

**QUESTIONNAIRE FOR COMPLETION BY THE
CHAIR AND SECRETARY
OF THE WORKING GROUPS or SUBGROUPS**

RESPONSE OF THE WORKING GROUP ON NEW DRUGS

COMPLETED BY

**JEROME PREMMEREUR - CHAIR AD-INTERIM
ANNA UPTON - SECRETARIAT**

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BACKGROUND INFORMATION

The Partnership's working groups have played a major role in TB control, research and advocacy. Depending on the issue in question the working groups and subgroups have taken different roles and activities. Probably the most important role of the working groups is the completion of their strategic 10-year plans within the Global Plan to Stop TB 2006-15. In general, however, the working groups and sub-groups also serve as forums for engaging TB partners, discussing issues and progress achieved, and coordinating activities.

Measuring the full effectiveness and efficiency of the working groups and subgroup has proven difficult. One of the recommendations of the Independent External Evaluation of the Stop TB Partnership highlighted the need for the Coordinating Board to review all the working groups periodically. The full recommendations are available at the following web address: http://www.stoptb.org/resource_center/documents.asp

In this regard, the Stop TB Partnership Secretariat has developed this questionnaire to initiate the process of a review and to collect information to assess the status of the current working groups and subgroups.

A. OBJECTIVES, ACTIVITIES and FUNDING NEEDS OF THE WORKING GROUP or SUBGROUP

1. Describe briefly the objectives of your working group or subgroup

The members of the Working Group on New Drugs (WGND) are currently conducting a review of their Modus Operandi, including the Group's goals, objectives, governance, structure and activities. The completion of this process is a major objective of the WGND for 2008. A description of the review process is given here, followed by a list of the current WGND objectives (as listed in their Strategic Plan 2006-2015).

The review process was initiated in May 2008 by the Chair Ad-Interim, Secretary and Secretariat and since the publication of the External Evaluation report, takes the recommendations of that report into account. The Group commits to completion of this review and re-launch of the WGND by October 17 2008, when a kick-off meeting will be held in Paris. Outcomes of this review process will include new Terms of Reference describing all aspects of the Group's operational modality in detail and the election of a Chair, selection of a Core Group and formation of Subgroups. Thus far, towards this end, WGND members have:

- Completed a Member's Survey, conducted by the Secretariat and Chair Ad-Interim, giving their views on the historical and current operational modality of the Group and recommendations for the future;
- Engaged in one-to-one discussions with the Chair Ad-Interim on the same subject;
- Participated in the first two teleconferences of a series planned to take place in the coming months to allow interactive discussions by as many members as possible on the future of the Group and to define new goals, scope of activities and elements of the Group's structure;
- Contributed to a draft Terms of Reference document proposing a way forward for the Group;
- Engaged in email discussions with each other, the Chair Ad-Interim and Secretariat to further clarify and flesh-out ideas for the Group's future;
- Contributed to planning the agenda for a face-to-face "kick-off" meeting of the newly re-launched WGND on October 17 2008.

Additional activities to be completed prior to the October 17 kick-off meeting are:

- Publication of the new WGND Terms of Reference, following review by all WGND members;
- Evaluation of the Group's current membership and the commitment level of all members – members will be asked to reaffirm their interest in and commitment to the WGND;
- Election of a Chair, selection of a Core Group and formation of Subgroups

A major aim of the review is to ensure actionable and achievable objectives for which the Group as a whole is accountable. The new Terms of Reference will include the redefined goals and objectives of the WGND and, for each objective, measurable outcomes and thus a definition of success.

A major objective of the WGND for 2008 is the completion of this comprehensive review.

For the purpose of this document, the 6 historical and current objectives of the WGND, as described in their Strategic Plan 2006-2015, are given below:

- (1) Identify validated drug targets for persistent bacilli and latent disease;

- (2) Ascertain mechanisms of action of drugs in the global portfolio to generate complementary or even synergistic combinations effective against *M.tb*;
- (3) Develop a sustainable portfolio of new drug candidates that meet the drug profile criteria;
- (4) Develop animal models that can predict compound activity and side effects;
- (5) Build clinical trial sites and initiate and conduct clinical trials that meet regulatory requirements and highest ethical standards. Develop 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
- (6) Establish harmonized regulatory guidelines, including fast-track approval for TB drug developers.

