

TERMS OF REFERENCE

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

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

TB elimination efforts have 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-), extensively drug resistant (XDR-) and the almost untreatable extremely drug resistant (XXDR-) TB. Additional factors contributing to poor outcomes include non-adherence, inconsistent treatment and inferior drug quality. Treatment of MDR-TB cases takes 9-24 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. New innovative regimens will be required if the Partnership is to achieve the targets set out in the Global Plan to End TB 2016-2020.

Since its inception in 2001, 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 to build the current portfolio. With its diverse membership, including representatives from scientific and clinical constituencies, public and private sector institutions, academic laboratories, regulators, donors and representatives of affected communities, the WGND remains a unique mechanism for ensuring a consistent pipeline of drug candidates and regimens.

Further, the WGND recognizes that affordability, adoption and access to new drugs and regimens are critical factors in ensuring impact of all new therapies. It is imperative that those involved in R&D work closely with members involved in regional and international health agencies and in-country work to understand the needs of patients and implementers, thereby ensuring rapid, successful introduction and adoption of the new regimens in the field. The WGND is positioned 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 mission and objectives of the WGND are to accelerate the discovery and development of new drugs for the treatment of tuberculosis by bringing together the stakeholders in TB drug development, including the patients themselves. Activities of the WGND include advocating for and ensuring awareness of the following goals:

- Identifying 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 *Mtb*;
- 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 to be key to successful TB drug R&D;
- Input into core publications and public policy recommendations developed by normative agencies;
- 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 part of the Stop TB Partnership's governing structure and reports 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 two prime qualifications:

- (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;

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 all WGND meetings including CG meetings. 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 Co-chairs 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 initiatives;
- 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, 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 for effective implementation of the Global Plan to Stop TB 2016-2020 and any subsequent strategic documents issued by the Partnership related to new tools for TB. 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, appointed members based on a vote of current CG members, and at least two community representatives. The CG should not exceed 20 members total. Although the main drivers of CG member selection will be competencies, motivation, and availability to do the required work, efforts should be made to ensure regional equity and institutional representation. Members will serve for three years with the possibility of one renewal.

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 terms of reference (TOR) listed below (see code of conduct referred to in paragraph 4.5).

The TOR of the CG include:

- Assisting with implementation of WGND initiatives;
- Assisting the Co-Chairs in determining and addressing strategic and operational issues;
- Initiating, overseeing and managing the activities of the WGND;
- Serving as an independent, technical, expert advisory group where needed by the WGND and/or the Partnership
- Closely collaborating with and consulting the other Stop TB WGs on crosscutting issues.

3.2.3 Secretariat

The Secretariat is staffed by at least 1 FTE (may be filled by partial effort from two employees), 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 Secretariat is answerable to the Co-Chairs and the CG. 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 include:

- Working with CG to implement the strategic direction of the WGND and develop action items;
- Proposing new actions to the CG;
- 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 the Partnership's and other relevant initiatives and documents;
- 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);
- Producing and distributing meeting reports;
- Updating membership information;
- Promoting year-round engagement of members (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 may be established as required with specific objectives to address particular scientific issues. Membership, achievements, and TOR/rationale for the subgroups will be reviewed at regular WGND meetings. Subgroups will be dissolved once objectives have been accomplished or by consensus of the CG and the members of the subgroup. Formal outputs of subgroups should be submitted to WGND secretariat. This may include budgets, reports, or any official communication intended for the Partnership.

Task forces (time limited groups focused on carrying out specific deliverables) may be established by the WGND when required. Task forces will be established for initial period (no longer than 2 years) renewable if justified. Task forces will automatically dissolve once task is completed.

4 Procedural Questions

The way of working of the WGND aims for full transparency and maximal input from members.

4.1 Meetings of the WGND

- The WGND will meet at least once each year;
- The annual meeting will be a forum structured to develop actions that support the rationale and objective of the WGND;
- The annual meeting can serve to:
 - Review progress in implementing recommendations and progress towards the Partnerships targets and indicators;
 - Discuss and endorse decisions proposed by the CG;
 - 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 WGND¹ 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 using electronic voting, managed by the Secretariat.

4.3 Election of Elected Co-Chair

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

The following procedure will be observed for the election process:

- The nomination process shall be transparent and open to all members of the WGND².
- The nomination process shall be administered by the Secretariat and be opened to all members of the WGND
- After discussion with the CG, the Secretariat will determine the period for nominations.
- The Secretariat will send out a notification to all WGND members at least 2 weeks prior to soliciting nominations for the post of Co-Chair. The elected Co-Chair must be external to TB Alliance. The members of the WGND will provide nominations within 10 to 15 business days.

¹ The Secretariat shall review once a year the active membership of the WGND.

² For membership criteria please refer to the paragraph 3.2 above.

- Each member of the WGND will have the right to nominate one person for Co-Chair and may self-nominate;
- After the nomination period has ended, the Secretariat will obtain confirmation from the nominees that the nomination is accepted and that the nominee is willing to assume the duties of Co-chair if elected by the CG.
- The candidates who accept the nomination will submit a short biography and their statements of intent to the Secretariat within 10 to 15 business days of accepting the nomination.
- The Secretariat will distribute a list of the names of the candidates together with their biography and statements of intent to the CG. If feasible, candidates may be invited to present themselves to CG via teleconference in advance of the election date.
- The CG will set a date for the election period and will have 5 business days to cast their vote by secret ballot using the system identified by the Secretariat.
- If one candidate does not receive the majority of the votes, the Secretariat will create a shortlist of two candidates based on the candidates with the highest number of votes and a run-off election will be held. The Secretariat will repeat the process followed for the first election.
- 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 submitted through the WGND website (www.newtbdrugs.org). A short statement of motivation is requested of all applicants. Applications will be reviewed by the WGND Secretariat and approved if in compliance with the provisions under paragraph 3.2. A welcome email will be sent to all new members.

4.5 The modus operandi of the CG

The modus operandi of the CG is as follows:

- The CG will have at least one teleconference each quarter, 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 cannot be reached, the majority vote will apply;
- Decisions and summary of proceedings of each meeting will be documented and kept by the Secretariat
- The CG may address the following in its meetings:
 - Progress in implementing WGND workplan and initiatives;
 - 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;
- Concept notes, agendas, or related documents for WGND organized meetings.

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 WGND 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 without notice or reason, 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, reviewing and providing feedback on documents, 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

The WGND operating budget comprises financing from the Stop TB Partnership, funding from the host institution of the Secretariat and contributions (kind and in-kind) from the entities of the WGND members. As the institution of the appointed Co-Chair, TB Alliance commits to financing the majority of the non-Partnership component of the WGND 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 or other host institution, acting on behalf of the WGND.