



Terms of Reference Global TB Community Advisory Board (TB CAB)

Background

In 2011, Treatment Action Group (TAG), along with other stakeholders in tuberculosis (TB) product development and access, identified the need for the TB research community to benefit from strong, research-literate community activists. As a result the Global TB Community Advisory Board (TB CAB) was created. The TB CAB acts in an advisory capacity to product developers and institutions conducting clinical trials of new TB drugs, regimens, diagnostics and vaccines, and provides input on study design, early access, regulatory approval, post marketing, and implementation strategies.

Mission of the TB CAB

The Global TB Community Advisory Board (TB CAB) is dedicated to increasing community involvement in tuberculosis (TB) research and to mobilizing political will regarding key TB product development and access issues.

Functions of the TB CAB

The broad goals of the TB CAB are to:

- Promote norms and standards that advance needs-driven research;
- Interact strategically with developers of TB drugs, diagnostics, and vaccines at key moments in the development process;
- Influence research and roll-out decisions of developers from a community perspective;
- Learn about the priorities and plans of the TB research world, then activate and share information with TB CAB member networks to build and expand our platform for influencing key stakeholders in the TB research and research funding communities;
- Bring special attention to neglected populations in the context of inclusion in research – e.g. children, people with TB/HIV co-infection, people with diabetes, women, pregnant women, people who use drugs, etc.;
- Demand high quality research and evidentiary standards and efficient regulatory processes;
- Advocate strategically to accelerate access to TB technologies and interventions and overcome barriers (e.g., normative guidance, regulatory, pricing, intellectual property, etc.); and
- Engage with donors and policymakers to drive development and access to new TB tools.

These terms of reference are for three years, from 2020– 2023, and will be

periodically reviewed and updated based on need. Any updates to the terms of reference will be proposed/ reviewed by TB CAB leadership (encompassing TB CAB co-chairs, TB CAB co-technical leads, and the TAG coordinator). The full TB CAB will then review the proposed changes. If the majority (defined as half plus one) agrees to the proposed changes, the new terms of reference will go into immediate effect. If at the end of three years a new terms of reference is not agreed upon, the existing terms of reference will remain in effect.

Priority TB Research & Access Advocacy Issues 2020-2023

- ***Informing research agendas and clinical trials protocols*** to ensure that TB prevention, diagnostics, and treatment research is needs driven, rigorous, efficient, equitable, and inclusive of community.
- ***Advancing vaccine research*** by participating in global discussions, calling for the advancement of promising vaccine candidates, supporting efforts to promote future accessibility, and improving community engagement in TB vaccine science and research.
- ***Improving community engagement in TB diagnostics development*** by engaging with TB diagnostics product sponsors earlier in the development process to ensure appropriate consideration of target population preferences and needs.
- ***Promoting pre-approval access programs*** to enable early access to and compassionate use of new TB drugs and regimens as soon as sufficient safety and efficacy data are available.
- ***Advocating for regulatory authorities to rapidly review new product applications and uphold rigorous evidentiary standards*** for new TB drugs, regimens, and other products.
- ***Supporting evidence-based policymaking*** by working with the WHO Chief Scientists Office, the WHO Global TB Program, and National TB Programs to improve transparency, the process for making and updating, and quality of normative guidance.
- ***Ensuring affordable pricing and availability*** for essential drugs, diagnostics and vaccines to facilitate rapid implementation and positive impact on individuals and communities affected by TB.
- ***Calling for research funding*** by supporting partners to foster country-level resource and research mobilization, focusing on currently under-contributing potential sources such as BRICS and high burden countries, and to build accountability around the country-level fair-share funding targets adopted by the WHO Global TB Research Strategy.

Structure and composition

The TB CAB is comprised of community-based research activists from around the world who are extensively involved in HIV and TB civil society networks. TB CAB members serve as individuals, and not in their capacity as members of or



representatives to any organization or other affiliation.

Membership is on a voluntary basis, and members are not compensated for their participation; however, TAG covers all TB CAB-related travel and teleconferencing expenses so that participation in the TB CAB is cost-neutral.