WGND members have carried out and continue to carry out independent or collaborative self-financed activities towards achieving these 6 goals. These objectives are referred to as Member Objectives 1-6.

In addition, the WGND, as a body, aims to:

- (1) Act as a forum to facilitate global collaborations for the development of new TB drugs, promoting coordination of all relevant stakeholders in TB drug development, including researchers working on new tools, regulators and public health stakeholders involved in TB control;
- (2) Serves as a mechanism through which members individually and collectively support the field of TB drug research by providing input into core publications and public policy recommendations developed by the Partnership;
- (3) Support the 6 specific objectives of the WGND members, as identified in the Strategic Plan 2006-2015.

These are referred to as Group Objectives 1-3.

2. Describe the key activities to be undertaken by the working group or subgroup in 2008 and 2009 (i.e. activities included in your work plan 2008-2009) (Short description has to be given for each activity)

As described above, the WGND is conducting a comprehensive review of its way of operating and also the scope, goals and objectives of the Group. The review activities, which are key, extensive and will be completed during 2008, are described in the answer to A.1.

Following definition of the Group's goals and objectives, a work plan describing relevant activities, deliverables and indicators will be developed. At the current point in the review process, a consensus has been reached on the following:

- The WGND commits to expand upon the activities currently listed in their 2008-2009 work plan. The WGND will re-develop this work plan, adding activities that directly link to their newly defined objectives;
- A WGND Core Group and Subgroups will be formed to enable an effective working dynamic of the Group. Each Subgroup will define the priority issues and actions needed in their subject area, then conduct activities towards achieving their objectives. The Core Group will include a representative of each Subgroup as well as the WGND Chair and will act as a steering committee to ensure timely progress of projects and success of the WGND as a whole, based on specific targets and indicators associated with each Group objective.
- The WGND Subgroups and their activities should encompass the following key elements required for success of the TB drug R&D effort: (1) *M. tuberculosis* biology and identification of new drug targets (2) TB drug discovery and preclinical development of candidates (3) Tools to aid new TB drug R&D (4) Development of basic knowledge that

For the purpose of this document, the activities listed in the current WGND 2008-2009 work plan are described below. The review activities are described in A1 and not included here. Because the WGND commit to expanding this work plan following re-definition of their goals and objectives, this represents the minimum Group activity expected for 2008-2009:

To promote coordination among researchers to support the advancement of the global TB drug pipeline:

- Organize and co-sponsor annual symposia on recent advances in TB drug development. Symposia will be held in conjunction with the IUATLD World Conference on Lung Health, and feature WGND member activities;
- Gather and disseminate data on TB R&D projects and resource needs through the WGND activity mapping project. The project comprises comprehensive mapping of the global TB drug portfolio via a web-based survey. Results will be updated annually, made available to WGND members and e-published on the WGND website.

To promote research resulting in development of biomarkers, surrogate endpoints and animal models:

- Contract and publish a review on the state of the art of biomarkers;
- Organize or co-sponsor a symposium on biomarkers, surrogate endpoints and animal models.

To identify strategies to evaluate new TB drugs for the treatment of M/XDR-TB:

- Sponsor and help to organize meetings of the WGND M/XDR Task Force; sponsor publications produced by this Task Force.

To promote development of harmonized regulatory guidelines for TB drug development, including drugs for treatment of MDR TB:

- Organize and co-sponsor annual Open Fora on key regulatory issues, with regulatory authorities, industry and WGND members present.

To promote dialogue between researchers and affected community representatives:

- Sponsor travel of affected community representatives to WGND annual meetings, symposia on TB drug development and Open Fora; provide support and training to facilitate their participation in meetings and WGND activities; solicit feedback from affected community representatives on WGND documents and projects.

