

22 PROTOCOL

ECAB - European Community Advisory Board

Statement of purpose

ECAB is a working group of the EATG; it is a pan-European network of activists, many living with HIV, working together to end the epidemic by advancing research on HIV/AIDS, broadening access to treatment, and training/mentoring new AIDS advocates.

ECAB is a volunteer, community-based structure, collaborating actively with other groups sharing our philosophy in other geographical areas and national CABs.

ECAB aims to promote the harmonisation of good clinical practice, standard of care and access to best available therapies and diagnostic tools throughout Europe, with particular regard to Central and Eastern Europe.

ECAB objectives

Treatment activism is an integral part of the drug development and research process since the beginning of the AIDS epidemic. Therefore, ECAB works with the HIV community, government, researchers, academics, the European Commission and the pharmaceutical industry to provide a systematic, efficient, manageable and accountable network of activists speaking from the unique perspective of the HIV-affected community in the WHO Europe region.

Its objectives include:

- Review clinical trial design at planning stage.
- Monitor ongoing trials with regard to adverse events, compliance, and community priorities.
- Stay informed of interim results.
- Suggest and initiate trials to reflect patient and community needs.
- Suggest strategic therapeutic trials and research driven by public health needs.
- Represent the interests of PLWHA and in particular of those participating in clinical trials.
- Review informed consent forms for both content and language.
- Promote best practice procedures and ethics.
- Represent the patients' perspective within other entities such as investigator and advisory meetings and DSMBs.
- Advocate for fair, sustainable, and affordable pricing and access to treatment.
- Promote universal access to treatment in the WHO Europe countries.
- Promote access to treatment for vulnerable groups (women, children, IV-users, etc).
- Support efforts to harmonise safety reporting in Europe, and better involvement of

- patients in adverse events reporting
- Promote research on new preventive technologies, and immune-based therapies.
 - Promote the development of new and effective therapies for hepatitis and TB co-infected patients.
 - Address the specific needs of women, children, injecting drug users, prisoners, migrants, transgender, MSM, sex workers, ethnic minorities and other vulnerable populations.
 - Work proactively, anticipating treatment needs of HIV-positive people.

Structure

ECAB comprises members, a chair or co-chairs, and/or a steering committee. The ECAB chair is elected by the EATG General Assembly for a one-year period. A BoD liaison is appointed to ECAB; s/he represents the BoD in ECAB, offers support and guidance, and participates in decision-making. In case of absence of the ECAB chair(s), the BoD liaison replaces the chair. Decision making power is shared between the ECAB chair(s) and the BoD (see below).

The majority of ECAB members should be EATG members as well.

Chair(s)

The ECAB chair is elected by the EATG membership at each GA by simple majority of the members present at the GA (half + 1) [same rule as for BoD members] for a period of one year. For the smooth running of ECAB and unencumbered decision-making, it is advisable to have either only one chair or two chairs who will candidate *together* and be elected *as a team* as co-chairs.

If only one chair is elected, s/he must appoint a steering committee. If two co-chairs are elected at the General Assembly, it is left at their discretion to decide whether they need to have a steering committee. If they choose to have one, the procedure mentioned below (steering committee) applies.

The ECAB chair can represent ECAB externally without specific remit from the BoD but should naturally keep the BoD informed of such representations.

Decision-making

Decision-making on matters that pertain to ECAB work (e.g. choosing companies, meeting agendas, etc) rests primarily with the ECAB chair(s), who consults the ECAB membership and steering committee, and discusses decisions with the BoD liaison, who represents the BoD. Such decisions are the responsibility of the ECAB chair. Decisions with regard to ECAB public positions (eg. position papers, open letters, etc.) need to be taken in agreement with the Board. If no consensus can be reached with the liaison, the matter must be taken to the entire BoD, and the ECAB chair's views must be heard before a final decision is reached. Final decision rests with the governing body of the EATG, the Board of Directors. **but the BoD must justify a decision that differs from**

the position of the ECAB chair.

