Terms of Reference and Modus Operandi of Partners in Science (PiS) Programme 2021-2025

Statement of purpose

PiS is a programme of the European AIDS Treatment Group, EATG. This pan-European network of activists, many of whom are living with HIV themselves, is working together to end the epidemic, a.o. by advancing research on HIV and other STIs, as well as viral hepatitis and TB, broadening access to treatment and biomedical prevention, and training/mentoring new advocates.

PiS, at EATG, is a volunteer, community-based programme, collaborating actively with others who share goals in different geographical areas and national Community Advisory Boards. The programme aims to promote the harmonisation of good clinical practice, standard of care and access to the best available therapies, diagnostic tools and prevention science throughout the WHO European region, with particular regard to Central & Eastern Europe and Central Asia.

The specific goals are described in the EATG Long Term strategy. The long-term strategy is public, continuously monitored and updated to best reflect community needs.

It is to be noted that all stipulations in this Modus Operandi are subject to EATG’s Privacy And Personal Data Policy, as described in the EATG Operating Guidelines.

Objectives

(1) Engage EATG members with relevant stakeholders in the design, development and implementation of research/programmes for new preventive and therapeutic solutions

(2) Communicate EATG needs, priorities and strategies for HIV, hepatitis, TB, and STIs with key stakeholders

(3) Ensure the latest scientific knowledge on HIV and relevant co-infections reaches EATG members

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1 Europe as defined by WHO Europe
(4) Provide EATG input into clinical research for treatment and prevention options and other research/programmes

(5) Engage EATG members in cure and vaccine research

(6) Provide EATG input on the HIV, viral hepatitis, TB, STI and other emerging infectious diseases drug pipelines

(7) Engage EATG members in Patient Reported Outcome Measures (PROM) related to HIV, viral hepatitis, TB, and STIs

(8) Address the specific needs of the EECA region

(9) Assess clinical trials\(^2\) in the WHO European region

(10) Monitor access to medicines\(^3\) and biomedical prevention methods in the WHO European region and support local access efforts

(11) Engage EATG members in improving and promoting Patient Engagement

(12) Provide patient experts for Data and Safety Monitoring Boards\(^4\), advisory boards and similar activities

(13) Monitor and stay informed of interim results of ongoing clinical trials

(14) Suggest strategic therapeutic trials and research driven by public health needs\(^5\)

(15) Promote awareness about readability and understandability of informed consent forms and consent delivery processes

(16) Address the specific needs of women, children/adolescents, people who inject drugs, prisoners, migrants, transgender people, MSM, sex workers, ethnic minorities and other vulnerable populations.

**Structure**

PiS engages all EATG members. The programme leadership is ensured by a chair

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\(^2\) HIV, hepatitis, TB, and STI

\(^3\) HIV, hepatitis, TB, and STI

\(^4\) For an explanation of Data Safety Monitoring Boards (DSMBs) please see the following link: [https://toolbox.eupati.eu/glossary/data-and-safety-monitoring-board/](https://toolbox.eupati.eu/glossary/data-and-safety-monitoring-board/)

\(^5\) ACTG, INSIGHT, RESPOND, observational/cohort studies and collaborations
or co-chairs and a committee. See ToRs for EATG programmes.

Activity: Document review
EATG reviews and offers input into a variety of documents from the community perspective such as:

- Clinical protocols
- Guidance documents
- Patient leaflets
- Other scientific material

There is an established pool of experienced reviewers, supporting reviewers and a group of interested observers. To ensure quality, training material is identified and made available to the pool members.

Review groups are established ad hoc, in general with 5 participants, with one participant from the expert pool acting as the review coordinator. The group is formed from the pools of reviewers plus at least one observer. The review coordinator communicates with pharmaceutical companies or relevant stakeholder and coordinates the review process inside the group. A review group register is kept by the Programme Manager.

Review process:

- Individual review by participants in ad hoc team
- Review & consolidation of comments by coordinator
- Round of approval with ad hoc team, depending on complexity
- Consolidated review sent to the relevant stakeholder, shared with EATG members under confidentiality
- Follow-up via established interaction with the relevant stakeholder

Stakeholders should notify EATG over upcoming requests for input at least 10 days in advance. However EATG will make an effort to consider urgent requests in the case of unforeseen circumstances.

Activity: ECAB meetings with stakeholders
The European Community Advisory Board (ECAB) was established in 1997 as a forum for interaction between the community of people living with HIV and AIDS and the pharmaceutical industry. The objective is to support EATG’s work
in the promotion of biomedical research & pharmaceutical development in HIV/AIDS and related co-infections\(^6\).