To maintain communication and collaboration among WGND members, between Working Groups and between the WGND and the Retooling Task Force, the Partnership and the public:

- Develop and publish an updated Strategic Plan;
- Provide annual reports detailing progress toward Global Plan milestones and indicators as outlined in the Strategic Plan; produce regular WGND publications including a brochure and advocacy material. Maintain and enhance the WGND website;
- Convene an annual WGND meeting;
- Provide representation at key Partnership meetings and events;
- Convene a core group to oversee implementation of the Strategic Plan;
- Form additional subgroups to put aspects of the Work Plan into action;
- Support the activities of the Partnership Task Forces, as and when requested.

3. Please indicate the annualized targets (2008 and 2009) quantified as far as possible, and demonstrate how each contribute to the Global Plan milestones.

As explained in the answers to A1 and A2, the WGND is currently conducting a thorough review of its Modus Operandi. As part of this, goals and actionable, achievable objectives will be defined. Following this, a work plan will be developed including activities to be undertaken towards achieving these objectives. For each activity, very specific deliverables and indicators will be defined, including annualized targets.

For the purpose of this document, the activities listed in the WGND's current 2008-2009 work plan, which will be expanded upon during the review process, are given in the two tables below, along with their associated deliverables and performance indicators, expected outcomes and links to the current WGND Strategic Plan objectives (listed in A1).

In addition, as mentioned in A1, specific targets for 2008, are:

- Completion of the review process;
- Publication of new Terms of Reference;
- Election of a Chair;
- Formation of a Core Group;
- Formation of Subgroups.

2008 Activity	Deliverables	Performance Indicators	Expected Results & link to Global Plan
IUATLD Symposium	<ul style="list-style-type: none"> ▪ Symposium conducted 	<ul style="list-style-type: none"> ▪ Number of attendees 	<ul style="list-style-type: none"> ▪ Wide exposure to the critical issues for new drugs ▪ Group objectives 1 and 2; Member objectives 1-6
Activity Mapping Project	<ul style="list-style-type: none"> ▪ Project updated and extended 	<ul style="list-style-type: none"> ▪ Number of R&D projects represented 	<ul style="list-style-type: none"> ▪ Improved coordination of researchers involved in TB drug R&D ▪ Group objective 1; Member objective 3
Biomarkers etc Review	<ul style="list-style-type: none"> ▪ Review published in peer-reviewed journal 	<ul style="list-style-type: none"> ▪ Number of citations 	<ul style="list-style-type: none"> ▪ Coordinated global research on biomarkers ▪ Member objective 5
M/XDR Task Force	<ul style="list-style-type: none"> ▪ Teleconferences and meeting held 	<ul style="list-style-type: none"> ▪ Number of teleconferences; number of attendees 	<ul style="list-style-type: none"> ▪ Agenda of the M/XDR Task Force advanced ▪ Group objectives 1 and 2
Open Forum on Regulatory Issues	<ul style="list-style-type: none"> ▪ Event conducted 	<ul style="list-style-type: none"> ▪ Number of attendees 	<ul style="list-style-type: none"> ▪ Dialogue continued on harmonization of regulatory standards for TB drugs ▪ Member objective 6; Group objective 1
Dialogue with Affected Community Reps	<ul style="list-style-type: none"> ▪ Participation of representatives at meetings and in activities 	<ul style="list-style-type: none"> ▪ Number of meetings attended and activities participated in 	<ul style="list-style-type: none"> ▪ Perspectives of communities represented in meetings and activities ▪ Group objective 1
Strategic Plan Update	<ul style="list-style-type: none"> ▪ Strategic plan updated, published and disseminated 	<ul style="list-style-type: none"> ▪ Number of copies distributed 	<ul style="list-style-type: none"> ▪ Up to date description of Working Group progress and future plans available to wide audience ▪ Member objectives 1-6; Group objectives 1-3
Annual Meeting	<ul style="list-style-type: none"> ▪ Annual meeting held 	<ul style="list-style-type: none"> ▪ Number of attendees; key priorities for 2009 defined 	<ul style="list-style-type: none"> ▪ Work Plan for 2009 developed; 2008 activities reviewed; structure and operations reviewed. ▪ Group objective 1
Partnership Meetings	<ul style="list-style-type: none"> ▪ Attendance at key Partnership meetings 	<ul style="list-style-type: none"> ▪ Number of meetings at which WG represented 	<ul style="list-style-type: none"> ▪ Working Group interests represented at key Partnership meetings ▪ Group objective 2

