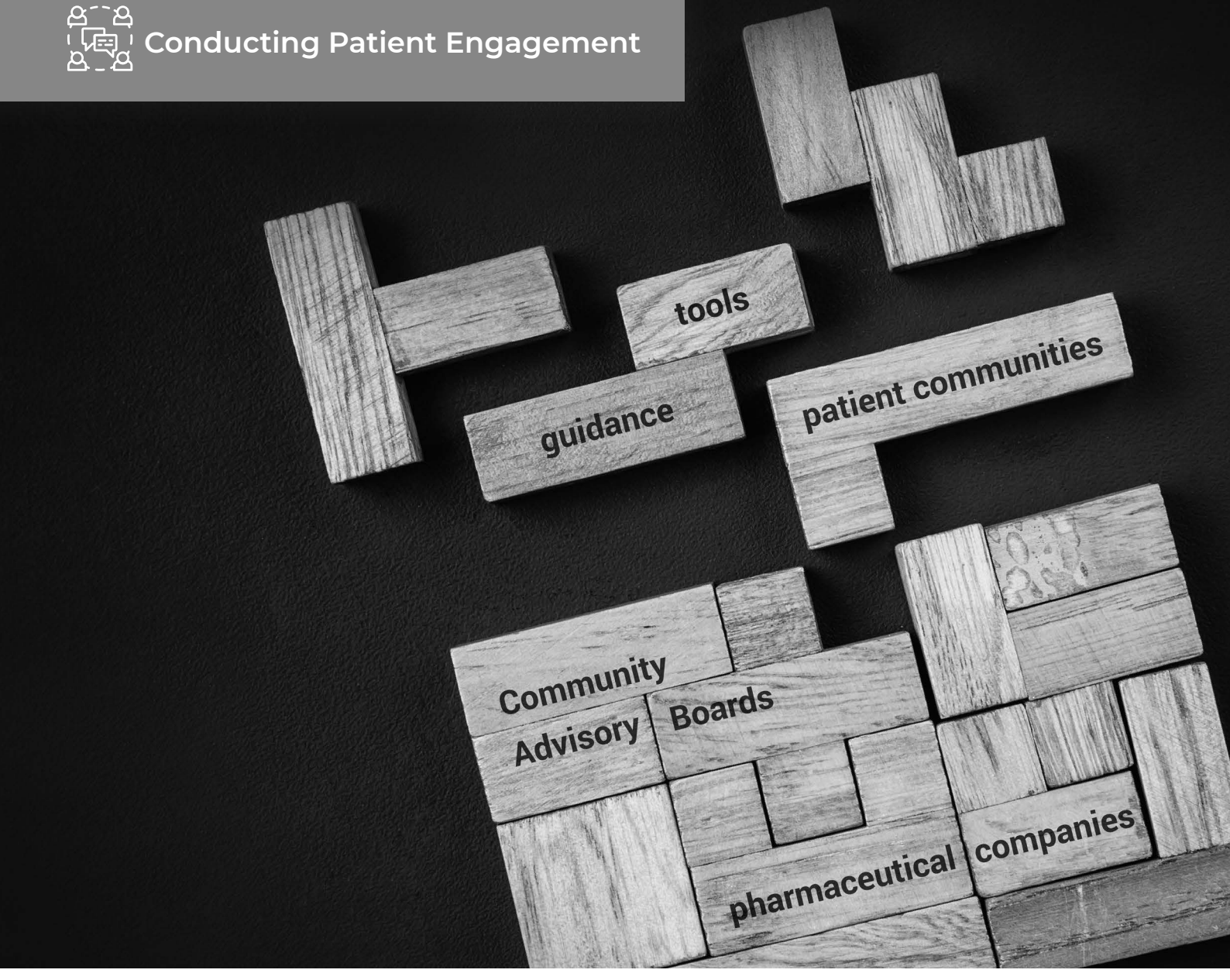
PARADIGM
Patients Active in Research and Dialogues for an Improved Generation of Medicines

innovative medicines initiative

Conducting Patient Engagement



Community Advisory Boards

Tool 1: Guidance

PARADIGM is receiving funding from the Innovative Medicines Initiative Joint Undertaking 2. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA

Introduction to the CAB toolkit

Contents

Basic information about Community Advisory Boards (CABs)

What is a Community Advisory Board?

