approximately the equivalent of 1.5 FTE. Such support includes:

- Staff time from the WHO Initiative for Vaccine Research to serve as Secretariat
- Staff time from Aeras to support Working Group operations
- Staff time from Aeras and TBVI to coordinate the Second Global Forum on New TB Vaccines in Tallinn, Estonia and to begin coordinating the Third Global Forum on TB Vaccines
- Staff time and support from Aeras, TBVI, SATVI, KNCV Tuberculosis Foundation, and the Bill & Melinda Gates Foundation to coordinate and convene meetings to discuss key Working Group and vaccine development objectives
- Staff time from Aeras and TBVI to coordinate the development of the *Blueprint for TB Vaccine Development*
- Staff time from SATVI to support the development of a comic book on TB vaccine clinical research for use in community outreach and engagement. The Working Group provided funding for the direct costs related to development of the comic book.

(viii) Country focus/priority Countries (if any):
TB vaccine research priority countries are generally those in which clinical trials are being conducted or in which trials are planned. As of 2011, those countries include but are not limited to:

- South Africa
- Kenya
- Uganda

- Mozambique
- India
- The Gambia
- Senegal

As vaccine candidates continue to advance through clinical trials, more countries will be added to this list.

(ix) Priorities in 2010-2011:
Priorities in 2010 included:

- Convened the 2nd Global Forum on New TB Vaccines, with over 200 participants from 30 countries
- Actively participating in the process to update the Global Plan to Stop TB
- Convened meetings of the Task Force on Economics and Product Profiles, the Task Force on Innovative Approaches to TB Vaccine Development, and the Task Force on Issues in Clinical Research
- Continued to work with the Developing Countries Vaccine Regulators Network (DCVRN) and the African Vaccine Regulators Forum (AVAREF), both WHO-led initiatives to strengthen regulatory capacity in developing countries – to begin discussions on regulatory issues related to TB vaccine clinical trials
- Provided a grant to Working Group Member the South African Tuberculosis Vaccine Initiative to develop a comic book, printed in Afrikaans, Xhosa and English, to communicate information on TB vaccine clinical research and address common questions and misunderstandings about TB vaccine clinical trials in communities

Priorities in 2011 include:

- Expanding the dialogue on regulatory issues by requesting an agenda item at the fall 2010 meeting of the Strategic Advisory Group of Experts (SAGE) and continuing engagement with the DCVRN and AVAREF vaccine regulators' networks.
- Continuing the process to develop the *Blueprint for TB Vaccine Development*, which was initiated at the 2nd Global Forum on TB Vaccines
- Beginning to plan for the 3rd Global Forum on TB Vaccines, tentatively proposed for spring 2013
- Identifying new mechanisms for community outreach and engagement
- Continuing to support the South-South collaborations fostered by the Tuberculosis Vaccine Trial Sites Network (TBVACSIN)
- Convening meetings of the Economics and Product Profiles Task Force and the Task Force on Harmonization of Assays

(x) Main achievements since establishment:

- Established task forces that bring together key stakeholders to discuss key aspects of TB vaccine development. These task forces have led to a project that focuses

on the use of functional assays in the field, a consensus strategy for advancing live vaccines through clinical trials, research and discussion on key economic issues related to new TB vaccines, and a forum for discussion on definitions of clinical endpoints.

- Providing support to enable South-South collaboration via TBVACSIN
- Convened a Global Forum on TB Vaccines in 2010, which brought together 200 researchers and other interested parties from 30 countries to discuss critical issues in vaccine development for the next decade
- Actively engaging with the DCVRN and AVAREF to support regulatory capacity building and to initiate discussions on regulatory issues related to TB vaccine development

(xi) 3-5 main (expected) outputs in 2010-2011:

- TB Vaccine Blueprint process will be nearly completed, with an anticipated launch in March 2012
- Increased number of advocacy materials appropriate for various audiences (community, national, global levels)
- Meeting reports and key next steps identified for issues related to economics and product profiles and harmonization of assays
- Conclusion of a study to comparatively evaluate several mycobacericidal assay with the aim of developing a functional assay useful for the evaluation protective efficacy of TB vaccine candidates
- Publication of guidelines on diagnosis of TB in clinical trials and definition of clinical endpoints of TB vaccine efficacy trials.