Members will, at a minimum, participate in monthly teleconferences and convene once annually for an in-person meeting. Participation in additional teleconferences and in-person meetings may be requested on an ad hoc basis.

Experts will be called on to advise the TB CAB members on a needs basis.

The global TB CAB does not accept industry funding or lobbying of members.

Members

Membership is based on skill and expertise in the research and development of diagnostics, treatment, and prevention interventions, and on technical literacy regarding access issues. Members belong to community networks and can disseminate information and bring about local, national, regional, and/or global action on issues.

Members commit to learn about the technicalities of research and access and apply that learning to their own work and the work of the TB CAB.

Members should promote and defend the interests of the public and affected communities and not participate in the TB CAB with the objective of personal gain. However, members are encouraged to use skills obtained through participation in the TB CAB in other work and initiatives.

TB CAB members are chosen so as to, as much as possible, represent the diverse needs, interests, and concerns of the entire spectrum of the TB and HIV affected communities.

Processes for new members

The TB CAB does not have a maximum number of members. However, membership may be limited by i) funding available to support TB CAB travel and activities and ii) concerns that a large group may be less able to act rapidly and engage in meaningful discussions. To ensure the ability of the TB CAB to continue to act swiftly and expertly, without too much interruption due to transitions in membership, the TB CAB may limit the number of new members who can join the TB CAB at a given time.

The TB CAB may take on new members when:

- 1) An existing member steps down from the TB CAB;
- 2) The need arises to add diversity in the geography, expertise or perspective of



the TB CAB;

- 3) An appropriate candidate is identified by or approaches the TB CAB for membership.

In the first two instances, the TB CAB may solicit applications for membership by reaching out to select known colleagues and/or by circulating an open call for applications. In all instances, the TB CAB should consider the merits and potential drawbacks to a candidate's membership, including, but not limited to:

- potential to add geographic and other diversity,
- connection to community and networks,
- familiarity with TB and/or HIV and research and/or technical aspects of access issues,
- advocacy experience,
- demonstrated interest in the scientific aspects of the TB CAB's work,
- ability to commit to the responsibilities of TB CAB membership,
- the overall size and composition of the TB CAB as a whole.

As English is the working language of the TB CAB, all prospective members must be able to work in English, including the ability to proficiently read, write, speak and understand English.

The TAG coordinator and TB CAB (co-)chair(s), and (co-)technical lead(s) will pre-screen new member applications (may include brief questionnaire, letter of interest, and letter of support from a peer), follow up with references, and conduct an interview (remotely or in person if feasible) before sharing its recommendation with the larger TB CAB for approval.

If an applicant comes recommended by an existing TB CAB member, the recommending TB CAB member will be invited to participate in the call when the new member's candidacy is being reviewed and discussed. The full TB CAB will then vote on each applicant's candidacy by simple majority (half plus one). If approved, a probationary period will ensue and last until after one face-to-face meeting. Following the face-to-face meeting, the TAG coordinator, and the TB CAB (co-)chair(s) and (co-)technical lead(s) will convene and re-evaluate the applicant's eligibility, and issue a final recommendation to the larger TB CAB for final approval (majority plus one).

Member responsibilities

- Participate actively in and meaningfully contribute to meetings and the TB CAB list serve;
- Respect group procedures/decisions and diverging opinions expressed by other members;

- Respect the diversity of people regarding considerations such as religion, gender, sexual orientation, and lifestyle;
- Be available for tasks such as protocol reviews, position statement development, letter writing, minute taking, etc.;
- Be involved, interact, and share (non-confidential) information with local and other community networks;
- Be informed about local and global research, and access issues;
- Provide input to meeting agendas and ensure personal meeting preparation;
- Identify/ mentor new members suitable for TB CAB;
- Respect confidentiality of TB CAB work;
- Agree to the TB CAB confidentiality agreement, declaration of interests and disclosure of financial contributions received from the industry for performing personal activities (NOTE: special accommodations can be considered for potential members unable to sign formal confidentiality agreements).