ECAB meetings that cover the research and design aspects of treatment, biomedical prevention, cure and other related topics are organised mainly by the EATG PiS programme. ECABs may also be organised by other EATG programmes, if relevant.

ECAB meetings can involve the following stakeholders:

- Industry
- Academic groups, universities, clinical societies such as EACS
- Governmental bodies, regulatory bodies, HTA
- Patient organisations

**Pool of experienced members**

EATG is maintaining a pool of members experienced in science and/or living with HIV, plus a pool of interested members, considered as supporting ECAB members. To ensure quality, training material is identified and made available to the pool members.

**Schedule**

- ECAB meetings are held in line with the EATG implementation plan. Additional and ad hoc meetings are possible. A portion of the meeting is open for external parties and another portion is available for training and lectures.
- Virtual ECAB meetings are possible.
- An annual ECAB meeting plan is established each Autumn for the following year.

**Participants**

The number of participants of the ECAB meeting is considered to be in the range of 15-20 people. The Programme Chair may decide to reduce/increase this number. Up to 20\% of the ECAB meeting participants can be from the pool of interested, supporting ECAB members.

\(^6\) Berezcky T. (2013) ‘The impatient Patient, from Anger to Activism - A systematic review of the history, working models, relevance and perspective of the European Community Advisory Board’, EATG, URL:
https://www.researchgate.net/publication/270158403_THE_IMPATIENT_PATIENT_-_FROM_ANGER_TO_ACTIVISM#fullTextFileContent
Participation criteria include good geographical representation, gender, age and key population group balance. Participants annually update their conflict of interest declaration with EATG. ECAB participants are committed to engage in internal work, lectures and training sessions.

**Process**

- Call, including programme outline, to pool of supporting and expert members to be sent by Programme Manager (approx. 8wks before the meeting)
- ECAB meeting participants are approved by the Programme Chair and Executive Director, based on the membership database and communicated to the participant industry partner (approx. 4wks before the meeting).
- The participant industry partner communicate their list of participants to EATG (through the PiS Programme Manager) approx. 4 wks before the meeting.
- Provisional agenda submitted to company / meeting partners (approx. 6wks before the meeting)
- Travel arrangements made by EATG office
- Minute-taker, moderator to be appointed
- Pre-meeting material (internal & external documentation) available to participants (approx. 2wks before the meeting), which may include:
  - Minutes & follow up points from last meeting
  - Scientific update (latest conferences)
  - Suitable training material/resources

**ECAB Meeting rules**

- Ensure enough room for discussion
- Respect meeting moderator
- Respect confidentiality
- Internal discussions limited to internal briefing and debriefing to align the participants.
- Respect good manners and colleagues.
- Limit use of social media during meetings
- One person talks at a time
- Avoid “jellyfish” moments⁷: interesting discussions out of the context of the agenda

⁷ As referred to in EUPATI communications
• Participants not respecting the rules will be asked to leave the room

Travel


Confidentiality

It is necessary for ECAB meeting participants to have access to confidential information from stakeholders. Therefore, the ECAB meeting requires partners to disclose information of scientific and commercial value as it is available and prior to publication. As a result, the ECAB meetings operate under confidentiality, which is of paramount importance for the smooth and efficient functioning of PiS. EATG ensures ECAB meeting participants have signed an agreement covering confidentiality.

Agenda, positions and decisions taken emerging from ECAB meetings are public. Internal discussions and contents are strictly confidential to EATG Members.

Meeting moderators

Meeting moderators are appointed by the Programme Chair in collaboration with the Programme Manager and Executive Director. Moderators can be external.

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 partners focused on these issues, allowing fair time for all members to speak.

Meeting minutes

ECAB meetings and decisions are recorded by the ECAB minute taker. The recording is deleted after the compilation of the minutes of the meeting. Draft minutes are shared with the participating industry partner. Feedback is expected within 4 weeks after being shared from the participating industry partner to be integrated to the final version. If the participating industry partner does not send further communication within 4 weeks EATG will consider the submitted draft as final. Once finalised, the minutes of the meeting are shared internally.

The minute taker is chosen by the Programme Manager. The fees for minute-taking are in line with the EATG rules regarding payment of EATG members. Timelines are stipulated in the contract.
Activity: Industry-initiated activities
If an industry partner organises advisory boards, focus groups or any other activity referred to in the EUPATI guidance at WHO European level, the first organisation to reach out to for input and for the identification of participants is EATG. EATG is committed to having a pool of trained experts who can provide feedback on all of the activities referred to in the EUPATI guidance (see table on page 7).

Activity: Interaction with industry on scientific collaboration
The general scope of interaction for the PiS programme is to lead the exchange on drug development questions which are disease and non-disease specific. The process of this interaction is set out below.