(xii) Advocacy activities:

a) Description of WG's advocacy activities for 2011

The primary focus of the Working Group's advocacy activities are on raising awareness and support for new TB vaccines at the community and country level. The Working Group has established a liaison with the Advocacy Network and the Advocacy Advisory Committee, and it is expected that global advocacy will be conducted in collaboration with the Advocacy Network and the Partnership Secretariat.

Country and community level advocacy will be coordinated primarily by the Working Group's two community representatives and Aeras' advocacy staff. Planned activities include a presence at targeted national, regional and international conferences; liaising with communications and advocacy staff at TB vaccine trial sites to collaborate and coordinate efforts; developing additional advocacy materials targeted at community and country audiences; and to work with the community representatives of other Working Groups to coordinate messages, identify new opportunities and strengthen outreach efforts.

b) Main targets of advocacy

As noted, the main advocacy targets for the Working Group are at the community and country level, which include but are not limited to NGOs and civil society; government officials, policy makers and other key decision makers; community leaders and others

interested in TB and global health.

Global level advocacy will be done in coordination with the Partnership Secretariat.

c) Key advocacy challenges
Our experience has been that when people hear about new TB vaccines, the progress that has been made and the potential that new TB vaccines could have on the epidemic, there is generally interest and support. However, there is still not enough overall awareness of the role for new TB vaccines or the tremendous progress that has been made over the past decade. It is also a challenge to be able to build and sustain momentum and support for a new technology that will not be available for use for several years, although that support and momentum is critical to helping us achieve the ultimate goal of a new TB vaccine. And, the global economic crisis has made it a difficult environment to secure additional resources for both implementation programs and urgently needed new technologies, including new TB vaccines.

d) Upcoming advocacy opportunities
The Working Group continues to seek opportunities for advocacy about TB and new TB vaccines at the country, regional and global levels, including the Kenya International Conference on Lung Health that is anticipated to take place in 2011 and the Union World Conference on Lung Health. The Working Group will liaise with its partners to identify, conferences, events, major announcements and other opportunities that can be utilized to build awareness and support for our work.

(xiii) Main challenges and opportunities:
Scientific challenges: The greatest scientific challenge in developing new vaccines is the uncertainty about identifying vaccine candidates that provide consistent protection against TB and the lack of experience with new TB vaccines in human populations. As a result, the scientific community is pursuing a dual strategy of maintaining support for relevant activities in vaccine discovery research while maximizing the number of candidates introduced into clinical trials. This approach increases the chances for developing an effective vaccine.

Operational challenges: As TB vaccines progress to larger-scale clinical trials in different target populations, multiple trial sites will be necessary to ensure sufficient enrolment for a licensure trial and to address immunological and other responses that may vary by region. These large-scale efficacy and licensure trials require appropriate capacity and infrastructure to enrol, monitor, diagnose and follow-up high numbers of participants. They also require access to accredited microbiological and immunological laboratories, staff that are trained in good clinical practice (GCP), clinical experience with trials and TB diagnosis, radiological expertise and quality control mechanisms.

Financial challenges: Despite impressive commitments by philanthropic organizations and the public sector, much greater investment will be required to achieve the goal of a new, more effective vaccine. Funds are being prioritized to support the maintenance of the vaccine delivery pipeline, performance of clinical trials, and the creating of an

enabling infrastructure. Without increased investment, promising vaccine candidates will not advance through large-scale efficacy trials and new, second generation candidates will not be brought into the pipeline

(xiv) Suggestions for strengthening coordination and collaboration with other working groups and subgroups:
The New Tools Working Groups held a joint meeting at the Stop TB Partners Forum in Rio de Janeiro in 2009. Joint activities like this can be useful in understanding areas of potential synergy and collaboration, and should be convened at least every other year. In addition, new tools will play an important role in addressing TB in general, and also drug-resistance and TB/HIV coinfection. Opportunities should be sought for greater cooperation and information-sharing between the implementation and research working groups.