Over the last decades, there has been an increasing recognition of the value of the contribution of patients to research. Among other ways of collaboration, Community Advisory Boards (CABs) are an important mechanism for members of the patient community to have representation in bio-medical research.

The concept of CABs was developed in the US in the 80s to address concerns of different patient communities (i.e. mental health and Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency syndrome (AIDS) groups) about the research that was conducted at the time, and it is currently a well-established model in this field.

The European Community Advisory Board (ECAB) was established by the European AIDS Treatment Group (EATG) in 1997. This approach emphasised the provision of independent input by the community of people living with HIV and AIDS on the development of and access to HIV medicines, and was therefore, a new forum for interaction between patients and industry.

More recently, and inspired by this work, there have been similar developments in the field of rare diseases and oncology. Some examples of definitions provided by patient communities working with CABs in Europe include:

- EATG defines their ECAB as “a high-level scientific platform that brings together civil society, scientific researchers, the industry and international institutions to address key science and policy issues related to HIV and its main co-infections like hepatitis C or tuberculosis”
- Myeloma Patients Europe defines the Myeloma-CAB as “a scientific working group of patient advocates to monitor pharmaceutical developments in the given disease area through active and targeted interaction and long-term cooperation with pharmaceutical manufacturers, regulators, and the scientific community working in the field. Pursuing this mission, CABs build on the work of volunteer expert patients in liaising with the industry and other stakeholders”.
- EURORDIS – Rare Diseases Europe, in their Charter for Collaboration in Clinical Research in Rare Diseases, states that “a CAB refers to a group of patients who offer their expertise”.

Although CABs can be involved in many different subjects and with different stakeholders and organisations, this Guidance document focuses on CABs in the context of medicines development and in particular, in the interactions between the pharmaceutical industry (hereafter referred to as “industry”) and patient communities.

Distinctive elements of this type of CABs are that they are initiated and driven by the patient

community (e.g. patient organisation or similar network) and that they can help to foster long-term relationships between the community and industry in order to improve outcomes for the patient community they represent. CABs can work simultaneously with different companies, but they are not related to the company and their work is independent from them.

They initiate the contact with the companies and have an active role in deciding the topics for discussion in the meeting according to what is important to the community. This typically includes aspects related to the general research conducted in a particular disease area (e.g. research and development, pipeline/ clinical trials, access to diagnostics and treatment) as well as more specific advice for trials (e.g. reviewing and monitoring clinical trials, helping to develop materials for trial participants).

This collaboration can help to make medical research and clinical studies more adapted to the needs and preferences of people affected by the condition and to address ethical issues, contribute towards the relevance and quality of the proposed research and its acceptance by the affected community, and can help to educate the patient community about research being conducted and to learn about new therapeutic options for their condition.

CABs can also address policy and advocacy issues which are a major concern for the patient community, such as access to treatment. Examples of this include:

- Obtaining treatment in territories where access to treatment is extremely limited (e.g. in case of hepatitis C in some countries or multi-drug resistant tuberculosis in Eastern Europe and Central Asia).
- Contributing to fair medicine prices and quality control where there might be inadequacy of regulations and monitoring systems.
- Bridging the gaps in communication between manufacturers, distributors, regulatory agencies and procurement agencies and the community.

For a summary of how CABs operate, please see Tool 2 “CABs at a glance”.

It is important to recognise that, in addition to CABs, other relevant frameworks of collaboration between patients and industry exist. Some examples include: patient-initiated working groups, industry-initiated advisory boards, steering committees, councils, panels etc. The decision about who to involve and the most appropriate form of collaboration should be made taking into consideration the aim of the activity, desired outcome, timeframe, budget, etc.

Examples of existing CABs in Europe

Some examples of patient communities who have developed and implemented CABs in Europe include[1]:

- **European AIDS Treatment Group(EATG):** ECAB
- **Chronic Myeloid Leukemia (CML):** CML CAB
- **Myeloma Patients Europe (MPE):** MPE CABs
- **Recent developments:** Hem CAB and Lymphoma CAB
- **The Eurasian Community for Access to Treatment:** ECAT

Some organisations have developed programmes and services to facilitate and support the development of CABs by different patient communities. Some of these include:

- The **EuroCAB programme**, developed by the umbrella organisation EURORDIS Rare Diseases Europe, assists patient organisations in setting up and structuring a CAB for their disease area.

