



Patient Engagement Tools

Session #2

09 July 2020

Welcome to the Patient Engagement Open Forum virtual session

Patient Engagement Open Forum is a series of virtual events (in 2020) where we will work together, in a multi-stakeholder context, **to turn patient engagement from an aspiration into reality.**

The Forum aims to provide **a holistic perspective** of patient engagement, the **landscape and actors**, and **foster collaboration** and **co-creation** while **breaking down fragmentation** that are often present in patient engagement work.

Patient Engagement Open Forum Agenda in 2020

June 25th

PEOF2020 opening plenary (PARADIGM, PFMD and EUPATI)

Parallel sessions:

- Patient Engagement tools session #1 (consultation organised by PARADIGM)
- Patient engagement within MedTech (panel organised by EUPATI)
- Patient experience in regulatory processes (workshop organised by PFMD)

June 26th

Parallel sessions:

- How to engage patients in the early phases? (workshop organised by PFMD)
- Patient engagement in co-creating plain language summaries (workshop organised by PFMD)
- National Health Council Patient Engagement Fair-Market Value Calculator Toolbox (organised by NHC)

TODAY

July 9th

Parallel sessions:

- Patient Engagement tools session #2 (consultation organised by PARADIGM)
- Flash presentations
 1. Sustainability roadmap for the patient engagement ecosystem
 2. Patient engagement agreements explained
 3. Patient engagement in medicines R&D in the CEE region
- Motherhood should not be a fight – better safety information on medicines use during pregnancy and breastfeeding, with patients for patients. (Workshop organised by IMI-Conception)

September 10th

Plenary session

- PARADIGM Patient Engagement Toolbox (webinar organised by PARADIGM)
- Patient Engagement Monitoring and Evaluation Framework (workshop organised by PARADIGM)

September 24th

Parallel sessions:

- How PE can foster access through improved affordability? (webinar organised by EUPATI)
- Patient engagement in clinical trial phase or/and in the regulatory submission phase (workshop organised by PFMD – to be confirmed at a later date)
- From diagnosis to treatment and beyond: personalised medicine – what's in it for patients and how to make it available to patients who could benefit from it? (workshop supported by PFMD)

October 15th

Parallel sessions:

- Patient Engagement and Quality by Design: Co-Developing an Implementation Roadmap for Clinical Trials (organised by CTTI)
- Good Lay Summary Practice, communicating trial results to the general public – How patient engagement can work (organised by EFPIA and EFGCP)

November 5th

THEME: Regulatory

November 23rd

Plenary session:

- PEOF2020 conclusion session

Let's work together to spread the word

#PEOF2020

@imi-paradigm

@eupatients

@PFMDwithPatient

Be Aware:

Sessions will be recorded to support preparing the workshop minutes; once done all recordings will be deleted (GDPR)

Work Package 4 – Outcomes

Raising awareness on managing competing interests in a multi-stakeholder environment: Guidance to patients and engaging stakeholders

Community Advisory Boards: guidance document and templates

Reporting and Dissemination: Guidance & Template for Patient Engagement Activities

Recommendations on the required capabilities for Patient Engagement + practical tools

Enhancement EUPATI industry guidance: suggested working practices, checklists

Recommendations for HTA bodies on patient engagement in early dialogue

Recommendations on how to find the right match for the right patient engagement activity

Code of conduct: for all stakeholders involved in patient engagement activities in medicines development

**Legal toolkit: For collaborations between the patient community and other stakeholders
(Lay language explanations on terms in legal agreements developed by PFMD and WeCan)**

Key Aims

- ❑ Overall feedback on the usability and practicality of the tools
- ❑ Refinement of the presented tools using insights and suggestions from participants
- ❑ Acceptance of the conveyed principles

Agenda

- 15:00 – 15:10 Welcome and introduction **Almost done**
Wolf See (Bayer) and Karina Huberman (EATG)
- Presentation of PARADIGM tools followed by Q&A***
- 15:10 – 15 :45 Community Advisory Board – Guidance document and templates
Ana Diaz (Alzheimer Europe)
- 15:45 – 16: 20 Enhancement of the EUPATI industry guidance
Kay Warner (GSK)
- 16:20 – 16:55 Code of Conduct
Ingrid Klingmann (EFGCP)
- 16:55 – 17:00 Wrap up

One last remark

The public consultation on the PARADIGM tools that will be presented in this session is ongoing.

Please respond

You can access and take part in the consultation here:
<https://imi-paradigm.eu/tools-consultation/>

Community Advisory Board – Guidance document and templates

The Actors



Working with Community Advisory Boards:
Guidance and tools for patient communities
and pharmaceutical companies

Copyright 2020 PARADIGM – Working with Community Advisory Boards: Guidance and tools for patient communities and pharmaceutical companies