At the 2010 Union World Conference on Lung Health in Berlin, the community representatives from the Research Working Groups met with the Working Group Secretariats and advocacy staff from product development partnerships to discuss opportunities for joint messaging and other joint advocacy activities. These efforts should continue and should expand to the other Working Groups via the Community Task Force. The Partnership should ensure sufficient support to the community representatives to enable them to fulfil their mandates and identify opportunities to collaborate across Working Groups.

(xiv) Task Forces of the WG on new TB Vaccines
The 5 Task Forces are not separate subgroups, but represent the operational arm of the Working Group on New Vaccines. They have been designed in such a way as to address the Global Plan objectives related to new vaccines in a logical and comprehensive fashion. Furthermore, the Task Forces provide a forum which allows for Working Group members to contribute to the Working Group in their specific area of expertise. Below there is a list of the 5 Task Forces with the corresponding Terms of Reference as well as the name of the Task Force chair, who normally is a member of the core group. Task Forces interact via teleconferences, email, and periodic in-person meetings.

(a) Task Force on Harmonization of Assays for TB Vaccine Development

Chair: Dr Michael Brennan, Aeras

Terms of Reference

- Serve as a resource body to the Working Group on New Vaccines in matters related to immunological correlates, surrogates and biomarkers for TB vaccines.
- Serve as a review group for the development of sections of the TB Vaccine Blueprint related to biomarkers, correlates and standardization of human and animal immunoassays.
- Act as an advisory body for the multicenter Mycobacterial growth inhibition assay project that is ongoing and originated from discussion groups organized by the Working Group on New Vaccines.

- Review cohort studies that are currently assessing natural immunity to TB and progression from latency to active disease and working with PIs to develop position papers that advance the field.
- Develop recommendations for banking human specimens for immunological analyses and publish commentary.
- Facilitate comparative and multicenter studies of biomarkers and immunological assays when possible.

(b) Task Force on Clinical Research Issues in TB Vaccine Development

Chair: Dr Hassan Mahomed, South African TB Vaccine Initiative

Terms of reference

- Define endpoints to be used in paediatric, adolescent and adult TB vaccine trials.
- Standardise TB diagnostic tools for use in TB vaccine trials.
- Develop a diagnostic algorithm for use in paediatric vaccine trials.
- Facilitate a clinical trials network involving multiple sites.

(c) Task Force on New Approaches to TB Vaccine Development ("out-of-the-box")

Chair: Dr Jelle Thole, TB Vaccine Initiative

Terms of reference

- To identify fundamentally new approaches to prevention of TB.
- To develop mechanisms to attract investigators from other disciplines and specialists on diseases other than TB diseases to develop innovative TB vaccine research proposals.
- To provide young TB researchers at PhD students and post-doc level with incentives to develop and test innovative ideas.
- To identify funding opportunities/pathways for high-risk research on next (third?) generation vaccination approaches.
- To develop a mechanism to ensure rapid transition of innovative TB vaccine discovery approaches into a standardized vaccine development pathway.

(d) Task Force on Economics and Product Profiles for new TB Vaccines

Chair: Dr Gerard Cunningham, Bill and Melinda Gates Foundation

(vi) Terms of reference:

- To develop estimates of the economic value of new TB vaccines/vaccine types in different epidemiologic scenarios:
    - as an advocacy tool for donors to TB vaccine development

    - as guidance for phased introduction of (initially limited) supplies of new TB vaccines
- To elaborate financing models/options for the introduction of new TB vaccines.
- To initiate a dialogue between vaccine developers and the vaccine implementation community regarding definition of realistic and useful target product profiles.
- To develop models that allow to place new TB vaccines into the context of (a) existing and in particular new tools in TB control and (b) mid-and long-term trends in the overall vaccine market (time horizon 10-20 years).

(e) Task Force on Advocacy, Communications and Social Mobilization

Chair: Mr Robert Nakibumba, TASO Uganda

Terms of reference

- To develop an advocacy strategy for new TB vaccine development.
- To ensure adequate representation of TB vaccine development/implementation/ financing issues in international public health fora.
- To provide potential donors with a realistic picture of the TB epidemic and the potential role of a new vaccine in that context.
- To inform endemic country governments and affected communities of the prospects and challenges for new TB vaccines and the importance of their participation.