  It includes three different modalities of collaboration between EURORDIS and the patient organisation, each of which would incur a different fee which is to be resourced from the participating company. Examples of CABs in the EuroCAB programme include the CAB on Cystic Fibrosis, Hereditary Hemorrhaegic Telangiectasia, Lymphomas, Cystinosis, Tuberous sclerosis complex, Scleroderma and Duchenne MD.
- Some other organisations such the Patvocates network in Europe and McKinsey and RX4Good in the US, have also developed programmes or services to support patient-advocacy organisations to develop or implement CABs or similar ways of involvement.

[1] Please note that this list of CABs and programmes providing support is not exhaustive and it mainly includes examples from the patient community linked to the IMI PARADIGM and EUPATI projects. Similar initiatives also exist in the US.

Points to be considered by patient communities when setting up/running a CAB

Why should a patient community consider setting up and running a Community Advisory Board (CAB)?

IIn the past, the perspective of patients in the development of medicinal products was not always sought or was very limited. More recently, the patient perspective has been considered as a way to improve outcomes for patients and to ensure that medical research and clinical studies are better adapted to the needs and preferences of patients.

Among other ways of involving patients, Community Advisory Boards (CABs) can improve research by providing direct and independent advice from the community of patients about different aspects of a clinical trial, such as the design and implementation of clinical trial protocols in ways that are more inclusive from the perspective of patients.

These activities can benefit the study participants, help ensure the scientific integrity of the research and help address the needs and priorities of the patient community.

Setting up and running a CAB requires careful planning, organisation, follow-up, monitoring and evaluation. It is important, for example, to reflect on the scope of the CAB, the resources needed and possible funding models, membership, how to organise meetings and how to monitor and look at the impact of the CAB.

There are different possible approaches to address each of these topics. Nevertheless, there are a number of common key principles shared by the existing approaches. These include:

- **Community-led:** the CAB initiates and leads processes regarding the invitation of partners from industry, development of the agenda and the preparation of the CAB meeting(s). The agenda and discussions focus on topics which are important to the patient community.
- **Independence:** CABs are independent from industry in their decision-making process.
- **Long-term relationships:** CABs are set up to promote long-term relationships between patient communities and industry, typically through regular meetings where CAB members meet with company representatives.
- **Resourced:** The administration of CABs and the running of meetings requires dedicated and appropriate human and financial resources. It is expected that the cost of CAB meetings is fully supported/ funded by the industry partners attending the meeting(s).
- **Respect:** CAB members should receive enough information to prepare for the meetings and follow-up information about the discussions and impact of their contribution. CABs can help to raise awareness and educate members of the patient community.

Main points to consider when setting up/running a CAB

Important aspects to consider include:

1. Aim and scope of the CAB
2. Human and financial resources
3. Membership
4. CAB meetings
5. Funding models and official/legal documents
6. Impact and follow-up activities

This section provides information on how some existing CABs in Europe have addressed each of these six aspects. It is hoped this information will help other patient communities to find their own approach for running a CAB. This section can be used in combination with the "Reflective questions" tool.

1. Aims and scope of the CAB

Before setting up a CAB it is important to define its purpose and scope. For example, how to define the patient community which will be represented in the CAB and what their main unmet needs in medicines research and development are, which pharmaceutical companies (or other stakeholders) to collaborate with and what the purpose of the collaboration with them may be.

How are the "aims and the scope of CABs" being addressed by some existing CABs?

- ECAB
- CML CAB
- EuroCAB programme

2. Human and financial resources

Setting up and running a CAB requires human resources, not just in terms of the CAB members who will attend the meeting, but also for the overall organisation and administration of the CAB. It is difficult to estimate the amount of human resources that are necessary for setting up and running a CAB as this may vary according to the specific community and their needs.

In general, it is advised to have a (scientific) Secretariat. Often this role is carried out by an existing patient organisation or network of patients. Depending on the size and resources, the Secretariat can provide support for different tasks such as coordinating the Call for Members of the CAB, training of members, collecting community concerns/unmet needs, organising the venue and travel of members for CAB meetings and liaising with industry. The Secretariat also often coordinates the follow-up actions and evaluation of the commitments made by companies during CAB meetings. The CAB Chair plays an important role in the overall organisation of the CAB and the liaison with industry.