2009 Activity	Deliverables	Performance Indicators	Expected Results & link to Global Plan
IUATLD Symposium	<ul style="list-style-type: none"> ▪ Symposium conducted 	<ul style="list-style-type: none"> ▪ Number of attendees 	<ul style="list-style-type: none"> ▪ Wide exposure to the critical issues for new drugs ▪ Group objectives 1 and 2; Member objectives 1-6
Activity Mapping Project	<ul style="list-style-type: none"> ▪ Project updated and extended 	<ul style="list-style-type: none"> ▪ Number of R&D projects represented 	<ul style="list-style-type: none"> ▪ Improved coordination of researchers involved in TB drug R&D ▪ Group objective 1; Member objective 3
Biomarkers etc Symposium	<ul style="list-style-type: none"> ▪ Symposium conducted 	<ul style="list-style-type: none"> ▪ Number of attendees 	<ul style="list-style-type: none"> ▪ Issues for research on biomarkers etc explored; global coordination and collaborations facilitated ▪ Member objective 5
M/XDR Task Force	<ul style="list-style-type: none"> ▪ Teleconferences and meeting held 	<ul style="list-style-type: none"> ▪ Number of teleconferences; number of attendees 	<ul style="list-style-type: none"> ▪ Agenda of the M/XDR Task Force advanced ▪ Group objectives 1 and 2
Open Forum on Regulatory Issues	<ul style="list-style-type: none"> ▪ Event conducted 	<ul style="list-style-type: none"> ▪ Number of attendees 	<ul style="list-style-type: none"> ▪ Dialogue continued on harmonization of regulatory standards for TB drugs ▪ Member objective 6; Group objective 1
Dialogue with Affected Community Reps	<ul style="list-style-type: none"> ▪ Participation of representatives at meetings and in activities 	<ul style="list-style-type: none"> ▪ Number of meetings attended and activities participated in 	<ul style="list-style-type: none"> ▪ Perspectives of communities represented in meetings and activities ▪ Group objective 1
Brochure and Website	<ul style="list-style-type: none"> ▪ Brochure produced, published and disseminated; website enhanced 	<ul style="list-style-type: none"> ▪ Number of copies of brochure distributed; number of hits on website 	<ul style="list-style-type: none"> ▪ Working Group promoted; new members attracted; current members better engaged ▪ Group objectives 1 and 2
Annual Meeting	<ul style="list-style-type: none"> ▪ Annual meeting held 	<ul style="list-style-type: none"> ▪ Number of attendees; key priorities for 2009 defined 	<ul style="list-style-type: none"> ▪ Work Plan for 2010 developed; 2009 activities reviewed; structure and operations reviewed. ▪ Group objective 1
Partnership Meetings	<ul style="list-style-type: none"> ▪ Attendance at key Partnership meetings 	<ul style="list-style-type: none"> ▪ Number of meetings at which WG represented 	<ul style="list-style-type: none"> ▪ Working Group interests represented at key Partnership meetings ▪ Group objective 2

4. Please describe briefly the structure of the working group or subgroup and its operational modality (core group or none, frequency of meetings, means of communications etc

As described in A1, A2 and A3, the governance, structure and operational modality of the WGND are currently under review by members. The review process, initiated by the Chair Ad-Interim, Secretary and Secretariat, is described in detail in A1. As noted in A4, the WGND commits to completing this review in 2008 and, specifically, publishing their new Terms of Reference, electing a new Chair, forming a Core Group and forming Subgroups before a kick-off meeting planned to re-launch the Group on October 17 2008.