Ana Diaz
Alzheimer Europe



Manuela Bruegger
Novartis



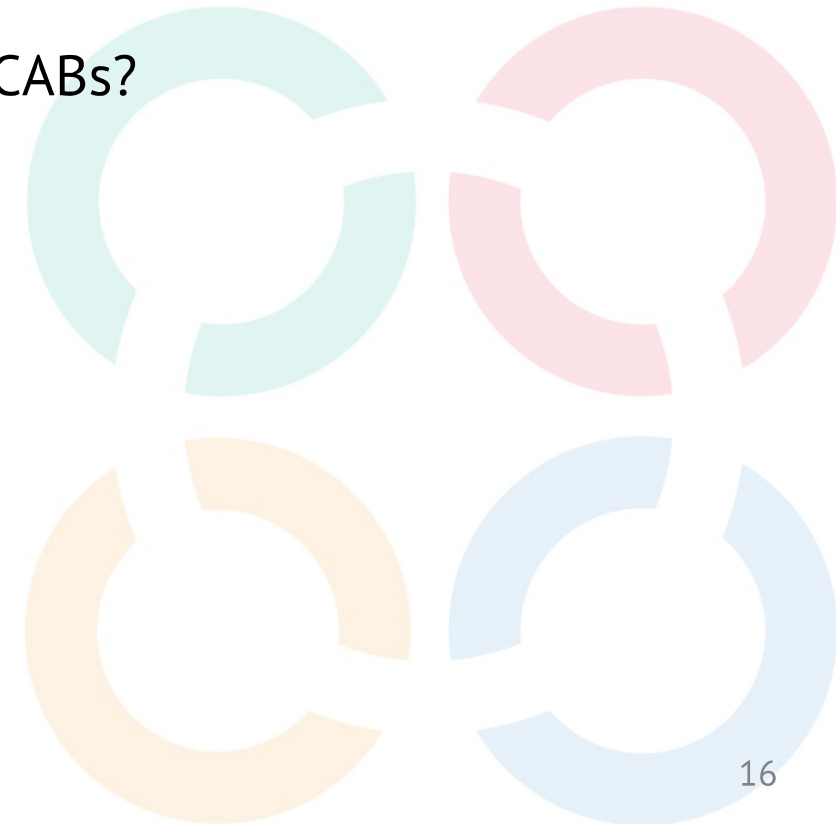
Giorgio Barbareschi
EATG



Daniel De Schryver
Janssen

Points to consider for the discussion

- Do you find the overall organisation of the tools easy to consult? If not, what would you change?
- In general, do you find these tools useful and practical? If not, what would you change?
- Do you think that providing examples can be of help to plan CABs?
- Which tool do you find more useful?



What is a Community Advisory Board?

- Community Advisory Boards (CABs) are an innovative concept, developed some decades ago in the United States and more recently in Europe, to establish long-term relationships between the patient community and industry in order to encourage patient engagement and input in the medicine research and development lifecycle.
- There are a number of patient communities working with CABs.
- Although other relevant ways of collaboration between patients and industry exists, a key element of this approach is that CABs are initiated and driven by the patient community.
- The decision about the most appropriate form of collaboration should be made taking into consideration the aim of the activity, desired outcome, timeframe, budget, etc.

How were the tools developed?

The CAB tools are the result of a close cooperation & partnership between the patient and industry stakeholders.



- Online searches for available information and materials and small survey to PARADIGM partners about their experience and work with CABs
- Involved representatives of the three main European CABs (EATG, EuroCAB, CML CAB) to provide further information, to review the materials and also some other colleagues at Novartis with experience with CABs
- In March 2020: two parallel workshops with representatives from the patient community, academia, companies and HTA.
- In May 2020: taskforce, composed by a mixed-group of representatives of patient organization and industry, provided final input on the 8 CAB tools
- The final documents are currently in the PARADIGM Public Consultation

Some relevant ideas:

- Often, lack of information and awareness about CABs and their role
- Different approaches and needs (e.g. communities starting work with CAB or planning vs communities with several years of experience)
- Planning and monitoring the work in the long term is very important and can be at times challenging



Tools At a Glance

Tools with information / to raise awareness

- ❑ Tool 1 “Guidance document” (PO, I)
- ❑ Tool 2 “At a glance” (PO, I)
- ❑ Tool 6 “Value adding factors of a CAB from a pharmaceutical company perspective” (I)
- ❑ Tool 8 “Examples of successful stories in CABs” (PO, I)

PO = Patient Organization, I= Industry

Tools for planning / working with CABs

- ❑ Tool 5 “Reflective questions & tracking Tool” + Tool 1 “Guidance document” (2 and 3) + Tool 3 “Comparative table” (PO,I)
- ❑ Tool 4 “Checklist of templates and documents” (PO)
- ❑ Tool 7 “CABs: practical briefing guidance for pharmaceutical companies” (I)

Examples of three of the Tools (tool 1, 5 & 7)

Tool 1: Guidance

Basic information about CABs

- Targeted at any person with a general interest in CABs.
- It provides a general description of CABs, how CABs are different from other models of patient-engagement and describes some existing CABs and related programmes in Europe.

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

- Targeted at patient communities which may want to establish or are already running a CAB.
- 6 topics: 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
- For each, information is provided about how existing CABs are addressing the topic
- By providing different examples and approaches, it is hoped that it helps other patient communities in developing and finding their own ways of working
- It does not provide recommendations or prescriptive guidelines about how to establish or run a CAB.

Points to be considered by pharmaceutical companies collaborating with CABs

- Targeted at representatives from industry who are already collaborating or would like to start a collaboration with CABs.
- It provides a perspective of relevant points to consider when invited and collaborating with a CAB.



Community Advisory Boards

Tool 1: Guidance

4. CAB meetings

Meetings of the CAB are organised regularly throughout the year, often over weekends, and meetings typically last 2 to 3 days. The exact number of CAB members attending a meeting will vary depending on several issues, such as the available budget, among others. 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.

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 the way 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 content on specific medicines. Another important decision is related to 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.

How are “CAB meetings” being addressed by some existing CABs?

- [ECAB](#)
- [CML CAB](#)
- [EuroCAB Programme](#)

Tool 5: Reflective questions

- It aims to stimulate reflection about different aspects to consider when setting up or running a CAB
- The reflective questions are organised around six different topics which coincide with the sections of the Guidance Document.
- The user can select from each topic the sections and questions which are relevant to him/her at a particular point in time.