Through the PiS programme, EATG aims to provide community input in to the following areas:

Research Priorities

- Setting research priorities (high expertise)

Research Design and planning

- TPP (therapy priority profiling) - the community should be invited to the meeting with key opinion leaders (KOLs) after they have a draft of the TPP (high expertise)
- Decision for clinical trial developments in different R&D phases (high expertise)
- Protocol synopsis (high expertise)
- Protocol design (high expertise)
- Fundraising for research (medium expertise)
- Patient information (medium expertise)

Research Conduct and Operations

- Information to trial participants (high expertise)
- Investigators meetings (high expertise)
- Data and Safety Monitoring Committees (high expertise)
- Study reporting (medium expertise)

Dissemination Communication Post-approval
- Regulatory affairs (high expertise)
- Health Technologies Assessments (medium expertise)
- Post-study communications (medium expertise)

**Patient involvement in medicines R&D**

**Table 1:** EUPATI Guidance on Patient Involvement in medicines R&D

**Transparency**

EATG should report on meetings and the agenda of the meetings on the website. Activities should be presented to the public (website, annual report etc) without disclosing confidential information.

**Compensation**

Meeting participations are not paid.

Trainers, minute takers, moderators, protocol reviewers (plus review coordination) are paid.

**Human Resources**

ToR of Programme Manager, Project Officer and Company's Liaison Persons.

**Evaluation/Assessment of interaction**

Following the Patient Engagement Quality Guidance developed by PFMD the
following criteria of interaction can be used to regularly assess the quality of the collaboration:

1. Shared purpose
2. Respect and accessibility
3. Representativeness of stakeholders
4. Roles and responsibilities
5. Capacity and capability for engagement
6. Transparency in communication and documentation
7. Continuity and sustainability
8. Achievements in relation to EATG strategy and implementation plan
9. Satisfaction about interaction

In addition, selected metrics from the four key components of the PARADIGM Patient Engagement Monitoring and Evaluation Framework can be used to evaluate specific outcomes:

1. Input metrics show whether or not the conditions for meaningful and sustainable patient engagement are in place.
2. Activities/process metrics show how the implementation of patient engagement is progressing and can elucidate areas for improvement.
3. Learning and change metrics show the short-term, direct results of patient engagement which give an indication of the progress made towards impacts.
4. Impact metrics (n=45)

Activity: Scientific education

PiS provides the following tools for its members to undertake training in order to participate effectively in scientific activities:

- Basic HIV advocate training: STEP UP programme; EUPATI toolbox
- Advanced HIV advocate training: EUPATI Open Classroom expert training on demand; learning with 1 per year training; case studies

Other interactions:

In addition to interaction with industry, the PiS programme ensures that community input is provided in other areas of research and in collaboration with relevant stakeholders. This collaboration is set out below:
- Implementation of external tools (EUPATI toolbox and guidance for interaction, PARADIGM, PFMD Quality Guidance Tool, etc).
- Public funded research (European Partnership for Health Innovation, Horizon 2020, Cohort collaborations, etc)
  - Horizon scanning
  - Implementation of possible guidances
- Academic funded research
  - Horizon scanning
  - Implementation of possible guidances
- Ethical considerations and discussions
  - Implementation of guidance from Council for International Organizations of Medical Sciences (CIOMS)
  - European Forum for Good Clinical Practice (EFGCP)
  - Participation in ethics committees for medical research
- Regulators (EMA)
  - Consider MHRA (UK), Swissmedic, Euroasian regulators including in Russia and Ukraine
- European Commission (EC)
  - DG SANTE
  - DG Research and Innovation
- HTA
  - Interaction with EUnetHTA
  - Consider collaboration between EMA and HTA bodies in early dialogue
- WHO Europe / UNAIDS (limited to scientific aspects)
  - Education
  - Quality and standard of care
  - Evidence-based advocacy
  - Healthcare policy
- Professional societies (EACS, EASL, etc)
  - Standard of care
  - Education
  - Evidence-based advocacy
  - Closed proactive collaboration
- Interaction with European communities in other indications (EPF, EUPATI, annual Patient Engagement Open Forum)
  - Exchange of information and practices
  - Collaboration on projects and initiatives
- Global communities interaction in HIV/Hepatitis/TB including HIV and viral hepatitis cure
  - Exchange of information and practices
  - Collaboration on projects and initiatives
Monitoring and evaluation
ECABs, document/protocol reviews, scientific interactions and all other activities mentioned above will be subject to ongoing monitoring and systematic evaluation.

Additional resources
The Partners in Science programme aims to uphold the principles and guidance set out in the following additional resources designed for patient engagement in medicine development:

- EUPATI Toolbox
- PARADIGM Toolbox
- PFMD tools and instruments