Financial resources are needed for the overall administration of the CAB and to cover the costs related to the meeting (e.g. venue, participants travel and accommodation, note-taking, etc.). The cost for this will vary depending on different aspects such as the number of members who participate in the meeting, number of days dedicated to the meeting (including dedicated preparation time) and other practical issues such as where the meeting is organised. If some members need to be accompanied for travelling or have specific needs (e.g. reduced mobility,

etc.), this needs to be considered and can also affect the budget.

How are "human and financial resources" being addressed by some existing CABs?

- ECAB
- CML
- EuroCAB programme

3. CAB membership

The composition of the CAB is decided by the patient organisation/network and should include a diverse mix of experiences, profiles and skills. Each CAB should establish its own procedures for membership and decide which criteria would be required for joining the CAB and attending the meetings. All members should receive adequate information and if necessary, training to develop sufficient knowledge and competencies to understand and discuss research and development (R&D) processes.

Training of members should be planned, and the needs of existing and new members should be considered. There should also be opportunities for people with less experience or skills to participate, who can gain knowledge and confidence in providing input by attending meetings.

The recruitment of CAB members should be considered as an ongoing process and its composition should be reviewed on a regular basis. Firstly, as some people may want to commit only for a certain period of time, but also, as the rotation and inclusion of new members could help to add new or different views and perspectives to the CAB.

Finally, in order to operate in an effective, respectful and transparent way, all members should understand their roles and share common expectations of how they should work together. If disagreements arise between members, the resolution of conflicts should be planned and addressed. For instance, those planning a CAB should prepare a set of rules which illustrate how to address the conflicts, such rules should be shared with the participants before the meeting.

How are "memberships" being addressed by some existing CABs?

- ECAB
- CML CAB
- EuroCAB Programme

4. CAB meetings

Meetings of the CAB are organised regularly throughout the year, often over weekends, and typically last 2 to 3 days. Although usually CAB meetings have been mostly face-to-face, virtual meetings have also started to be organised and can be an important resource.

The decision about which companies to invite to the meeting is made by the CAB. A proposed agenda is prepared by the CAB and discussed and agreed with industry partners. The company may suggest including additional topics, which might be added to the agenda if they are of mutual benefit and are appropriate. Consideration should be given also to the amount of time that should be allocated to each topic.

The number of CAB members attending a meeting can vary depending on several aspects such as expertise, availability and budget. Although it is not possible to generalise a number, typically a minimum of 6 members attend the meeting and, in some cases, 10-12 members can be invited.

The procedure to decide which members will attend the meeting can be different in each CAB, but CABs should be open and transparent about the criteria and processes involved. Another relevant consideration is the number and profile of company representatives who should attend the meeting and how to ensure a good balance between representatives from industry and from the community

Different patient communities have different needs, and this would influence what may be necessary in terms of preparation and facilitation of meetings. As a principle, relevant materials should be sent to CAB members in advance and the venue and way in which the meeting is facilitated should be accessible and adapted to the needs of the patient community attending the meeting. The EUPATI/PARADIGM tool on recommendations for venue and hospitality when organising meetings with patients can provide useful guidance on this

On the day of the meeting, before convening the session with industry representatives, CAB members often meet to brief and prepare for the meeting. In addition, an allocated time of the meeting can be dedicated to address internal issues of the CAB (e.g. member training, community discussions, etc.).

CABs may develop internal rules about how the CAB operates and how to interact with industry during meetings. A common rule is that the information shared with members (as part of preparation or during the meeting) is considered confidential (if it is not already in the public domain). Also, materials provided to CAB members and discussions during the meeting,

should avoid any promotional, commercial or marketing messages or any content on specific medicines.

How are "CAB meetings" being addressed by some existing CABs?

- ECAB
- CML CAB
- EuroCAB Programme

5. Funding models and official/legal documents

Financial resources are needed to cover the administration and meetings of the CAB. A fair and transparent funding mechanism is crucial. The costs are expected to be fully supported or sponsored by the pharmaceutical companies involved in the meeting(s).

CABs should be transparent regarding the amount of funding and support received from industry, as well as the payment received by members of the CAB and the costs which have been covered or reimbursed.

There are no standard figures about the overall cost of organising a CAB meeting. However, the following costs are typically considered for calculating the budget:

- the administrative costs of the Secretariat,
- the meeting room,
- travel and accommodation expenses of CAB members,
- other costs related to remunerating members for specific tasks (e.g. for notetaking) or compensating CAB members when attending meetings.