Area 4: CAB meetings

Patient Community

Meetings

1. How will it be ensured that the meeting is meaningful for all involved and aligned with the aims and priorities of the CAB?
2. How will the CAB work with each company to organise the meeting and to ensure a two-way dialogue in all relevant issues?
3. How and where will the meetings be organised (e.g. face-to-face, virtual meetings? If face-to-face, same country for all meetings, rotating system etc.)?
4. How long and on which day(s) should a CAB be planned? How can this respect the need of participants (e.g. over weekends for those attending on a voluntary basis, in the first half of the day for those with fatiguing conditions, etc.)
5. How many participants should be invited from both community and industry?
6. Who will moderate the CAB meeting? Who will take the minutes?
7. Will there be a briefing session with members before the meeting and a debriefing afterwards?

Members attending meetings

8. Which procedure and selection criteria may work best for your patient community to decide which members will attend the meeting? Who will be in charge of these procedures and decisions?
9. Which needs of the patient community should be considered when planning the meeting (e.g. mobility problems, fatigue, cognitive problems)? Which type of support will you provide to CAB members?
10. What pre-meeting material do you plan to share in advance of meetings? What should be considered when preparing this material? What timelines will be required for the pre-meeting material (e.g. not to receive materials the day before of meeting so conversations can be as rich as necessary)

Industry

1. How will the company representatives attending the CAB be optimally prepared?
2. What and when pre-meeting materials need to be sent to allow sufficient lead time for CAB members to prepare?
3. Have all relevant company functions such as Legal, Compliance, Finance, been engaged early on to ensure full compliance with laws and regulations and review and approval processes?

Tracking - Stakeholder:

Area & question number	Actions	Challenges	Follow-up		Achievements
			Who?	When?	



Community Advisory Boards

Tool 5: Reflective questions & tracking tool

Tool 7: Briefing guidance for companies

- It is recommended to brief pharmaceutical company associates prior to a CAB, as it is good practice for every external event.
- Explaining the objective of the CAB, how it works and some practical tips will ensure associates are optimally prepare for the meetings.
- This becomes especially important for associates with no or little experience with CAB



Community Advisory Boards

Tool 7: Practical briefing guidance for pharmaceutical companies

Practical tips - things to keep in mind

Refrain from using acronyms, short forms used inside a company

CAB participants do not understand the many acronyms and short forms that are used within a pharmaceutical company (and they also vary from one company to the other). The use of such terms may slow down their comprehension. Practice eliminating such terms in speech and slides and/or spell them out if used.

Be prepared to be challenged

Be prepared for high-level and well-informed questions. POs may challenge independent of function or hierarchy with quotes from press releases and evidence from peer-reviewed publications. Assume POs know the basics, pitch the information accordingly and check frequently for comprehension ('Am I making sense?', 'Are you following me?', 'Any questions so far?'). POs will tell you if they do not understand.

Seek understanding

If challenged, ask open-ended questions and ensure to get the clarification needed. Avoid using phrases like:

- "We can't talk about that because of legal/compliance reasons".
- "We're a big company and change takes a long time."
- "There's no way we could ever do that for A, B, C reasons."
- "It doesn't matter what Health Care Professionals (HCPs) or patients think. This is what regulatory agencies expect from pharma."
- "It's too late to change that now. We can't do anything about it."

Listen

Knowledgeable patients are assertive and can, at times, get quite emotional. Remember that they are talking about their own lives, the lives of loved ones or of those they represent. Don't let these emotions get in the way of an open dialogue. Acknowledge their feelings, ideas and thoughts.

Be open, honest and transparent

The POs have signed confidentiality agreements. Information should be shared freely within the comfort zone of the pharma representative. Be honest when you don't know something

Annexes 3: Acknowledgments

Lead contributors

- **Giorgio Barbareschi** (EATG)
- **Ana Diaz** (AE)
- **Manuela Bruegger** (Novartis)
- **Daniel De Schryver** (Janssen)

Other contributors

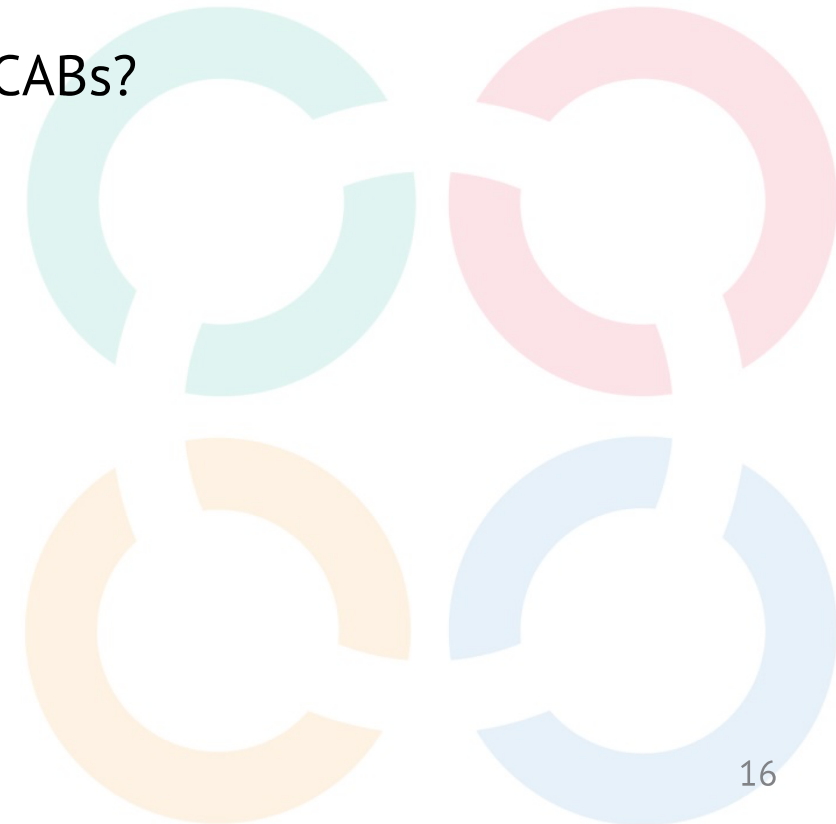
- **Rob Camp** (Eurordis)
- **Jan Geissler** (Eupati/ Patvocates/ CML)¹
- **Tatyana Khan** (EATG)
- **Giulio Maria Corbelli** (EATG)
- **Fiona Greenhalgh** (EATG)
- **Dianne Gove** (AE)