Term limits

The term limit is four years. TB CAB members will have the option to re-apply. Applications will consist of a letter of motivation, which should include (1) a description of your contributions to the work of the TB CAB; and (2) how you plan to help advance TB CAB advocacy priorities should your membership be renewed. Members should re-apply with the intention to serve a full four-year term and to undertake the responsibilities outlined in these terms of reference.

Early termination of membership

Members who are not fulfilling these responsibilities may be asked to leave the TB CAB. In case of most issues, the TB CAB (co-)chair(s) and TAG coordinator will try to work with individual members to improve their contributions. If after intervention, including at least one written warning, issues have not improved within 6 months as per consensus by the (co-)chair(s), (co-)technical lead(s), and TAG coordinator, an individual's membership may be discontinued. In case of an egregious violation of TB CAB policy, membership may be terminated immediately.

TB CAB membership status may be reviewed under any of the following circumstances:

- A TB CAB member has participated in fewer than 2/3 of monthly calls;
- A TB CAB member has an unexcused absence from an in person TB CAB meeting;
- A conflict of interest triggered by an employment or other change arises that threatens a TB CAB member's ability to meet their responsibilities as a TB CAB member; and/or
- A TB CAB member is found to be publicly or otherwise championing



positions in conflict with those agreed upon by the TB CAB.

List-only members

List-only members will be added and removed at the discretion of TB CAB leadership. List-only members may attend TB CAB meetings if invited. List-only members are asked to sign confidentiality agreements before participating in meetings, being added to the TB CAB mailing-list, obtaining access to information, and contributing to discussions.

Guests

TB CAB can invite guests to its meetings. Guests will not be routinely added to the TB CAB mailing list. All guests are obliged to sign the confidentiality agreement.

Chair(s)

The TB CAB (co-)chair(s) are elected by the members at a face-to-face meeting every two years by simple majority of the members present at the meeting (half plus one). For continuity and stability, TB CAB (co-)chair elections should be staggered, meaning only one chair should be up for election every two years; as a result, TB CAB chairs should expect to serve a four-year term, though re-election is also possible. The TB CAB may also choose to elect a single chair.

The TAG coordinator and the TB CAB (co-)chair(s) will jointly appoint technical lead(s). These appointments will be staggered/ aligned with the process described immediately above.

Termination of the chair or technical lead's position

If the chair or technical lead is not properly undertaking their responsibilities (inactivity, lack of commitment, serious mistakes, untoward behavior, etc), members should raise the issue with the TAG coordinator, who will then either address the matter with the chair or technical lead directly, or if necessary raise the issue for group decision.

Resignation by chair or technical lead

In the event a chair or technical lead resigns from their position early, the remaining chair(s), (co-)technical lead(s), and TAG coordinator will nominate a replacement to be approved by a majority decision of the full TB CAB (half plus one). This vote may be conducted virtually or during the next in-person meeting.

Duties & responsibilities of the chair

The chair has the following duties and responsibilities, some of which s/he may share with or delegate to the technical lead(s) or other members as needed:

- Serve as the public face of the TB CAB
- Prepare and facilitate meetings with product developers, speakers and TB

CAB members;

- Establish and lead contact with industry, research institutions and other partners;
- Promote regular collaboration with similar bodies around the world;
- Inform the development of agendas and content for TB CAB meetings and trainings;
- Facilitate TB CAB meetings;
- Oversee TB CAB governance, including by ensuring participation of existing members and recruitment and development of new TB CAB membership;
- Review membership applications;
- Assign specific tasks to TB CAB members;
- Approve public facing communications prior to distribution;
- Represent TB CAB at external meetings;
- Ensure transparent decision-making.

Duties & responsibilities of the technical lead(s)

The technical lead(s) has the following duties and responsibilities, some of which s/he may share with or delegate to the chair or other members as needed:

- Foster TB CAB discussions and strategy development;
- Lead development of TB CAB positions on and approaches to research and access issues;
- Contribute to design and content of TB CAB trainings and meeting agendas;
- Support (co-)chair(s) engagement with product developers, industry, research institutions and other partners;
- Support (co-)chair(s) to recruit and develop new TB CAB membership;
- Review membership applications.