Annex I: Independent Evaluation of the Stop TB Partnership, Section on working groups, pages 41-46 (Final Report 21 April 2008)

Full report is available at:
http://www.stoptb.org/resources/publications/achievement_evaluations.asp

What impact has the Partnership had in 2001-06 over and above what would have happened without the Partnership?

Detailed findings:
Page 14: The Partnership and its Working Groups have strengthened guidance for TB in 4 ways: (1) providing input to the technical guidance developed by WHO; (2) identifying and prioritizing issues on which technical guidance is needed; (3) endorsing and supporting the dissemination and adoption of WHO guidance; and (4) supporting the development, dissemination, and adoption of other guidance. *Exhibits 7 and 8* show examples of Partnership contributions in these areas."

Page 17: "The Partnership's Working Groups have played a major advocacy role, by signalling the importance of different areas of tuberculosis control and research, and by serving as a forum for building consensus and commitment."

Page 20: " The new tools Working Groups have facilitated coordination between researchers, with Working Group members reporting examples of better collaboration (e.g., to develop lab assays for vaccines), sharing key information (e.g., drug targets being screened), and acceleration of development (e.g., introduction of more vaccines into clinical trials). The Working Groups are broader communities than the PDPs (and TDR, which also contributes to diagnostics), and interviewees report that this “additional” contribution of the Partnership to PDPs is valuable."

How effectively and efficiently has the Partnership delivered this impact?

Working groups
The Stop Tuberculosis Partnership’s Working Groups have been the major mechanism for bringing Partners together on issues that the Partnership has deemed critical. Depending on the issue in question and on Working Group members’ own choices, the Working Groups have taken on different activities and roles. All serve forums for engaging Partners, discussing issues, and coordinating activities. Many also perform other activities. For example, the GLC now sits as a subgroup of the MDR-TB Working Group; the ACSM Working Group has task forces charged with specific projects, including supporting national TB partnerships.

The number, structure, and composition of Working Groups appear to have been in line with the priorities of the Partnership over the last 5 years. The loose

structure has encouraged partners to engage and to commit funds and resources. The current structure has however raised 3 specific concerns for many interviewees:

- That the structure and hierarchy of Working Groups are the main reflection of the priorities of the Partnership. If this is the case, how should this be modified to reflect current priorities – e.g., some feel that if Laboratory Strengthening is a priority, then it should be a Working Group
- That the "status" of being a Working Group influences attention from the Coordinating Board, members' commitment, and fundraising ability
- That there is overlap of activities in certain areas (e.g., TB-HIV has an ACSM component, MDR-tuberculosis has a new drugs and diagnostics component) and not enough collaboration in others

Effectiveness of the Working Groups

It has proven challenging to assess *comprehensively* the effectiveness of the Working Groups, for a number of reasons related to how they define, adapt, and measure progress against their objectives. In many cases, a Working Group's objectives are clearly defined and deliverable by the Working Group, and progress against this objective is tracked. However, this is not always the case.

- In some cases, objectives set by the Working Group are goals for overall tuberculosis control and research, which must be delivered by countries or by individual Partners, not by the Working Group itself. For example the Working Group for New TB Drugs has objectives including "identify and validate drug targets for persistent bacilli and latent disease", and "develop a sustainable portfolio of new drug candidates that meet drug profile criteria". The specific objective of the Working Group itself, rather than the TB Alliance, pharmaceutical companies or academic centers, is not clearly articulated. The 2008 - 09 Biennial Work Plan submitted to the Coordinating Board in October 2007 lays out Working Group activities (e.g., "organize and co-sponsor annual open fora on key regulatory issues") but does not describe the expected results of such activities, or how these help achieve the goals set out in the Global Plan.

- In other cases, Working Groups have not succeeded in aligning stakeholders against their specific objectives. For example, some interviewees would have preferred the MDR-TB Working Group to also address the problem of inadequate supply of second-line drugs.