Reviewers

- **Tamás Bereczky** (Eupati/Patvocates)
- **Apostolos Kalogiannis** (EATG)
- **Karina Huberman** (EATG)
- **Wolf R. See** (Bayer)
- **Laura McKeaveney** (Novartis)
- **Iris Van den Brande** (Roche)
- **Carol Priestley** (Covance)
- **Lukas Eichmann** (Novo Nordisk)
- **Anne-Claire Julianne** (Servier)
- **Lidewij E. Vat** (Athena -VU Amsterdam)
- **Stuart Faulkner** (CASMI-OXFORD)
- **Michaela Dinboeck** (Novartis)
- **Paul Robinson** (Merck Sharp & Dohme)

Points to consider for the discussion

- Do you find the overall organisation of the tools easy to consult? If not, what would you change?
- In general, do you find these tools useful and practical? If not, what would you change?
- Do you think that providing examples can be of help to plan CABs?
- Which tool do you find more useful?





Enhancement EUPATI industry guidance

The Actors



Kay Warner
GSK



Ingrid Klingmann
EFGCP



Enhancement EUPATI industry guidance: Suggested working practices



Enhancement EUPATI industry guidance: Events and hospitality

Key points

- advice given is not intended to be exhaustive or applicable at all times
- judgement is needed on whether a recommendation can, should or must be followed
- both guidance documents and tools can be applied to patient engagement related to a specific disease; or for input/colloboration in areas unrelated to a disease
- links to other PARADIGM tools and guidance and PEQC

Suggested working practices: purpose

- provide more detail on how an engagement could be defined with specific actions
- describe what should happen during pre-engagement planning and discussions
- ensure mutually beneficial interactions with adequate preparation

TOOL: Checklist

- designed to help organisers planning patient engagement activities
- addresses the PARADIGM recommendations on the required capabilities for patient engagement
- self-assess the quality of preparedness and identify areas for improvement

Appendix 1 – Suggested working practices checklist

This checklist has been designed as a practical tool which may be used during pre-engagement planning of patient engagement activities. It defines specific actions that may be appropriate to the activity and can aid discussions to ensure mutually beneficial interactions with adequate preparation.

Action & associated description	Yes	No	Comments & self assessment (good, moderate, poor, Not applicable) (Aim to reach at least "moderate")
Is the purpose of the activity and the rationale for engaging patients clear? Refer to National Health Council Patient Activities in Medical-Product Development Framework (Patient Activities Framework)	<input type="checkbox"/>	<input type="checkbox"/>	
Are the main topics/areas that will be part of the activity defined?	<input type="checkbox"/>	<input type="checkbox"/>	
Is it clear when the activity should start and by when the results are needed? Indicate any flexibility in these timelines (+/- weeks/months), often patient identification can take longer than anticipated, depending on topic under discussion, stakeholder's capacity and capability	<input type="checkbox"/>	<input type="checkbox"/>	
What time commitment is required from patients? This should include pre-read, preparation time as well as time in the activity	<input type="checkbox"/>	<input type="checkbox"/>	
Is there a central point of contact for the patients? Someone who can coordinate the patient engagement throughout, be on hand to liaise with patients before, during and after the activity. Do not underestimate how important this is for patients but also to follow data privacy regulations (e.g. restrict the exchange of personal information allowing the identification of a patient)	<input type="checkbox"/>	<input type="checkbox"/>	
Are the defined aims, priorities, expectations and purpose of the activity aligned with	<input type="checkbox"/>	<input type="checkbox"/>	

Action & associated description	Yes	No	Comments & self assessment (good, moderate, poor, Not applicable) (Aim to reach at least "moderate")
Have the roles and responsibilities of all individuals involved been defined and agreed? Provide in a clear and accessible manner, in writing including a plan to be maintained throughout the project/timeframe of interaction.	<input type="checkbox"/>	<input type="checkbox"/>	
Have rules of engagement been defined in terms of format? For example face-to-face, online meetings etc, frequency, and time commitment (including payment if applicable)	<input type="checkbox"/>	<input type="checkbox"/>	
Is there agreement on what can be shared between the different participants involved?	<input type="checkbox"/>	<input type="checkbox"/>	
Have conditions for patient interaction with each other and other patients outside of the group been agreed?	<input type="checkbox"/>	<input type="checkbox"/>	
Has sufficient budget been secured to reimburse patients for time and expenses (where allowed)? Don't forget to allow for any patient organisations costs, audio/visual recording, transcription services, service providers, etc.	<input type="checkbox"/>	<input type="checkbox"/>	