Duties & responsibilities of the TAG coordinator

The TAG coordinator has the following duties and responsibilities. The (co-)chairs and (co-)technical lead(s) may request help with additional duties and responsibilities as needed:

- Facilitate monthly calls and listserv discussions;
- Meeting logistics and administration;
- Contribute to design and content of TB CAB trainings and meeting agendas;
- Support (co-)chair(s) engagement with product developers, industry, research institutions and other partners;
- Maintain developer prep slides and other TB CAB resources;
- Support (co-)chair(s) to recruit and develop new TB CAB membership;
- Review membership applications

Confidentiality

It is important for treatment activists to have access to confidential information from the pharmaceutical industry and product developers. Therefore, TB CAB requires companies to disclose information of scientific and commercial value as it is available and prior to publication. As a result, TB CAB operates under confidentiality, which is of paramount importance for the smooth and efficient functioning of TB CAB.

The confidentiality agreement also covers discussions held on the group's mailing list.

All information disclosed by product developers is considered non-confidential unless expressly stated otherwise. Positions and decisions taken by TB CAB are public. Internal discussions and contents are strictly confidential to members.

A breach of the TB CAB's confidentiality agreement is considered a serious offense and may result in disciplinary action, up to and including dismissal from the TB CAB.

Conflicts of Interest

TB CAB members serve as individuals, and not in their capacity as members of or representatives to any organization or other affiliation. However, given the sensitive nature of the information discussed within the TB CAB, members must disclose any new position(s) or affiliation(s) that may present conflicts of interest and/or influence the ability of a member to support TB CAB positions and advocacy initiatives. We don't believe having an evidence-based opinion constitutes an intellectual conflict of interest.

Sexual Harassment

The TB CAB is committed to providing its members with a working environment free of discrimination. In keeping with this policy, the organization will not tolerate any sexual harassment of or by any of its members. All TB CAB members must be diligent in preventing such conduct. The following is a sample list of prohibited practices:

- Abusing the dignity of a TB CAB member (or other party) through unwelcome, insulting, or degrading sexual remarks or conduct, or creating an intimidating, hostile, or offensive work environment;
- Making threats, demands, or suggestions that a TB CAB member's status or any decision affecting a TB CAB member is contingent upon his or her tolerance of or acquiescence to sexual advances or requests for sexual favors;
- Engaging in sexual relationships in the work place that adversely affect the opportunities of other TB CAB members;
- Retaliating against TB CAB members for complaining about such behavior,



furnishing information about, or participating in any manner in any investigation of such behavior.

As the administrator of the TB CAB, Treatment Action Group is responsible for administering this policy. If a TB CAB member or other party believes that she or he has been or is being harassed, the individual should immediately contact the TB CAB coordinator and/or member(s) of the TB CAB leadership team [chair(s) and/or technical lead(s)], as appropriate.

TB CAB members can also directly contact the Executive Director of Treatment Action Group to discuss these issues. Complaints of sexual harassment should be made in writing and signed by the complaining party and must detail the facts of the incident. Treatment Action Group encourages TB CAB members who believe they are being harassed to firmly and promptly notify the offender that his/her behavior is unwelcome.

Treatment Action Group and the TB CAB leadership team have the responsibility of investigating and resolving any complaints of sexual harassment. All complaints will be fully investigated and, where necessary, appropriate action taken. All actions taken to investigate and resolve such complaints are conducted in the strictest confidence where possible unless otherwise authorized by the complaining party. Upon completing the investigation, Treatment Action Group and TB CAB leadership will communicate its findings and intended actions to the complaining party and the party accused of engaging in the harassment.

Sexual harassment is a serious matter. Any TB CAB member found to have sexually harassed another member or outside party will be subject to disciplinary action, up to and including termination. TB CAB membership is a privilege; if/when an investigation is inconclusive, Treatment Action Group and TB CAB leadership will err on the side of the complaining party.