The following serves as historical information, with the expected changes, based on the consensus of members at the current point of the review process, given below.

Historical Information:

From its inception until April 2008, the WGND was Chaired by the CEO of a partner organization, TB Alliance. In addition, TB Alliance was designated “lead agency”. TB Alliance has always provided and continues to provide funding for WGND support activities (i.e. activities aimed at achieving Group objectives 1-3 listed above). TB Alliance also supplies a staff member as WGND Secretariat. TB Alliance provided 100% WGND funding from 2002-2004; since 2005, financing has been shared between TB Alliance and the Stop TB Partnership with matching funds.

The WGND formed a Core Group in 2003. This was disbanded in 2004 in favor of the formation of limited term Task Forces and writing and other committees which have carried out specific activities and tasks from 2004 until the present time. The WGND has always convened an Annual Meeting at the time of the Union World Conference. The Core Group, Task Forces and writing committees have communicated via teleconference on an as-needed basis throughout the year. One exception to this is the M/XDR Task Force which met face-to-face in 2007.

The WGND Secretariat maintains a member’s roster and listserv; the listserv is used as the main means of communication to and among members between Annual meetings. Members contact the Secretariat who facilitates communication with other members or the entire WGND body. In addition, the Secretariat sends periodic updates including news items, funding and other opportunities and articles of interest to the WGND membership. The WGND maintains a website to serve as an additional means of communication. This currently includes news of upcoming meetings, presentations and agendas for previous meetings, WGND documents and the WGND’s global R&D activity charts as well as contact and background information.

Expected Changes, to Occur Following the WGND Member Review Process:

- A Chair will be elected by or on October 17th 2008; candidates will self-nominate. The TB Alliance CEO is included as a candidate but will no longer be *de facto* Chair.
- TB Alliance will no longer be designated “Lead Agency”.
- Subgroups will be formed to address specific areas of concern for TB drug R&D, as explained in A2;
- A Core Group will be established by or on October 17th 2008 (see A2);
- The WGND will meet face-to-face 1 or 2 times per year and by teleconference 2-4 times per year. The Core Group will communicate by teleconference and meet face-to face on a basis to be determined;
- An enhanced website will be developed to serve as a superior means of communication and engagement.

Completion of the review process is required to elucidate all details of the WGND’s revised structure and operational modality (and Terms of Reference).

B. PARTNERS AND STOP TB PARTNERSHIP'S CONTRIBUTION

To evaluate the level of effort the working group or subgroup is expecting to put in (staff and funding).

1. Indicate names of key partners/people responsible and working in developing and delivering each activity described in A.2 in 2008 and 2009.

As explained above, the WGND work plan will be re-developed and expanded following re-definition of WGND goals and objectives through the member review process. For the purpose of this document, the members responsible for delivering the activities listed in the current 2008-2009 work plan are:

IUATLD Symposia	TB Alliance & Secretariat
Activity Mapping Project	Barbara Laughon & Secretariat with input from all WGND members
Review on Biomarkers etc	Gerhard Walzl
Symposium on Biomarkers etc	Secretariat & partners to be determined
M/XDR-TB Task Force Activities	Andrew Vernon, members of the Task Force & Secretariat
Open Fora Meetings	TB Alliance, TAG, BMGF & Secretariat
Dialogue with Community Reps	Wim Vandeveld, Tamari Trapaidze & Secretariat
Strategic Plan Update	Core group (to be formed) & Secretariat
Annual Meeting	Core group (to be formed) & Secretariat
Brochure and Website	Core group (to be formed) & Secretariat
Support Partnership Task Forces	William Wells & Secretariat
Partnership Meetings	Chair or Secretary
Additional Activities	Subgroup Representatives (to be determined)
The review process is a major activity of the WGND for 2008:	
Review process	Chair Ad-Interim, Secretary, Secretariat

2. For the concerned activity, indicate the expected contribution(s) (funding, contractual services, facilities, training, travel, consulting, research, etc) from the partner(s) and the Stop TB Partnership Secretariat.