The BoD (in their entirety or through their liaison) cannot ‘veto’ the ECAB chair’s decision without firstly trying to reach consensus and secondly justifying their differing position. Likewise, the ECAB chair must justify his or her viewpoint in such matters. The ECAB chair must be present and heard in situations of disagreement.

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), either the co-chair, steering committee, members, or the Board of Directors liaison have to take the matter to the BoD. The Board of Directors will decide by qualified majority about the termination of the chair’s position and will appoint a replacement until the next GA. Before the chair’s position is terminated, the chair has the right to be heard by the Board of Directors and present his or her side of the matter.

Duties & responsibilities of the chair

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

- Prepare meetings with companies, speakers and ECAB members;
- Establish and maintain contact with industry and other partners;
- Promote regular collaboration with similar bodies around the world;
- Organise trainings;
- Ensure recruitment and development of ECAB membership;
- Evaluate members on an ongoing basis;
- Assign specific tasks to ECAB members, and define terms of reference;
- Guide and oversee company liaisons and thematic portfolios;
- Guide and oversee the minute taker;
- Approve reports and minutes prior to distribution;
- Represent ECAB at external meetings;
- Liaise with EATG working groups;
- Ensure the ECAB protocol update;
- Ensure transparent decision making.

Steering Committee

A steering committee is a group of ECAB members chosen by the chair(s) and endorsed by group members. Its role is to assist the chair(s) in their tasks and act as a consulting body. It is not a decision-making body.

It is mandatory to have a steering committee if only one chair is elected at the GA, but if there are two co-chairs, it is up to them to decide whether they need a steering committee.

To set up the steering committee, the chair(s) announces a call for candidates over the list, proceeds to nominate a steering committee, and asks members to voice any objections in private to the chair. At the next ECAB meeting, the chair asks present ECAB members to endorse the steering committee. If the group does not endorse the chair's nominations, then the chair will have to nominate new members to the steering committee.

Members

ECAB members are chosen so as to represent the diverse needs, interests, and concerns of the entire spectrum of the European HIV patient community (women, men, IDUs, ethnic minorities, people in detention, vulnerable groups etc.). In terms of membership priority is given to people living with HIV.

Members ideally come from patient-based, non-profit organisations in their respective countries, but neither this, nor being a member of EATG, is considered a necessary qualification. Nevertheless, people become ECAB members as individuals and not as representatives of their own home organisation.

ECAB members are recruited from all European countries (Europe as defined by WHO). Care is given by ECAB to have as broad a geographical coverage as possible. Members are expected to demonstrate activity in this region.

There is no limit to the number of members per country but as ECAB aims to have all European countries represented, there are also geographical criteria for the recruitment of new members.

Member responsibilities

- Participate actively in meetings and on the ECAB list;
- Respect confidentiality of ECAB work;
- Respect group procedures/decisions and diverging opinions expressed by other members;
- Be available for tasks such as company liaison, protocol reviews and thematic portfolios;
- 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 ECAB;
- Annually sign the ECAB confidentiality agreement, declaration of interests and disclosure of financial contributions received from the industry for performing personal activities.

Guests – New Members

Recruitment of new members is the responsibility of the chair, steering committee, and all members. People who are likely candidates are invited to attend ECAB meetings as

guests. All guests are obliged to sign a special confidentiality agreement. Guests that have proved that can actively contribute to ECAB are encouraged by the chair or steering committee to become ECAB members after two attendances at the earliest, following a positive evaluation by the chair(s). Depending on their commitment, ECAB members are encouraged to become EATG members within a few months after becoming ECAB members. (People may be on the mailing list without being ECAB members for a period of up to six months maximum).

List-only Members

For practical reasons, there is a possibility of being a list-only member, following a decision by the chair. 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 ECAB meetings unless invited by the chair.

Suspension of Membership

ECAB members who temporarily move out of Europe can stay on the ECAB list as list-only members. Their membership is automatically reactivated without formal procedure when returning to Europe if their absence has been shorter than two years.