- In other cases, Working Groups have not defined what they will achieve through certain activities and how these will further broader Partnership goals. For example, the ACSM Working Group has promoted a theme for World TB Day, developed a messaging platform, compiled an international calendar of events, developed guidance and tools for countries, and run ACSM workshops in countries, but has not stated what specifically it will achieve by doing so.

- And in yet other cases, Working Group objectives have changed over time, and previously stated objectives have not in fact been pursued.

It is nonetheless clear that all Working Groups have made significant contributions and driven much of the Partnership's impact over 2001 - 06. Many examples have been described in the Partnership Impact section. Below, we lay out further examples by Working Group:

ACSM Working Group: The Working Group has contributed to *advocacy to national governments and donors* leading to additional funding for ACSM and tuberculosis. It has also contributed to *supporting monitoring and evaluation* of ACSM activities in countries. Examples include:

- Approached PEPFAR for funding for consultants to visit countries and support GFATM applications of ACSM. The success of this initiative supported PEPFAR's more broad funding of TB-Team as well as making more money available in country for ACSM activities.

- Provided questions for WHO country questionnaire on ACSM activities, which should improve monitoring of progress by countries.

DOTS Expansion Working Group: The Working Group has contributed to *improving tuberculosis care in countries* and to *supporting monitoring and evaluation* through the expansion of DOTS globally by aligning and supporting country activities. By bringing together NTP managers from high burden countries and international partners, it has facilitated the adoption and implementation of the DOTS strategy by all 22 high burden countries, and fostered a sense of commitment and accountability in countries. Many interviewees have described DEWG as a key driver of DOTS expansion, because of the sense of commitment and accountability that it has engendered in NTP and other Working Group members. Examples include:

- Created Global DOTS Expansion Plan endorsed and followed by all HBCs.
- Held annual meetings for the NTP managers, providing an opportunity to monitor progress, share experiences and stimulate action where necessary.

MDR TB Working Group: The Working Group has contributed to *improving tuberculosis care in countries*, supporting the progress made globally in MDR control primarily through the work of the GLC. Additionally, the Working Group has raised the importance of infection control in tuberculosis. Examples include:

- Members of the Working Group serve voluntarily on the GLC committee
- Participated in the writing committee of WHO on MDR guidance
- Encouraged its members to exert pressure on the Global Fund to commit to the GLC mechanism, with success.

TB-HIV Working Group: The Working Group contributed to *setting and building consensus on a common agenda* around TB-HIV collaboration. It has gone beyond its original objectives of conceptualizing, testing, and monitoring tools

and policies for TB-HIV prevention and care and contributed to *improving tuberculosis care in countries* by supporting the rollout of TB-HIV programs. Examples include:

- Contributed to the development of WHO documents 'Strategic framework to decrease the burden of tuberculosis/HIV' and 'Interim Policy on collaborative tuberculosis/HIV activities', through reviews, contribution of evidence, discussion, and debate.
- Held annual meetings that brought NTP managers together to share their experiences and provide support for implementation.
- Actively recruited community activists into the Working Group and ran training on tuberculosis HIV advocacy to develop country champions.

Working Group on **New Diagnostics**: Individual members of the Working Group have made significant progress on the development of new diagnostics over the period of the evaluation, many of which are being piloted or rolled out. Collectively the Working Group has also started to contribute to *supporting R&D for new tools* by mapping out the current development state of different diagnostics and identifying and describing problems preventing the development of new diagnostics.

Working Group on **New Drugs**: The Working Group has contributed to *supporting R&D for new tools* by ensuring stakeholders in drug development are working together to speed the development of new drugs, and by involving public stakeholders through the work of the retooling task force. Examples include:

- Provided a forum for sharing information. Working Group members report that in some cases this has resulted in closer collaboration
- Created a document that includes all current activities in drug development allowing researchers to have visibility on the total landscape

Working Group on **New Vaccines**: The Working Group has contributed *supporting R&D for new tools* by increasing collaboration between researchers and accelerating the introduction of vaccines into clinical trials. Examples include:

- Held a series of meetings that have resulted in players collaborating more on specific topics, e.g., development of lab assays.
- Supported alignment of the work and objectives of WHO vaccine development with the Global Plan.
- Encouraged vaccine candidate owners to enter their candidates into clinical trials by 2005 – without which pressure 4 of 7 vaccines currently in trials would not have entered as early as 2005.