The following relates the expected funding contributions from WGND members and from the Partnership Secretariat. Other types of contribution expected will be discussed through the WGND's internal review and are as yet undefined.

Following discussions with the Stop TB Partnership Executive Secretary, it is understood that the mechanism of funding the WGND will continue as at present, i.e. the organization holding the WGND Chair will provide half of all WGND funding, with matching funds provided by the Stop TB Partnership via grants managed by the WGND Secretariat.

Presently, because the TB Alliance CEO is acting as Chair Ad-Interim, the TB Alliance provides \$100,000 per year to finance the WGND. An additional \$100,000 is supplied by the Stop TB Partnership. As explained above, a WGND Chair will be elected by October 17th 2008. The TB Alliance CEO, if elected, pledges to continue to contribute to financing of the WGND. Additional candidates for Chair, once identified, will be asked to make similar pledges.

For the funding breakdown reflected in the 2008-2009 work plan, which is currently under review, please see pages 12 and 13.

2008 Activity	Funding Request from Partnership	Description of Requested Costs	TB Alliance Contribution	Description of TB Alliance Contribution Costs	Total Cost
IUATLD Symposium	\$6,000	<i>Sponsorship of scientific symposium on new drugs</i>	\$20,000	<i>Sponsorship of scientific symposium on new drugs</i>	\$26,000
Activity Mapping Project	\$1,500	<i>Web tool design</i>	\$0		\$1,500
M/XDR Taskforce	\$10,000	<i>Meeting and teleconferences</i>	\$0		\$10,000
Open Forum	\$0		\$10,000	<i>Staff support, web design</i>	\$10,000
Dialogue with Community Reps	\$10,000	<i>Travel support for community representatives</i>	\$0		\$10,000
Strategic Plan Update	\$8,000	<i>Design and printing</i>	\$2,000	<i>Writing committee teleconferences</i>	\$10,000
Annual Meeting	\$12,000	<i>Venue, A/V, speaker travel, catering, supplies</i>	\$8,000	<i>Staff travel & accommodation</i>	\$20,000
Partnership Meetings	\$6,000	<i>Travel to one Coordinating Board meeting</i>	\$6,000	<i>Travel to one Coordinating Board meeting</i>	\$12,000
Working Group Secretariat (1 FTE)	\$28,000	<i>Secretariat</i>	\$44,000	<i>Secretariat</i>	\$72,000
Additional activities to be determined	\$19,500	<i>To be determined</i>	\$10,000	<i>To be determined</i>	\$29,500
TOTALS	\$100,000		\$100,000		\$200,000

2009 Activity	Funding Request from Partnership	Description of Requested Costs	Partner Contribution	Description of Partner Contribution Costs	Total Cost
IUATLD Symposium	\$6,000	<i>Sponsorship of scientific symposium on new drugs</i>	\$20,000	<i>Sponsorship of scientific symposium on new drugs</i>	\$26,000
Activity Mapping Project	\$1,500	<i>Web tool design</i>	\$0		\$1,500
Biomarkers Symposium	\$10,000	<i>Venue, A/V, speaker travel, catering, supplies</i>	\$0		\$10,000
M/XDR Task Force	\$10,000	<i>Meeting and teleconferences</i>	\$0		\$10,000
Open Forum	\$0		\$10,000	<i>Staff support, web design</i>	\$10,000
Dialogue with community reps	\$10,000	<i>Travel support for community representatives</i>	\$0		\$10,000
Brochure and Website	\$8,000	<i>Design and printing</i>	\$2,000	<i>Web design</i>	\$10,000
Annual Meeting	\$12,000	<i>Venue, A/V, speaker travel, catering, supplies</i>	\$8,000	<i>Staff travel & accommodation</i>	\$20,000
Partnership Meetings	\$6,000	<i>Travel to one Coordinating Board meeting</i>	\$6,000	<i>Travel to one Coordinating Board meeting</i>	\$12,000
Working Group Secretariat	\$28,000	<i>Secretariat</i>	\$44,000	<i>Secretariat</i>	\$72,000
Additional activities to be determined	\$9,500	<i>To be determined</i>	\$10,000	<i>To be determined</i>	\$19,500
TOTALS	\$100,000		\$100,000		\$200,000