Respect and accessibility

Action & associated description	Yes	No	Comments & self assessment (good, moderate, poor, Not applicable) (Aim to reach at least "moderate")
Is the PE activity established as an equal partnership, with mutual trust, respect and transparency?	<input type="checkbox"/>	<input type="checkbox"/>	
Has consideration been given to where patients are acting as consultants?	<input type="checkbox"/>	<input type="checkbox"/>	
Does the activity consider the diversity, rights and autonomy of the individuals involved?	<input type="checkbox"/>	<input type="checkbox"/>	

Representativeness

Action & associated description	Yes	No	Comments & self assessment (good, moderate, poor, Not applicable) (Aim to reach at least "moderate")
Is it determined how patients will be identified, e.g., through patient organisations (via existing relationships/new approaches), through Healthcare Professionals, experts, institutions, etc., and method of outreach (such as open letter or adverts)? Refer to PARADIGM's recommendations on How to find the right match for the right patient engagement activity	<input type="checkbox"/>	<input type="checkbox"/>	
Do the patients or patient groups identified fully represent the topic of the planned PE activity?	<input type="checkbox"/>	<input type="checkbox"/>	
Can the patient organisation involved represent the patient community?	<input type="checkbox"/>	<input type="checkbox"/>	
Does the plan aim to engage patients who reflect the diversity of the target population, patients' circumstances and vulnerability and clinical representativeness of the indication under discussion?	<input type="checkbox"/>	<input type="checkbox"/>	
Does the plan aim to engage with underrepresented groups who are appropriate to the population and questions being asked (sometimes referred to as seldom-heard) or vulnerable populations with specific needs? If so make sure you have adapted the engagement to the needs and possibilities of these groups	<input type="checkbox"/>	<input type="checkbox"/>	
Have the challenges and barriers for engagement of a given community been understood so that flexibility with different methodologies can be considered to achieve appropriate patient representativeness?	<input type="checkbox"/>	<input type="checkbox"/>	
Has geographical diversity been considered	<input type="checkbox"/>	<input type="checkbox"/>	

Transparency in communication and documentation

Action & associated description	Yes	No	Comments & self assessment (good, moderate, poor, Not applicable) (Aim to reach at least "moderate")
Has an appropriate agreement and contract been prepared and agreed with consideration for confidentiality clauses included where appropriate? Refer to guiding principles and contract templates developed by WE CAN/PFMD/MPE. Refer to Patient engagement agreements explained	<input type="checkbox"/>	<input type="checkbox"/>	
Is it ensured that communication to participants is transparent throughout the project?	<input type="checkbox"/>	<input type="checkbox"/>	
Does the appropriate contract account for differences between involving individual patients vs patient organisations?	<input type="checkbox"/>	<input type="checkbox"/>	
Does the confidentiality agreement and contract clearly describe the activity and its objectives, the nature of the interaction, consent (if relevant*), release, confidentiality, compensation, data privacy, compliance, declaration of conflict of interest, timelines and not limit appropriate knowledge sharing? Note: Clauses will be different depending on whether you are involving individual patients or patient organisations * remember to respect the autonomy of the person and for vulnerable populations legal capacity to sign may be different	<input type="checkbox"/>	<input type="checkbox"/>	
Does the confidentiality agreement take into account the possibilities of the individual patients in terms of having their names mentioned outside of the project, their options for compensation, contact person within the company?	<input type="checkbox"/>	<input type="checkbox"/>	
Has a generic discussion guide with questions been developed to ensure consistency in	<input type="checkbox"/>	<input type="checkbox"/>	

Events and hospitality: purpose

- provide more detail on level of attention needed when arranging patient engagement activities
- consider specific patient needs for travel, meeting venues, accommodation and associated elements
- ensure patients have the best experience
- describe what should happen during pre-engagement planning and discussions

TOOL: Checklist

- designed to help organisers planning patient engagement activities
- high level considerations, not exhaustive list
- best practice: to have basic knowledge of the disease, symptoms before you start

Appendix 1 – Events and hospitality checklist

This checklist has been designed as a practical tool which may be used during pre-engagement planning of patient engagement activities. It defines high level considerations for events and hospitality and is not intended to be an exhaustive list. Best practice is to have basic knowledge of the disease, typical symptoms and then apply as appropriate for the patients being engaged and their associated needs.

Considerations	Comments
Travel	
Identify in advance the patient's travel preferences, plus understand (and if possible) support the provisions patients may need to make at home to allow them to participate (i.e., childcare, eldercare).. For example, they may prefer train travel to flights. Try to achieve these where possible. Consider patient journey from start to finish. Identify all points of the activity requiring transport:	
Think about travel from the patient's home to the airport/ station and return journey home	
Avoid long transfer times and instances where heavy traffic is likely. Arrange assistance and adapted vehicles for meet-and-greet service at meeting destination and airport or train station if required. Arrange for similar transport to restaurants if required.	
Can early starts be avoided by travelling the day before an activity? Many patients have a morning routine to manage their disease. Check what the patient's needs are to enable optimal participation in the meeting.	
Make sure you agree on arrival and departure times with the patients, allow ample time between arrival time and activity start time in case there are delays.	