Understandably, Working Groups have not always been able to deliver against objectives they have set themselves. For example, the Working Group on New Vaccines had an objective to "prioritize actions needed and areas of new resources, that will advance the sustained access of improved tuberculosis vaccines to endemic countries" in its terms of reference. Working Group members report that they have not delivered against this objective due to insufficient resources. Similarly, DEWG members would like to have delivered more impact

against coordinating technical assistance to countries, involving the private sector, and ensuring tuberculosis control efforts contribute to broader health sector and poverty reduction strategies.

Efficiency of the Working Groups

We have evaluated the efficiency of the Working Groups along 6 dimensions, based on interviews, observations of Working Group meetings, and the previous evaluation of the Working Groups. The dimensions are: (1) performance management, (2) communications, coordination, and collaboration, (3) resources, (4) partner engagement, (5) leadership, and (6) meeting management. By design the first three of these overlap directly with the categories of the previous Working Group: action and accountability, communications, coordination and collaboration, and resources. In particular, we should note that the Secretariats for most of the Working Groups are provided by WHO, rather than by the Partnership itself.

Performance management: Performance management in this context includes setting clear objectives which can be delivered by the Working Groups (as opposed to by individual Partners, or by governments or other entities), establishing appropriate metrics and targets to track progress against these objectives, reviewing performance regularly, and taking corrective action where necessary. While there is clearly variation between Working Groups, and perhaps even within a Working Group over time, we have identified 3 issues are sufficiently widespread to merit discussion:

- As described above, there are many cases where objectives set by the Working Groups cannot be delivered by the Group itself (e.g., "ensure that MDR-TB patients worldwide have access to adequate diagnosis and treatment"), and cases where the link between Working Group deliverable objectives and the broader goals of the Partnership is not sufficiently clea.r
- Some metrics used by Working Groups are at too high a level (e.g., total global number of treatments), not closely linked to specific activities, or set with targets for the distant future (e.g., 2015), making it difficult to track progress on a sufficiently detailed basis to guide actions (e.g., country-by-country, annually).
- Many Working Groups do not have a regular formal process for reviewing their performance against agreed objectives and targets, and agreeing on what needs to be done to address any problems or gaps.

Communication, coordination, and collaboration: The level of communication, coordination, and collaboration varies across Working Groups but most interviewees recognize that there is a need to do more to keep partners informed and coordinate with other Working Groups. Good practice examples identified include regularly updating the website (e.g., TB-HIV) and sending out newsletters (e.g., TB-HIV). The previous external evaluation of the Working Groups has covered this topic in significantly more detail.

Resources: Different Working Groups have different levels of Secretariat support and different levels of funding. Resourcing generally depends on the commitments of individual Working Group members (e.g., WHO provides the Secretariat for the TB-HIV Working Group, the TB Alliance has been the main funder of the Working Group on New Diagnostics, and the Partnership is supporting the ACSM Working Group). Most Working Groups do not keep comprehensive records of their budgets, funding sources, activities conducted, and objectives met. It is therefore not possible from an external perspective to comment on resource need vs. resource use, or on the efficiency or resource use. Core members of the Working Group generally feel resources to be inadequate and to limit activities (e.g., New Drugs Working Group would like to have reached out proactively to partners, DOTS expansion Working Group would like to have been able to support more activity in countries). Some Working Groups are looking to the Partnership Secretariat for more resourcing – and some interviewees have raised questions about whether the Secretariat should be the right funding source for these Groups.

Partner engagement: The Working Groups have been successful in actively engaging appropriate partners in their work via participation in meetings and input into discussions or guidance. Membership of Working Groups and attendance at meetings is reported to have significantly increased over the evaluation period. Many Working Groups recognize that there is room to do more with certain key partners (e.g., the TB-HIV Working Group would like to engage the HIV community to a greater extent, and the Working Group on New Drugs would like to further engage national laboratories).

