



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 2024– 2026, 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 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 2024-2026

- ***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 improving the transparency, accessibility, and inclusivity of TB vaccine science and building community literacy and connection to TB vaccines research.
- ***Improving TB CAB knowledge and capacity on TB diagnostics*** to support engagement with sponsors, donors, and stakeholders that shape markets to ensure appropriate community consideration and generate demand.
- ***Promoting pre-approval and post-trial access programs*** to enable early access to new TB drugs and regimens and new TB vaccines as soon as sufficient safety and efficacy data are available.
- ***Advocating for regulatory authorities to rapidly review new product applications and uphold rigorous evidentiary and quality standards*** for new TB drugs, regimens, vaccines, biosimilars, and other products, and generics.
- ***Supporting evidence-based policymaking and accelerated access to innovations*** by working with the World Health Organization (WHO) Global TB Program, WHO regional offices, and National TB Programs to improve adoption of new normative guidance.
- ***Ensuring affordable pricing and access to essential drugs, diagnostics and vaccines*** by working further upstream to promote conditions on public funding and downstream to address intellectual property, licensing strategies, shortages, stock outs and other supply constraints.
- ***Calling for research funding*** by supporting communities to foster country-level resource and research mobilization to build accountability around the new country-level fair-share funding targets published by TAG.
- ***Challenging de-prioritization of countries in the Latin America and Caribbean (LAC) region and in “transition” from donor funding*** to ensure continued inclusion in research, regulatory, and access to innovation strategies and initiatives for new TB drugs, vaccines, and diagnostic technologies.

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 compensated for their participation, time, and expertise at a flat rate that assumes four hours of work per month plus a data stipend. TAG also 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 or their term limit expires;
- 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 an independently-convened selection committee will review and score new member applications (may include brief questionnaire, letter of interest, and letter of support from a peer). The selection committee will rank and vote on each applicant's candidacy by simple majority (half plus one). Once new members are selected and notified, 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) can convene and re-evaluate any new member's eligibility and membership status.

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) 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 TB CAB member participates in act(s) of misconduct, misrepresents themselves or the TB CAB, or behaves unprofessionally;
- 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.

TB CAB Observers

TB CAB observers will be added and removed at the discretion of TB CAB leadership. TB CAB observers are not voting members of the TB CAB but can join the listserv and participate in TB CAB calls and activities. TB CAB observers can attend in-person TB CAB meetings if invited. TB CAB observers will be required to sign confidentiality agreements before participating in calls and 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. At least two years of experience on the TB CAB is required before a member is eligible to serve as chair or co-chair.

Termination of the chair position

If the chair 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 directly, or if necessary raise the issue for group decision.

Resignation by chair

In the event a chair resigns from their position early, the remaining chair 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 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 TAG coordinator

The TAG coordinator has the following duties and responsibilities. The (co-)chairs 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 other research and product sponsors. Therefore, TB CAB requires companies and other stakeholders 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 companies and research and product sponsors 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 a 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 TAG coordinator and/or (co-)chair(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.