In some CABs, members participate in the meeting on a voluntary basis (i.e. unpaid), whereas in others, CAB members are remunerated for their time. Some of the CAB members might also be contracted (i.e. paid) to carry out a particular task (e.g. minute taking, chairing, etc.). To cover these costs, different funding models between the patient organisation/CAB and industry are possible. In some cases, this may involve a general financial agreement or sponsorship arrangement with the patient organisation/CAB where the CAB meetings are included.

Another relevant aspect of CABs are legal documents such as contracts, Memoranda of Understanding (MoU), confidentiality agreements, etc. These documents outline the terms

and conditions of the collaboration between the CAB and the company, and can cover points such as confidentiality, conflict of interest, intellectual property, copyright, data protection and compensation, among others.

Members of a CAB should have a clear understanding of aspects such as confidentiality, conflict of interest, and, if their contribution is paid, how payment may impact on their annual taxes. It is recommended to set up agreements for patient organisations running CABs or for individual CAB members outlining the terms of the engagement (e.g. role in the meeting, date and duration of the meeting, confidentiality, payment terms, reimbursement of travel expenses, etc.) For further information please look at the PARADIGM tools for the management of competing interests and conflicts of interest.

Currently, the contract/confidentiality agreements are often prepared by the industry, and each company uses their own models. The WECAN project "Reasonable agreements between patient advocates and pharmaceutical companies (RAPP)" has developed guiding principles that provide the guiding baseline for the development of more accessible contracts and contract templates as well as a toolbox for patient advocates and companies. For further information about the RAPP project please visit https://wecanadvocate.eu/rapp/.

PARADIGM has collaborated with this initiative to make these documents more accessible.

How are "funding models and legal documents" being addressed by some existing CABs?

- **ECAB**
- **CML CAB**
- **EuroCAB Programme**

6. Impact and follow-up activities

After the meeting, the minutes are prepared by the CAB and agreed on with the company representatives. This also includes a compilation of the issues which require further follow-up after the meeting (e.g. responses to the questions raised in the meeting which require further work or input from the company). Industry representatives and CAB members receive a copy of the minutes and follow-up actions.

The overall evaluation and monitoring of the work of the CAB and industry is a topic which has often been neglected. The PARADIGM project has worked with different existing CABs (e.g.

ECAB, EUROCAB) and helped them develop a tailored impact framework.

How are "impact and follow-up activities" being addressed by some existing CABs?

- ECAB
- CML CAB
- EuroCAB Programme

Points to be considered by pharmaceutical companies collaborating with CABs

1. What is a Community Advisory Board and why should a pharmaceutical company consider participating in a Community Advisory Board meeting?

Community Advisory Boards (CABs) offer strategic advice from a patient perspective on industry projects in a certain disease area. They are driven by the patient community (e.g. patient organisation or similar network) and therefore, they invite industry, set the agenda and timing and will ask for input on these from the participating company.

As the meeting agenda is driven by patients, new or different aspects might be discussed which the company would not have considered themselves.

This can include aspects related to the general research conducted in a particular disease area (e.g. research and development, pipeline/ clinical trials, access to diagnostics and treatment) as well as more specific advice for trials (e.g. reviewing and monitoring clinical trials, helping to develop materials for trial participants). CAB meetings are usually recurrent events over a period (e.g. once or twice a year). Typically, companies are invited one by one to a private, confidential discussion.

Companies participating in these meetings should be prepared to contribute to the costs and expenses of the members for the CAB. In some cases, a company might decide to decline the invitation to work with a CAB due to a multitude of reasons (e.g. resources, financial restrictions). Based on their nature, CABs can be ideal for longer-term cooperation with patient organisations/ networks. It facilitates long-term understanding of what occurs in the community; which aspects are important to the members and what changes over time.

It can also allow a company to look at changes it can make to the way it operates to positively affect outcomes over time. On the other hand, it can foster the capacity-building of the patient community which may result in improved understanding and a more efficient interaction over time.

2. What to expect from a CAB?

CABs are open, two-way discussions providing advice on strategic and practical aspects on pre-defined and agreed topics in a disease area. Often, an outcome of the meeting is a report (e.g. minutes of the meeting) which is produced by the CAB. This typically contains details of the discussions during the meeting and recommendations, but it may also contain requests for

further clarification or follow-up actions.