Meeting management: The meetings attended in Cape Town in December 2007 demonstrated the commitment of individual members to the groups both in terms of the high level of attendance and the high level of engagement in discussion and debate. The sessions that were devoted to work planning for the group were significantly less well attended. The main focus of the meeting agendas appeared to be to inform members of progress in the field and to share experiences. In general, there appeared to be little emphasis on taking decisions or committing to action as a result of the meetings – although the objective of many sessions may have been information sharing rather than decision-making.

Recommendations:

Page 63 Recommendation 7: The Partnership should continue to use Working Groups as a major vehicle contributing to TB control and research, systematize the processes for their establishment and performance review, and provide them support from the Secretariat

Context: Working Groups (WGs) have been the Partnership's main mechanism to bring Partners together on critical issues in TB control and research. While WGs have played different roles and conducted different activities depending on the

issue in question, they have contributed significantly to the overall impact of the Partnership over the Evaluation period. However, measuring the full effectiveness and efficiency of Working Groups over the Evaluation period has proven difficult: in some cases, WGs have not clearly articulated the specific objectives, in others they have not adequately defined metrics, targets, or performance review mechanisms for their work, and in most cases, they have not tracked resource commitment and use for their work. Some WGs report that they are currently addressing these issues. Many stakeholders also report that the Partnership should revisit the number of WGs, the issues they address, their organization structure, and their Board representation.

Detailed recommendations:

7.1 Establishment: The Coordinating Board should establish Working Groups on selected strategic topics for a fixed duration of 3 years, and review these every 3 years, starting with the May 2008 Coordinating Board. *Exhibit 33* lays out proposed selection criteria for Working Groups and alternative mechanisms for addressing strategic issues.

Given the complexity of the issues requiring a Working Group approach, our view is that the total number of Working Groups should ideally not be more than 7 - 8, to ensure that the Partnership as a whole and the Coordinating Board in particular can devote sufficient time and energy to each. If there are more than eight issues that meet the criteria for WG status, the Coordinating Board should debate and prioritize the 7 - 8 that are most critical over the 3-year period, and review after 3 years.

The Partnership should in this context review the status and objectives of the ACSM WG: The Partnership Secretariat carries out advocacy and communication for TB, particularly at a global level, and the other Working Groups, product development partnerships, and individual Partners do so for their own areas of focus. The Secretariat and ACSM WG should work together to ensure that there is no duplication of activities, either by developing a remit for the WG that is consistent with the establishment criteria above and clearly non-duplicative, or by absorbing the WG activities into the Secretariat Advocacy Unit and the Coordinating Board subcommittee on Advocacy (*see* Recommendation 9).

7.2 Review: The Coordinating Board should review the impact, effectiveness, and efficiency of all WGs every 3 years, and address the following:

- Existence: Dissolve WGs that no longer meet establishment criteria (e.g., because they have successfully addressed the issues they were created for).

- Performance: Assess how well and how efficiently each Working Group has delivered against its internal objectives, and make necessary

recommendations on how to improve performance.

- Membership and leadership: Review the appropriateness of Working Group broad membership and core membership. Rotate the Chair, unless there is a very compelling reason to maintain the Chair for a second 3-year term.

7.3 Activities: All Working Groups should serve as topic-specific forums for discussion and debate, which Partners can use to inform their own activities. Each Working Group should also prepare:

- A 3-year strategic plan laying out the external goals it is targeting, the specific internal goals, deliverables (e.g., reports, draft guidance, endorsement statements), and milestones it is *voluntarily* setting itself, the main activities involved, and the resources and funding required.

- A more detailed annual operational plan.

- An annual performance report vs. the operating plan.

The Partnership Secretariat, in consultation with WG Chairs, should prepare templates for the strategic plan and operational plan and for the annual report.

Each WG should publish its strategic plan to increase transparency, encourage cooperation, and incentivize accountability.

7.4 Funding: Working Groups should be established with a funding plan. This would call for use of existing Partnership funds, or funds or donations-in-kind directly contributed by Partners. Working Groups should also identify where they need Partnership Secretariat or broader Partnership support in raising necessary funds. They should report on use of funds in their annual performance report.