Considerations	Comments
Patients may wish to drive themselves, in these cases remember to reserve appropriate car parking close enough to the entrance of the venue.	
Support the patient when arranging their travel so that the extra luggage allowance in the cabin and the hold and special allowance for taking medication/oxygen, wheelchair etc. on the plane is organised with the airline beforehand.	
Remind patients to bring necessary medication, replacement oxygen cylinders, etc, with them. Inform the patient on what they need to bring as extra documentation (medication overview such as list of treatments, allergies, medicine passport, health records, letter from dietician and doctor on what is necessary like extra fluids/special foods/oxygen/needles or other devices (like implants, insulin pumps) etc). Identification may also be required by meeting venues, and at hotels.	
Companions/supporters	
Considerations	Comments
To facilitate and encourage patient involvement, allowing a patient to be accompanied by an adult supporter (carer, family member, friend, member of a patient organisation) even if not for health reasons is really important. Some people may be intimidated by the travel itself (particularly international travel), being in another country, with unknown people, in a completely different environment or need support at the meeting. If this is the case, the cost of travelling and accommodation, etc, of the supporter should be covered. In some cases, the supporter may be required before and/or during the meeting. If the latter, the supporter should be able to receive pre-readings and have a seat at the meeting next to the patient. If a supporter is needed, this person is expected to be able to provide the support needed and it should be made clear what is expected from them.	

Accompanying minors	
Considerations	Comments
For rules on accompanying minors, before arranging travel please check EU Reference document or legal regulations within the country the child is travelling both to and from. Each country has their own rules and individual insurance may be required.	
Travel time	
Considerations	Comments
Remember that travelling is tiring so providing support and adequate facilities is important. Depending on meeting duration be flexible, give patients the option to travel the day before the meeting and leave the day after the meeting. For example, if meeting start means the patient is expected to travel earlier than 07:00 and meeting end means the patient is likely to arrive home later than 22:00. Treat on a case by case basis, but ensure compliance with guiding principles.	
Think about the proximity of the venue closer to, or central to, where patients are generally located bearing in mind to keep their journey times manageable.	
Any meeting organiser should arrange and pay for travel and hospitality for patients and carers in advance to avoid patient(s) needing to pay in advance and then request reimbursement.	
Accessibility	
Considerations	Comments
Understand what special accessibility requirements are required. Don't forget toilet facilities.	
Ensure transport provider (airline/airport/railway station) is advised of special assistance requirements and this is organised at time of booking. For example, some airlines have seating for patients with Inflammatory Bowel	

Hotel accommodation

Considerations

Where applicable and possible, try to ensure availability of accessible accommodation for individuals with mobility restrictions or cognitive impairment considering the following requirements:

Additional hostess assistance (shown to their room, wheelchair navigation, etc.).

Bedrooms that are within close proximity to meeting space and/or near elevators to promote independence by aiding spatial orientation (check for preferences before booking).

Wider door access with low spy holes, low-level wardrobe rails, and furniture. Avoid steps in room.

Low-mounted (or remote control), comfort-control panel, and light switches (ideally with dimmable lighting) at bedside.

Minimalist furniture, wall art, and coverings; wooden or laminated flooring; easy-pull blinds (rather than curtains); contrasting colours such as light switch next to doors (where possible).

No transparent glass walls, such as those leading to bathroom.

Telephone easily accessible (by bedside).

Soft furnishings that can be changeable (such as pillows). Be aware of items that may trigger atmospheric allergies (dust, pillows, carpets, etc.).

Option to have adjoining room for carers.

Option to have a fridge/freezer in the room to keep medication cool and/or option for ice to be available for

Comments

Considerations

Facilities for service animals to accompany patient.

Bed and mirror height suitable for wheelchair users.

Seating (chair) available in the hotel room.

Wider bathroom door access and wheelchair-friendly shower with fold down seat.

Easy-to-use shower mechanics.

Grab rails on both sides of a higher-level toilet, shower and bath. An emergency pull cord in bathroom linked directly to the Guest Services desk, which must be manned 24/7.

Low-mounted towel storage and shelving as well as soap and other amenities. Ensure soap and amenities can be easily opened and ideally contrasted with sink (not white on white).

Meeting venues

Considerations

Walk the route patients will take, are there elevators available where needed? Complete this with people living with the condition where possible. Plan an alternative route if patients have limited mobility to avoid too much walking or stairs.

Are the toilets clearly signposted, in easy reach and wheelchair accessible?

Are you familiar with the fire evacuation and emergency procedures (and are these made available for participants)?

Consider onsite medical assistance to be available (or where to go in case medical assistance is needed).

Comments

Meet and greet	
Considerations	Comments
<p>Make sure someone is assigned to meet and greet the patient and companions on arrival at the meeting venue and ensure departure process is smooth. Exchange mobile numbers for ease of contact on the day between the patient and the host.</p> <p>Build in time for patients to settle, receive refreshments, meet hosts and others plus for receiving any final briefing or clarification, if they are willing so – otherwise allow them to take their time until the meeting starts. Make sure the patient is comfortable before the activity starts.</p>	
Catering / Dietary Requirements	
Considerations	Comments
Hospitality is essential. Never underestimate the importance of hospitality, whether in the meeting venue or hotel bedroom. Tea and cakes/cookies/vegetable sticks/fruit are a small cost but provide great benefit.	
Understand the patient's dietary requirements and make these available for the patient also in the small snack selection.	
Make sure water and other refreshments are available throughout the meeting. If people with dementia are at the meeting, remind them/encourage them to drink, hydration is very important.	
Consider (disease-specific) dietary requirements i.e. Paleo/vegan, remember certain food types can severely affect medicines.	
Consider certain patients have a heightened sense of smell, so try and keep very strong-smelling foods to a minimum.	
Ensure accurate and large font food labelling to allow for	