Termination of ECAB Membership

Membership can be ended for any of the following reasons:

- Breaching confidentiality;
- Disrespect of group procedures and other members;
- Unexplained inactivity and lack of commitment;
- Not submitting / renewing the ECAB membership form with the declaration of interest form.
- Not showing up at two meetings without serious reasons after registration has been confirmed, costing the EATG loss of money.
- A request by a member to terminate his or her membership.

Inactivity and lack of commitment

Members are expected to inform the chair and steering committee if for any reason they have to stay inactive for any long period of time (e.g. health reasons, workload, travelling, etc). During this period, they may stay on as list-only members.

When a member fails to attend ECAB meetings for one year (6 meetings) without having let the chair know why, the chair and/or steering committee send a letter asking the member whether s/he wishes to continue being a member of ECAB. If one month after this letter has been sent the member has not responded, his or her membership is terminated. If the member responds, explaining his or her legitimate reasons, then s/he stays on as a member. If, however, s/he remains inactive (either through failure to attend meetings or participate actively on the mailing list) during the next 12 months, then her or his membership is automatically terminated, and a letter is sent by the chair and steering committee informing the ex-member of the

decision.

Disrespect of group procedures or other members

If a member disrespects group procedures or other members, the chair must bring this to their attention immediately and ask the member to respect rules, procedures and show good conduct. If the member continues to breach group procedures, or if the chair deems that the problem is too serious, then s/he together with the steering committee will bring the matter to the Board of Directors liaison's attention, asking for a suspension of membership. The final decision for a termination of ECAB membership rests with the chair. All parties must be heard before a decision is reached.

Breaching confidentiality

Confidentiality is of paramount importance for the smooth and efficient functioning of ECAB. However, there may be extremely serious exceptional cases when confidentiality may have to be compromised if patients are at risk. In such cases, it is absolutely imperative to seek discuss the matter with the chair before any action is taken.

In case of a breach of confidentiality the following procedure will be followed:

- A hearing will be held with the chair and steering committee of ECAB at which the member in question will have to explain why s/he breached confidentiality.
- If the explanation is not deemed satisfactory, the person's ECAB membership will be terminated.
- This ECAB decision will be communicated to all interested parties.

If the member in question has already broken confidentiality before, membership is automatically terminated without applying the procedure described above. The final decision rests with the chair.

Not submitting / renewing ECAB membership form with the declaration of interest form

All ECAB members are obliged to fill in a declaration of interest form once a year. Failure to do automatically leads to termination of membership.

A letter is sent out by the office once a year asking ECAB members to send in their declaration of interest form by an appointed date. The office reminds members to do so once more. Failure to send in the form after the second reminder letter automatically leads to termination of membership. The ECAB chair and steering committee notify the office of this decision.

Termination of ECAB membership v. EATG membership

For ECAB members who are also EATG members, if their ECAB membership is terminated because of failure to send in the declaration of interest form, then their EATG membership is also automatically terminated and vice-versa.

ECAB members whose membership is terminated may stay on as EATG members. However, depending on the reason for termination, the ECAB chair should take the matter to the BoD, particularly if the EATG has been compromised because of this member's actions.

Re-activation of membership

As mentioned above, ECAB members who have been inactive for over two years are automatically terminated or may become list-only members. Members whose membership has been terminated for any reason and who wish to become ECAB members again have to go through the same procedure as new members, i.e. be invited as guests.

Evaluation

The ECAB chair and steering committee evaluate the work of members as well as the group as a whole. Evaluation is an ongoing process, but once a year, the chair and the steering committee must update the membership, i.e. ask dormant members whether they wish to carry on or stop, encourage members who attend but do little work to become more engaged, address recruitment needs keeping in mind specific criteria (gender / geographical / HIV+ representation, etc), and so on.

The chair's work is evaluated through the quarterly reports s/he has to submit to the Board of Directors and the entire membership. Moreover, the Board of Directors liaison evaluates the work of the chair and informs the Board of Directors accordingly. To this purpose, the Board of Directors liaison may consult the steering committee or other ECAB members.

Financing

Pharmaceutical companies contribute to the funding of the group's activities (e.g. meetings, travel and accommodation of the ECAB members, and expenses for the training sessions).

