



## 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 issues.

### Functions of the TB CAB

*The broad goals of the TB CAB are to:*

- 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 TB CAB members' networks to educate them and build an advocacy platform to influence the TB research community;
- Bring special attention to neglected populations – e.g. pediatrics, TB/HIV co-infection, migrants, women;
- Drive high quality research and accelerate/support regulatory approval processes; and
- Engage with TB research funders and policymakers to drive development and uptake of new TB tools.

These terms of reference are for three years, from 2012-2015.

### Priority TB Research Advocacy Issues 2012-2015

- **Drug Combination Studies** to ensure investigational new drugs are studied together *in vitro*, *in vivo* and in pharmacokinetic studies in order to provide information about drug-drug interactions, and whether they are safe to use together.

- ***Compassionate Use and Expanded Access Programs*** to enable early access to and compassionate use of new TB drugs as they enter Phase III, or as soon as sufficient safety data are available.
- ***Pediatric Investigational Plans (PIPs)*** to ensure that developers and sponsors of new drugs and regimens create PIPs for new agents clinical trials and begin to implement them as soon as adequate safety data are available. This is especially important as when new agents receive accelerated approval from the FDA that meet a critical unmet medical need, they receive waivers from the FDA on pediatric studies.
- ***Harmonization of Regulatory Agencies*** for accelerated approval and to shorten the length of TB trials for new TB drugs and regimens.
- ***Promote affordable pricing*** for essential drugs and diagnostics to ensure rapid implementation and positive impact on millions of people who get TB each year.
- ***Address the gap of quality assurance for TB diagnostics*** by advocating for quality assurance for TB diagnostic tools—perhaps via the establishment of a competent body—since most limited resource countries do not have adequate regulatory capacity to conduct such evaluations.

## **Structure and composition**

The TB CAB is comprised of research activists from Asia, Europe, Africa, North America, and South America who are extensively involved in HIV and TB research networks.

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, convene once annually for an in-person meeting, and participate in quarterly teleconferences. 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 areas of diagnostics, drug development, and general research and development issues. Members belong to networks and can disseminate information and bring about global action on issues. TB CAB members are chosen so as to represent the diverse needs, interests, and concerns of the entire spectrum of the TB and HIV patient community.

### ***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 approaches the TB CAB for membership.

In the first two instances, the TB CAB may solicit applicants 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,
- advocacy experience,
- ability to commit to the responsibilities of TB CAB membership,
- and 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 TB CAB will vote on each applicant's candidacy by simple majority.

### ***Member responsibilities***

- Participate actively in meetings and on the TB CAB list;
- Respect confidentiality of TB CAB work;
- Respect group procedures/decisions and diverging opinions expressed by other members;
- Be available for tasks such as protocol reviews, minute taking;
- Be visible and interact with the local community when possible;
- Be informed about local patient, clinical trial and treatment issues;
- Provide input to meeting agendas and ensure personal meeting preparation;
- Identify and propose new members suitable for TB CAB;
- Agree to the TB CAB confidentiality agreement, declaration of interests and disclosure of financial contributions received from the industry for performing personal activities.

### ***Guests***

TB CAB can invite guests to its meetings and on the TB CAB mailing list. All guests are obliged to sign the confidentiality agreement for guests.

### ***List-only Members***

There is a possibility of being a list-only member, if requested by the member. List-only members are obliged to sign confidentiality agreements and then they can participate on the mailing list, have access to information, and contribute to the discussions, but they cannot attend TB CAB meetings unless invited.

### ***Alternates***

For practical purposes (good geographical representation, member availability, workload, avoidance of overbooked meetings), a twinning system is available with alternates, according to which two members from a specific country may interchange at meetings and support each other with the TB CAB workload. Only one member can attend a given meeting at the same time.

To facilitate a smooth and efficient twinning relationship, the twin present at the meeting is responsible for updating the absent twin on all the items discussed at the meeting and the internal discussions and training sessions, so that both twins can perform effectively in any following meetings.

### ***Chair***

The TB CAB chair is elected by the members at a face-to-face meeting every two years by simple majority of the members present at the meeting (half + 1).

### ***Termination of chair's position***

If the chair is not doing their job properly (inactivity, lack of commitment, serious mistakes, untoward behaviour towards members, etc), members may take the matter to the next meeting where the group will make a decision.

### ***Duties & responsibilities of the chair***

The chair has the following duties and responsibilities, some of which s/he may share or delegate:

- Prepare meetings with product developers, speakers and TB CAB members;
- Establish and maintain contact with industry, research institutions and other partners;
- Promote regular collaboration with similar bodies around the world;
- Organise trainings;
- Ensure recruitment and development of TB CAB membership;
- Assign specific tasks to TB CAB members, and define terms of reference;



- Approve reports and minutes prior to distribution;
- Represent TB CAB at external meetings;
- Ensure transparent decision-making.

### **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 of the TB CAB.