Considerations	Comments
Consider time requirements for breaks/meals.	
Avoid working lunches/coffee breaks if possible (lunch is a break).	
If the venue/ hotel is not in a central location provide information about restaurants near the venue / hotel where the person stays and their accessibility	
Communication	
Considerations	Comments
Communication is essential, make sure to ask patients about their preferences for methods of communication and do not make assumptions about them. If possible, provide the phone number of a person who could provide support or clarify any issue to the person before, during or after the event if necessary.	
Send detailed pre-meeting information, including any pre-reads, slides, agenda, and information about the venue and how to get there (maps, useful info).	
Some people may prefer to receive the documents electronically and others as printed materials (ask the person about his/her preference).	
Consider alternative registration process (telephone, email, etc). Possibly communicate with carer rather than patient.	
Be discreet – i.e. use closed discussion between event planner and some high-need patients.	
Use blind copy option when communicating to groups via email so you do not share email addresses without patients' consent (either within group of patients or within your organisation).	

Recommendations (1)

- early stage: organisers should speak to patients / carers to get the arrangements right for the individual
- right mind set and empathy is crucial: the activity coordinator and other people in direct contact with patients should be appropriately trained to work with patients
- there are many different ways to interact with patients; always consider using virtual methods to minimise the need for travel

Recommendations (2)

- virtual interaction including software should be accessible; support may be required before and during activity
- patients do value the opportunity to meet and learn from each other
- F2F meetings during start up phase of an activity can help build trust, rapport and understanding plus address any concerns
- respect times and breaks
- ensure compliance with PARADIGM code of conduct, as well as legal/local requirements

Contributors

Lead contributors:

- Ingrid Klingmann (EFGCP)
- Wolf See (Bayer)
- Kay Warner (GSK)

Other contributors:

- Giulio Maria Corbelli (EATG)
- Irmi Gallmeier (Roche)
- Camilla Habre (EPF)
- Dominique Hamerlijnck (EUPATI fellow)
- Karina Huberman (EATG)
- Laurence Maes (Janssen)
- Matthew May (EPF)

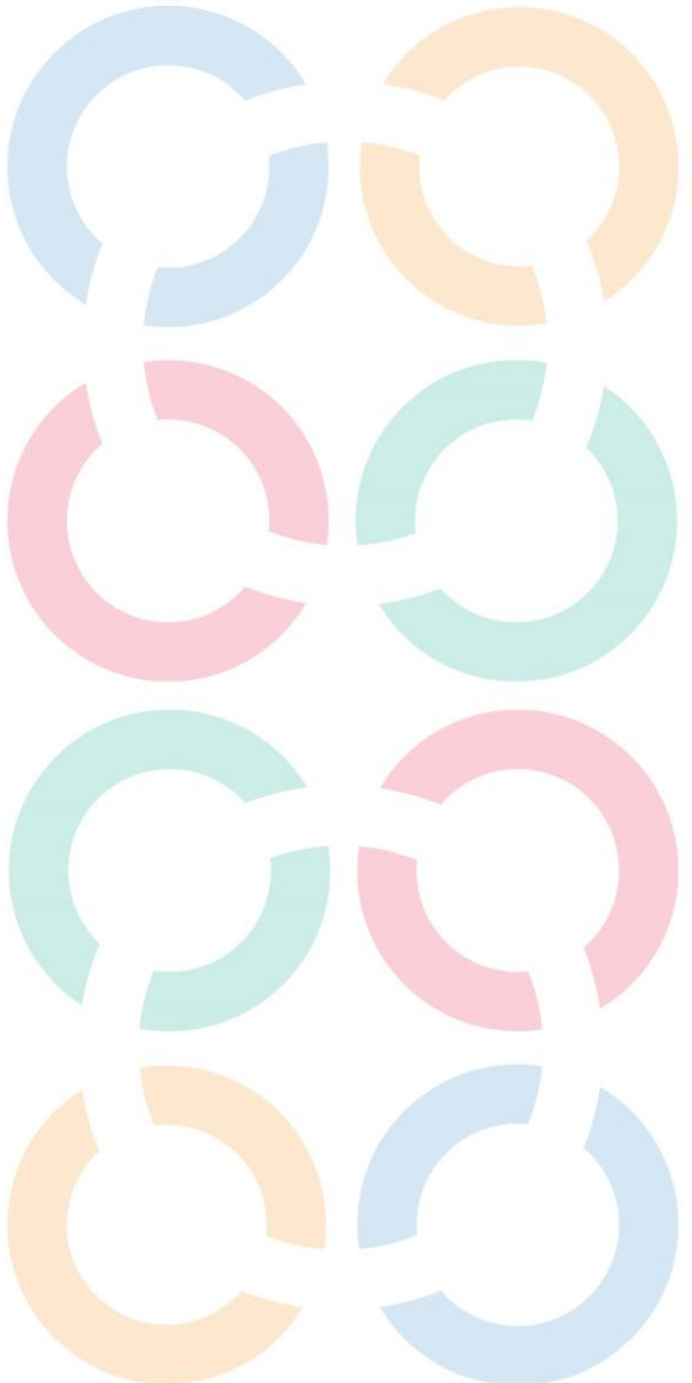
Editorial committee:

- Stuart Faulkner (CASMI-OXFORD)
- Michaela Dinboeck (Novartis)
- Begonya Nafria Escalera (FSJD)

Consultation period

- Your input today is important – ask questions / tell us what you think
- Online consultation ends July 12
- Link in agenda and also chat window

THANK YOU



Code of Conduct

for all stakeholders
involved in
patient engagement activities
within medicines development

The Actors



Ingrid Klingmann
EFGCP



Wolf See
Bayer

What is the Tool?