3. Please indicate how the working group or subgroup engages with its constituencies in a regular manner.

As explained above, the WGND engages and plans to engage with its constituencies by:

- Convening at least one Annual face-to-face meeting;
- Holding teleconferences 2-4 times per year to track progress;
- Forming Subgroups representing constituencies of the WGND;
- Forming a Core Group to act as a steering committee, including representatives of each Subgroup and the WGND Chair. The Core Group will meet face-to-face at least twice per year;
- Engaging affected communities via proactive dialogue with WGND affected community representatives
- Convening Symposia/meetings to discuss and review Advances in TB drug development; Biomarkers, Surrogate markers and Animal models for TB; Key Regulatory Issues.
- Maintaining a roster of members and listserv; the listserv will be used as the main means of communication to and among members between Annual meetings and calls. Members contact the Secretariat who facilitates communication with other members or the entire WGND body; in addition, the Secretariat sends periodic updates including news items, funding and other opportunities and articles of interest to the WGND membership.
- Maintaining and enhancing the WGND website. This currently includes news of upcoming meetings, presentations and agendas for previous meetings, WG documents and the WGs global R&D activity charts as well as contact and background information. It is proposed that including the membership roster, a database of information on compounds, slide decks on the global TB drugs pipeline, space for member comments and other enhancements will result in better engagement of the WGND.

C. WORKING GROUP vs. SUBGROUP

1. Indicate the added value for your group to be a working group or subgroup?

The following uses the full criteria given in Exhibit 33 of the External Evaluation Report, to explain the added value for the WGND to be a Working Group of the Stop TB Partnership:

Criterion 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 Working Group would have a positive impact on relevant TB control or research goals and associated Global Plan metrics

Current short-course (6-month) combination therapy for 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.

In recognition of the above, an objective of the Global Plan to Stop TB 2006-2015 is to "Accelerate the elimination of TB by promoting research and development for new TB diagnostic tests, drugs and vaccines". The importance of the WGND to achievement of this objective is alluded to on page 17 of the External Evaluation Report: "The Partnership has increased awareness of the need for R&D by describing the need in the Global Plan and by establishing dedicated Working Groups for drugs, diagnostics, and vaccines". Further, as noted on page 43, the WGND has already and can continue to help to deliver the Global Plan by "*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 (1) Provided a forum for sharing information. Working group members report that in some cases this has resulted in closer collaboration (2) Created a document that includes all current activities in drug development, allowing researchers to have visibility on the total landscape". The external evaluators also recommended that the Partnership should focus on "performing roles where it can add significant value to global TB control and research, over and above the contributions of existing organizations involved in TB control and research "setting the global vision for tuberculosis control and research, building consensus, and building and maintaining an effective partnership of organizations to deliver the vision". Through development of Strategic Plans, the WGND has been and will continue to be critical in setting the global vision for TB research and promoting research and development for new TB drugs.

The internal objectives and deliverables of the WGND, described in detail in the WGND Strategic Plan 2006-2015, and above, were and will continue to be formulated with relevant TB research goals in mind in order to make a positive impact on these goals and associated Global Plan metrics. As explained above, WGND members are currently reviewing their objectives and plan to take the External Evaluation Recommendations into account when redefining these for future years.

Criterion 2: Complex issue whose solution is likely to require a sustained multi-year effort

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. Members of the WGND are carrying out R & D activities in all stages of the pipeline — from early discovery projects through to clinical testing. 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 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. 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. The WGND serves as a venue for interaction among partners to increase efficiencies and decrease risk for the process as a whole.