7.5 Administrative support: Working Groups should have dedicated administrative support, detailed in their Operating Plans, with funding or resourcing ideally provided by WG Partners themselves. The Partnership Secretariat should provide funding adequate for a baseline level of administrative support (e.g., 0.5FTE per Working Group) and could consider further funding support based on the WG Operating Plans.

7.6 Performance transparency: Working Groups should review their performance against their Strategic and Operating Plans, and make these visible to the Coordinating Board. We recommend that Working Groups review their performance with the Working Group sub-committee of the CB every 6 months for informal feedback and joint problem-solving. These

meetings should be attended by all Working Group Chairs and Secretaries and the Executive Secretary, and also serve to identify and manage potential synergies and duplications among Working Groups. The Working Group sub-committee should then report on Working Groups' performance to the Board every year.

7.7 Board Representation: Working Group representation on the Coordinating Board will be discussed in the CB section.

Potential implications for Partnership organization and resources:

- Resourcing for 3-year reviews of Working Groups (recommendation 7.2) would ideally be provided by dedicated resource from individual Partners (e.g., equivalent to 3 - 4 months of 2 - 3 FTEs familiar with the Working Groups and the issues involved).

- Resourcing for administrative support (recommendation 7.5): 0.5 FTE per WG, provided by Secretariat, unless already provided by WG – 3 - 4 FTE in total.

Page 67 Recommendation 8: The Partnership should increase performance transparency for Partnership bodies, and also use performance transparency to encourage Partners to deliver on commitments

Context: The Stop TB Partnership is organized on the principles of a loose partnership, where Partnership bodies are accountable to the broader Partnership, and individual Partners remain accountable to their own governing bodies, with no formal accountability to the Partnership. The Partnership makes use of some elements of good performance management, e.g., the GDF has an appropriate set of performance metrics and targets, and has regular performance discussions. It has also shown that it can influence country and other Partner commitment and activities by making performance information transparent and visible. However, while all Partnership bodies have had some impact over the Evaluation period, some – Working Groups in particular – have not been able to clearly and comprehensively demonstrate their impact and efficiency.

Looking ahead, it will be important for the Partnership to increase performance transparency on impact and efficiency, for the following reasons:

- The work of Partnership bodies (e.g., Working Groups, GDF, and GLC) is designed to have impact in the fight against TB. Greater transparency on the objectives, targets, and impact of these efforts will a) at minimum ensure no duplication, b) make it easier for Partners to see how they can help deliver it, and c) enable Partnership bodies to get more input and feedback from the broader Partnership on how to maximize impact.

- In the future landscape in which the Partnership will operate, there will be a greater need to show impact, results, and efficiency, driven in part by evolving donor demands and in part by a increasingly complex landscape with more organizations carving out specific roles for themselves.

We explicitly do not recommend that the Partnership adopt private-sector-style performance management mechanisms. We do however recommend that the Partnership make greater use of performance transparency.

Page 104: Exhibit 33: Proposed selection criteria for establishing working groups (WGs)

Proposed criteria for establishing a WG to address a critical challenge in TB control and research

1. Important strategic issue in TB control and research, critical to delivering the Global Plan to Stop TB, where the Partnership can clearly show how the internal objectives and deliverables of the WG would have a positive impact on relevant TB control or research goals and associated Global Plan metrics.
2. Complex issue whose solution is likely to require a sustained multi-year effort
3. Requires involvement or cooperation of multiple constituencies who do not have existing forum to focus on this issue.
4. Has the commitment of a sufficient number of appropriate Partners who are willing to participate, and ideally fund.
5. Would be likely to attract more funding or other resource to global TB control and research efforts.

Alternative approaches to consider for issues that do not meet WG criteria

• *Interest groups or discussion groups*, e.g., for issues which are not considered 'strategic' but which have significant stakeholder interest and excitement.
• *Task forces*, e.g., for issues that require focused attention by a small group for a limited duration.
• *Partner-led projects,* for issues which a Partner has the most appropriate expertise and experience to lead on behalf of the Partnership.
• *Consultant-led projects*, e.g., for 'one-off' issues, issues which an external consultant has the most appropriate expertise and experience to lead on, and issues which Partners are not able or willing to lead on.