Confidentiality issues should be discussed and agreed with the CAB prior to the meeting and it should be clear which aspects can be shared publicly (e.g. with other members of the patient community) and which ones are not for broad dissemination and should remain confidential.

3. How to prepare for a CAB meeting?

3. 1. Discuss the agenda proposed by the CAB

The CAB will propose an agenda. Companies will have the opportunity to discuss details with the organisers and can propose to add additional topics of mutual interest to the agenda.

Examples of topics that can be covered in a CAB include (non-exhaustive list):

- Disease area strategy of the company (long-term presence and involvement of the company in a disease area)
- Upcoming trials including access to trials in countries with specific barriers
- Review of protocols (detailed protocol review may happen as a follow-up outside the CAB meeting). The high-level review by a CAB may include inclusion and exclusion criteria, geographic spread, etc.
- Discussion of data (presented at congresses or in peer-reviewed publications) to better understand implications for treatment, drug interactions, pharmacokinetics, etc.
- Discussion around access to medicines
- Discussion around tools and service

Important:

In countries with no direct-to-consumer advertisement law, patients and patient organisations are considered general public and therefore laws and industry codes govern engagements with the patient community.

For example, this includes the prohibition of any promotion, marketing, advertisements or commercial discussions around specific medicinal products.

3. 2. Do you have any topics or projects that you may want to add to the discussion?

The agenda proposed by the CAB should be carefully reviewed. Consideration should

be conducted if there is a need for additional questions. A proposal of additional topics should be discussed with the CAB organiser in a timely manner.

Prior to this conversation, companies should ensure they have a clear agreement with the organisers on the topics where patients' insights are required and whether a CAB is the optimal platform to obtain this information. They should also be prepared that, for different reasons, in some cases it might not be possible to add the suggested topics to the agenda.

3. 3. Prepare to ensure a follow-up after the CAB

After the meeting, generally, the CAB will provide a report of the meeting (e.g. the minutes) and will highlight the topics that were discussed that need to be followed-up (see also 4.1).

Examples of these follow-up topics are:

- Questions raised for which the company representative present at the meeting did not have all
- the answers and needs further clarification with in-house specialists.
- Issues raised that need resolution by the company
- Suggestions on changes in strategy, trials, protocols, etc.

3. 4. Working closely with the Legal & Compliance team and understanding the regulatory environment

It is advised to involve the Legal and Compliance team as early as possible in the discussion. Consider that not all Legal and Compliance associates will be familiar with CABs, even if the company has been active in this area before. Therefore, dedicate sufficient time educating them on this topic, e.g. by using this tool.

Companies may want to consider conducting a risk-based assessment of a CAB. This might help to identify any potential risks and stipulate timely mitigation actions. These risks may be company internal, such as additional contractual confidentiality clauses needed, copy right permissions to be obtained, internal review and approval processes including several other countries, etc.

However, they could also be externally driven by different country regulations (in the location where the CAB meeting is taking place). For example, some countries prohibit

sharing of non-publicly available information with individual patients, there might be a restriction on questions that can be asked, or participation of associates from certain functions such as commercial may be prohibited, etc.

As a part of the initial assessment, companies should also review potential conflict of interest (CoI) for themselves, the organising patient organisation/network or other CAB participating competitors. There might be a need to introduce and agree on additional confidentiality measures. Please also see the PARADIGM tools for the management of competing interests and conflicts of interest.

Some organising patient organisations/networks might have agreement templates for the CAB. Others will require companies to prepare an agreement. In any case, legal departments must be involved and ensure adequate clauses are included in the contract. Companies should ensure to communicate the rationale for specific clauses, such as specific country limitations.

3. 5. Selecting the right representatives from industry to attend

It is very important to carefully consider who to select as the standing industry representative at a CAB meeting. They should:

- Have the necessary qualifications and expertise to answer questions and actively discuss the topics on the agenda
- Be open and able to listen and know how to interact with the patient community
- Have the seniority and decision-making authority needed
- Have the ability to commit to the long-term nature of CABs to ensure the best possible outcome

The number of representatives from the company who will join the meeting may need to be discussed in advance with the CAB organisers.