Criterion 3: Requires involvement or cooperation of multiple constituencies who do not have existing forum to focus on this issue

In 2007 the WGND conducted its second annual web-based survey to map global TB drug R & D activities. WGND members from dozens of private and public institutions around the world reported on 5 novel TB drug candidates in clinical trials as well as 12 trials of new approaches to treatment, 8 preclinical candidates, over 30 discovery projects and 9 translational research projects. The number of activities in each category has increased compared to those reported in 2006, representing progress towards member objectives 1-3 of the Working Group's Strategic Plan 2006-2015. This achievement is the result of 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. This portfolio would not be possible without support and funding from governments, foundations, and industry.

The WGND recognizes that affordability, adoption and access to new drugs and the implementation of new 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 members 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 therefore aims to act as a forum to facilitate global collaborations for the development of new TB drugs, promoting coordination of all relevant stakeholders in TB drug development, including researchers working on new tools, regulators and public health stakeholders involved in TB control. To this end, the WGND supports meetings and other information-sharing activities to inform partners about global TB drug development activities and progress.

Success in this area, during the evaluation period, is noted on page 17 of the External Evaluation Report: "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.

As noted above, the WGND is re-evaluating its structure and operational modality, including its current membership. It is proposed that under-represented constituencies be identified and additional members recruited in order to optimise the use of this Group as such a forum.

Criterion 4: Has the commitment of a sufficient number of appropriate Partners who are willing to participate, and ideally fund

Since its inception, the WGND has attracted a large and broad membership of those involved in or interested in TB drug development. Current membership is 115 high-level individuals from 72 organizations; membership is presently open and inclusive. Members represent private and public sector institutions from diverse geographical locations. Thus, the WGND currently comprises a large network of partners including those involved in R & D, regulation, policy, advocacy and implementation.

Annual Meetings typically attract more than 50 members, demonstrating willingness of members to participate. As noted in the McKinsey evaluation report, page 45: "The meetings attended in Cape Town 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." In addition, it should be noted that the on-going review of the WGND's structure and operational modality has attracted input from representatives of 30 out of 72 partner institutions of the WGND, demonstrating a strong commitment of partners to the Group's future success. As explained above, as part of this review process, members plan to enhance the Group by attracting additional appropriate partners.

Since its inception, the Stop TB Partnership has required the Chair organization to contribute to the WGND operating budget. Hence, by definition, the WGND includes partners willing to fund its activities. As explained above, the TB Alliance CEO has held the Chair or Chair Ad-Interim until the present time and has provided financing and human resources throughout that tenure. Currently, financing is shared between TB Alliance and the Stop TB Partnership Trust Fund, with matching funds. The TB Alliance and the Partnership Trust Fund have committed, between them, a total of \$200,000 to fund WGND activities in 2008. As explained above, the WGND governance, structure and way of operating are under review. Members plan to enhance the Group by continuing this arrangement and exploring additional funding opportunities.

Criterion 5: Would be likely to attract more funding or other resource to global TB control and research efforts

Drug R&D is an expensive enterprise. The momentum achieved in the past several years has been possible because of the financial commitment made by public and private entities. To deliver on the objectives of the WGND, substantial additional resources and political commitment will be needed in future years. As noted on page 16 of the External Evaluation Report "The Partnership's working groups have played a major advocacy role, by signaling the importance of different areas of tuberculosis control and research, and by serving as a forum for building consensus and commitment." and on page 17 "The Partnership has also contributed to increasing funds for new tool R&D: the Bill & Melinda Gates Foundation reports that the process of developing the first Global Plan helped it better understand where it could contribute, and thereby helped secure the Foundation's financial support". Thus it seems likely that the WGND has already and will continue to attract funding and resources to global TB research efforts. It is of particular note that several individual members of the WGND represent major funders of TB drug R & D; thus, the WGND affords interaction with these funders, opportunities for direct advocacy and, hopefully, their continued commitment.

2. Please specify why you need to continue as a working group or becoming a working group (for subgroups)? Please specify an estimated duration of time for the working group?

Please see the response to C. 1 (in particular, Criterion 2).