All fundraising and financial operations are the responsibility of the Board of Directors and the office manager.

Schedule

- ECAB meets on a regular basis 6 times per year over the weekend. Additional and ad hoc meetings are possible. Friday and Saturday are open for meetings with external parties. Sundays are available for training and lectures.
- Sufficient time is to be dedicated to internal work, lectures and trainings.
- Care is taken to take into account workload, health issues, and travel fatigue when planning meetings.

Registration

Certain registration criteria apply. These include good geographical representation,

member availability, workload, avoidance of overbooked meetings, financial capacity, room capacity, level of commitment, etc. In case of overbooking, the chair will try to find a solution by getting in touch with applicants from countries with several applications in an effort to find a solution. The chair will eventually choose which applicants will attend according to the criteria mentioned above.

Travel

An annual programme of meetings will be distributed in the autumn of the previous year to help members plan their attendance.

A call for each meeting will be sent by the chair by email 4 weeks before each meeting. Members are expected to register within 4 working days following the call.

Once tickets are issued, only emergencies allow for cancellation. The office and the ECAB chair should be contacted immediately about the reasons.

Any cancellation will be considered as 'no-show' (including missing planes). Two no-shows costing the EATG loss of money could forfeit membership with the ECAB.

Registrations for meetings are to be approved by the ECAB chair.

Confidentiality

It is important for treatment activists to have access to confidential information from the pharmaceutical industry. Therefore, ECAB requires companies to disclose information of scientific and commercial value as it is available and prior to publication. As a result, ECAB operates under confidentiality, which is of paramount importance for the smooth and efficient functioning of ECAB. Therefore, a confidentiality agreement is signed by ECAB members when they join the group.

ECAB guest participants must sign the ECAB confidentiality agreement in order to protect the group and the rights of companies/other stakeholders and to remove the latter's objection to reveal confidential items (annex 2). The confidentiality agreement also covers discussions held on the group's mailing list.

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

Breaking confidentiality

See Breaching confidentiality without prior consultation with the chair.

Meeting moderators

The moderator's main responsibility is to ensure that the issues raised in the agenda and pre-meeting are followed in a timely way - i.e. momentum of the meeting, keeping the company to these issues. The moderator is in charge of conducting the meeting with fair time for all members to speak. The moderator summarises the meeting to the company at

the end.

Participants should respect the position of moderator and speak when given the floor.

Meeting minutes

ECAB meetings and decisions are recorded by the ECAB minute taker. The minute taker must sign a contract at every covered meeting. The minute taker delivers a confidential and a non-confidential set of the minutes. Both sets are published on the internal password protected ECAB site. The non-confidential set can be circulated to national CABs, and the EATG membership.

The minute taker is chosen by the ECAB chair. The fees for minute-taking are decided by the BoD. Timelines are stipulated in the contract.

Conflict Resolution

In cases of conflict between ECAB members (including the chair) who are also EATG members, if they fail to resolve the matter on their own they can enter the procedure provided for EATG members, i.e. contact the Ombudspersons, and if that fails to resolve the conflict, DMWG. See Grievance Protocol.

In cases of conflict between ECAB members who are not EATG members, or conflicts between ECAB/EATG members and non EATG members, the matter is dealt with by the chair in collaboration with the steering committee and the Board of Directors liaison. Final decision rests with the ECAB chair and the Board of Directors liaison. If there is disagreement between them, the matter is taken to the BoD, where the opinion of the chair must also be heard before a final decision is taken. Ideally, decisions on such matters are reached consensually, but in the extreme case when there is a difference of opinion between the ECAB chair and the BoD, final decision rests with the BoD. Both parties must justify their opinions.

In cases of conflict between the ECAB chair and the Board of Directors liaison, the regular conflict resolution procedure applies (effort to solve the problem by themselves → ombuds → DMWG → BoD).

Annex documents:

1. ECAB member form including declaration of interests;
2. ECAB confidentiality agreement;
3. Terms of reference company liaisons and thematic portfolios;
4. Protocol reviews
5. Minute-taking