As a general guidance there should be one or two standing members as main representatives (e.g. from the Patient Engagement or Communications function) with additional experts joining depending on the topic. These standing members should recruit and prepare any new participants. The following two aspects should also be considered when selecting ad-hoc CAB attendees:

- Only active contributors to the discussion should attend. While the CAB can be an opportunity for the company to learn, it should not be seen as a training opportunity.

- Associates should be from functions permitted to attend CABs according to local country regulations.

In addition, appropriate infrastructure should be established from the beginning to ensure knowledge transfer to new industry members as part of their induction but also in case the responsible industry members change. This could be a central database where not just all key documents (e.g. meeting minutes, reports, etc.) are kept but where key milestones, agreed deliverables, etc., are being tracked and stored.

3. 6. Materials used

Should a company intend to share materials prior or during the event, it must be fully approved for external use and adequately classified (strictly confidential, confidential, public use, etc.). Approval will depend on company and local regulations, but may include legal, regulatory and medical review.

Enough time should be planned for the review and approval of materials. If publications will be shared, distribution permission (copyrights) must be in place. To ensure optimum advice, materials should be sent to the CAB organisers with enough time. The amount of time needed for this should be agreed with the CAB organisers.

3. 7. Briefing industry participants

To ensure optimal outcome of a CAB, it is essential to brief and train all company participants ahead of the meeting. CABs are a new concept of engagement in many disease areas, company representatives might not yet have a lot of experience.

It is important to ensure that the participating associates understand their role and responsibility but also their limitations (i.e. what they cannot discuss, what they may not be able to answer, what input they may not be able to receive). Please also see the briefing tool.

3. 8. Meeting timings and managing agenda expectations

The CAB organiser and the industry organisation will have the opportunity to discuss the proposed agenda. Additional topics suggested by industry should be of mutual interest for the patient community and the company. There should be realistic time allocated to topics to be discussed. Being overly ambitious on the number of topics suggest to be added for the session should be avoided.

It is important:

- That the agenda proposed by the CAB is discussed and agreed on well in advance of the meeting The responsible person within the company managing the CAB participation needs to carefully review the agenda and if appropriate, suggest any potential additional action items to the CAB organisers.
- To identify internal experts and secure their participation at the CAB.
- That any material or data needed (e.g. publication, internal study data, etc.) are timely approved for external use.

3. 9. Securing recurrent budget to cover the costs of the CABs

- CABs are funded by the companies who are invited to participate with them. This can either be done as cost per meeting or be part of the overall funding support to a patient organisation/network.
- As the nature of CABs are longer-term, companies should consider how to secure sustainable financial support stretching beyond the annual budget planning cycle (e.g. budget cuts, re-prioritisation of funds, turn-over in staff). Internal functions such as finance can be instrumental in ensuring budgets will be secured.

4. After the meeting

4. 1. What to expect after the meeting?

The CAB organisers will provide a report (i.e. the minutes) with details of the topics discussed, and in some cases recommendations and a list of questions that remain open or topics that needed further follow-up (see also 3.3).

The CAB will usually be responsible for the minute-taking and the preparation of the minutes. It is important for companies and the CAB to align on the next steps and follow-up actions, and for companies to recognise that there are multiple stakeholders involved in the process and that CABs tend to have fewer resources available.

4. 2. CAB output

Once companies receive the CAB report, all open questions should be answered in a timely manner. If needed, an internal debriefing meeting to discuss the results and agreed steps should be set up, alongside an action plan.

CAB organisers should be provided with an overview on the progress of the agreed action points or how the company has embedded the advice provided.

4. 3. How to ensure efficient communication

Irrespective of whether a company engages in a one-off meeting or works over a longer period, a single point of contact between the patient organisation/network and the company should be established.

4. 4. Ongoing relationships between company and patient community

Via the single point of contact, the outcomes of the meeting (e.g. meeting reports, action points, etc.) should be communicated internally to the appropriate functions.

4. 5. Evaluating your work with CABs

Short- and long-term evaluation should be considered. Whenever possible, the evaluation of the engagement with the CAB should be communicated to the CAB.

The short-term evaluation could consider, for example, changes made in strategy, trials or access approach and the responses to topics that needed clarification in the CAB meeting. The long-term evaluation could focus on issues such as success of trials, the time needed to provide access and feedback of end-users via advocacy channels or following the CAB meeting.

The PARADIGM project has worked with different existing CABs (e.g. ECAB, EuroCAB) and industry and has helped them develop a tailored impact framework.