

DRAFT

The form and function of the Stop TB Working Group on New Drugs, Its Core Group, Subgroups and Secretariat

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.

DRAFT

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 six 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.

DRAFT

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

DRAFT

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 subgroups¹, 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);

DRAFT

- 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, Tools subgroup, Critical Knowledge subgroup and Clinical Trials Capacity subgroup (*the last of which may combine the proposals made in subsections 3.2.4.4, 3.2.4.5 and 3.2.4.6 below*).

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.

3.2.4.1 Biology/Targets subgroup

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

DRAFT

- 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

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.

DRAFT

3.2.4.3 Tools Subgroup (Preliminary draft kindly provided by Gerhard Walzl; additions kindly provided by Barbara Laughon)

Objectives:

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 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:
 - 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.
 - research into biomarkers for TB treatment outcome and drug efficacy including research into imaging technologies to improve understanding of TB pathophysiology and treatment response;
 - 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 and analytical methodologies 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
 - 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 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 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 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

DRAFT

- Annual subgroup meetings during appropriate conferences, including IUATLD meetings to align subgroup strategies to achieve its objectives
- **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 on Critical Knowledge, 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;
- 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, and managerial expertise. Its membership rests with individuals with specific areas of expertise relevant to tools for drug development.

3.2.4.4 New Drugs in Clinical Trials Subgroup (Preliminary draft kindly provided by Carol Nacy)

Note that this subgroup does not currently exist and objectives and scope of work are primarily being covered by the Clinical Trials Capacity Subgroup.

Composition:

Group comprised of one representative from each of the organizations with a new TB drug in clinical development, Phase 1-3.

Org Structure:

DRAFT

Chair and secretary rotated within existing members every 2 years and elected by membership.

- Chair is a member of Core WG and (a) chairs meetings of the subgroup, (b) provides updates on clinical trial progress of each drug to Core WG as requested, and (c) distributes any Action Items to the membership.
- Secretary sets subcommittee meeting dates with Chair and (a) determines venue (teleconference or face-to-face) based on topics for discussion as proposed by Chair or membership, (b) assembles the meeting Agenda, (c) provides any materials to membership that relate to a specific topic under discussion, and (d) keeps the minutes of the meetings.

Purpose:

- Update WG and each other on the progress of each drug through its clinical development
- Identify issues and obstacles in common for the drug clinical development process that will need resolution by the subcommittee or by interaction with other groups within or outside the WGND.
 - Current concerns overlap with Subcommittee on Clinical Trial Sites
 - Regulatory bodies in high burden TB countries that (a) elongate the approval process for initiating clinical trials, sometimes for >12 months, and (b) could impede approval of effective drugs in a timely manner, once registration documents are filed.
 - Uncertain or unclear regulatory pathways for approval of new TB drugs in high burden TB countries with rudimentary governmental regulatory bodies.
 - Unclear mechanism for introduction of an approved new TB drug(s) into standard of care
 - High-level acceptance (WHO, CDC, other)
 - Country-level TB Control groups
- Provide a forum for identification of potential interactions between organizations.

3.2.4.5 Clinical Trial Sites for New TB Drugs Subgroup (Preliminary draft kindly provided by Carol Nacy)

Note that this subgroup does not currently exist and objectives and scope of work are primarily being covered by the Clinical Trials Capacity Subgroup.

Composition:

The PI of each existing or planned (within 1 year) clinical trial of a new TB drug; a representative from each clinical trial site where an ongoing or planned (within 1 year) clinical trial is performed.

Org Structure:

Chair and Secretary rotated within existing members every 2 years and elected by membership.

- Chair and Secretary will both be selected from among the clinical trial site representatives.
- Chair is a member of Core WG and (a) chairs meetings of the subgroup, (b) provides updates on clinical trial sites to Core WG as requested, and (c) distributes any Action Items to the membership.
- Secretary sets subcommittee meeting dates with Chair and (a) determines venue (teleconference or face-to-face) based on topics for discussion as proposed by Chair or membership, (b) assembles the meeting Agenda, (c) provides any materials to membership that relate to a specific topic under discussion, and (d) keeps the minutes of the meetings.

Purpose:

DRAFT

- Update the WG and new TB drug developers on issues regarding regulatory climate, timelines, laboratory services, and other topics of concern to the sites, the PI of the trial(s), and the new TB drug developers.
- Identify impediments to the timely and efficient conduct of clinical trials of new TB drugs that will need resolution by the WG or groups outside the WG.
 - One concern overlaps with Subcommittee on New Drugs in Clinical Trials
 - Unresponsive regulatory bodies in high burden TB countries that elongate the approval process for initiating clinical trials, sometimes for >12 months.
 - One concern overlaps with WGMDR-TB and WGND
 - Laboratory capacity, specifically to identify DR-, MDR- and XDR-TB to stratify patients into appropriate subgroups within a clinical trial or to exclude patients from inappropriate trials
 - Clinical trial training for responsible site personnel below the level of PI
- Provide a forum for identification of potential collaborations between sites.

3.2.4.6 Clinical Trials Capacity Subgroup

Clinical Trials Capacity Subgroup

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 trial sites in synergy with FHI, USAID, TBCAP, EDCTP, World Bank, RESIST-TB.

DRAFT

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.

3.2.4.7 Critical Knowledge subgroup (Preliminary draft kindly provided by Barbara Laughon)

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. Its objectives are:

- To identify gaps in current knowledge to support new drug development;
- To promote and support:
 - Compiling knowledge required at the interface of preclinical and clinical development, in particular the data required by multiple regulatory authorities;
 - 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;
 - Exploring preclinical predictors of toxicity, especially hepatotoxicity;
 - Development of a critical path for candidate TB drugs to regulatory approvals;
 - Studies of drug/drug interactions, between TB drugs and drug candidates and, for example, between TB drugs/drug candidates and ARVs

Tasks:

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

- To review guidances and requirements issued by regulatory authorities for new TB drug development through workshops and discussion forums;
- 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.

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

4 Procedural questions

DRAFT

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 WGND² 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 WGND³.
- 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;

² The Secretariat shall check once a year the active membership of the WGND, using electronic mail.

³ For membership criteria please refer to the paragraph 3.2 above.

DRAFT

- 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 4th 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;

DRAFT

- 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.