Code of Conduct in Patient Engagement

This “Code of Conduct for all stakeholders involved in patient engagement activities within medicines development” is intended to be:

- **a stand-alone document that highlights, summarises and refers to the key patient engagement principles, rules and recommendations for collaboration**

presented in the different PARADIGM documents in the Toolbox in a comprehensive, understandable format.



Why is it Important?

Code of Conduct in Patient Engagement

This Code of Conduct

- **Describes** ethical and professional standards to enable successful and meaningful collaboration between all partners in PE
- **Addresses** the values, ethical principles, and rules for all stakeholders
- **Protects** all involved stakeholders' interests and rights
- **Ensures** reliable transparency in collaboration
- **Intends** to facilitate systemic, comprehensive and consistent patient involvement in all aspects of medicines' research, development and access to treatment activities

The document Structure

Code of Conduct in Patient Engagement

Table of contents

Definitions.....	2
Executive Summary and Purpose of the Document.....	6
1. Introduction	7
2. Purpose and Scope	8
3. Ethical Principles for Patient Engagement in the Life Cycle of a Medicine.....	8
4. Contractual Framework	9
5. Competing Interests, Conflict of Interest, and Conflict Management.....	10
6. Intellectual Property, Confidentiality and Data Protection	12
7. Access to Information and Transparency.....	13
8. Accessibility of Patient Engagement Opportunities.....	14
9. Representativeness.....	15
10. Competencies and Capacity Building.....	16
11. Adherence to the Code of Conduct.....	17
12. Concluding Remarks.....	17
13. References.....	18
14. Annex 1: Fact Sheets of PARADIGM Documents.....	19

***Topic:* Ethical Values and Principles**

Code of Conduct in Patient Engagement

Values

- **Relevance**
- **Fairness**
- **Equity**
- **Capacity-building**

Principles

- **Respect**
- **Integrity**
- **Trust**
- **Clarity of purpose**
- **Beneficence**
- **Equality**
- **Transparency**
- **Independence**

***Topic:* Contractual Framework**

Code of Conduct in Patient Engagement

- the purpose, roles and responsibilities
- confidentiality
- intellectual property rights
- copyright
- data protection
- independence of partners
- declaration and conflict of interest

- anti-bribery compliance
- liability
- compensation (fair market value, no undue inducement)
- dispute resolution
- a statement to the effect that outcomes of and experiences with the patient engagement activity will be jointly reported

***Topic:* Competing Interests, Conflict of Interest, and Conflict Management**

Code of Conduct in Patient Engagement

- The acknowledgement of difference between competing interests and conflict of interest
- The principle of Declaration of Interest by all involved parties
- The principle of proactive mitigation strategies in all stakeholder groups
- The principle of developing and enforcing a policy to manage competing interests covering proportionality, transparency, accountability, and fairness
- The principle of mediation and dispute resolution with potential for immediate termination of an agreement in case of breach of trust, entire contract or a specific clause

***Topic:* Intellectual Property, Confidentiality and Data Protection**

Code of Conduct in Patient Engagement

The Principles of

- joint ownership of Foreground for ALL involved contributors, defined and agreed upfront where appropriate
- access rights granted on an equal basis to all partners
- achieving open access to joint project results whenever possible
- agreed joint dissemination activities on Foreground, including timelines and modalities
- confidentiality obligations for all involved partners incl. third parties
- patients having the right to consult with members of their patient organisation to maximise their contributions

***Topic:* Access to Information and Transparency**

Code of Conduct in Patient Engagement

The Principles

- of the fundamental right on access to comprehensive, reliable information for all partners
- of obligation of all partners in patient engagement activities to make their information rapidly and comprehensively accessible in formats suitable for all partners involved and the public at large
- that efficient and reliable dissemination of patient-relevant information requires input from the end user, in particular patients and carers
- of the right on timely information about opportunities for education and collaboration

***Topic:* Accessibility of Patient Engagement Opportunities**

Code of Conduct in Patient Engagement

The Principles that

- diverse patient perspectives should be taken into consideration
- successful collaboration depends on the involved patients' competency level (patient profile) and capacity required in the respective activity
- clearly defined, comprehensive and easy to understand information on upcoming and completed collaboration activities must be broadly disseminated
- patients or POs with interest, capabilities and capacity for PE activities provide information on available patient profiles and capacities proactively on neutral communication platforms
- agreement exists between the partners that engaged patients provide their input as equal members of the team, including accountability for their input.
- the patient or patient representative should ensure objectivity in assessments, decision-making and advice as well as independence from his/her organisation's interests and strategies.

***Topic:* Representativeness**

Code of Conduct in Patient Engagement

The Principles that

- for each task the engaging partner must define upfront the desired input and level of representativeness
- partners should ensure that they have a common understanding of the patient's level of representativeness
- before and during patient engagement activities, patient organisations should strive to improve the representativeness of their delegate by generating new/additional information on gaps identified during the patient engagement activity

***Topic:* Competencies and Capacity-Building**

Code of Conduct in Patient Engagement

- **The recognition** that patients are equal partners in the PE activity but with a motivation different from that of the other partners as they are “concerned parties” due to their personal experience
- **The principle** that all partners should constantly strive to increase their knowledge in the areas of their contributions as well as their communication and collaboration skills
- **The agreement** that constant increase of capacity, the availability of competent resources, partners experienced in patient engagement and maximising the efficiency of patient involvement should be common goals for all partners in medicines’ lifecycle activities.

Topic: Adherence to the Code of Conduct

Code of Conduct in Patient Engagement

- **The agreement** that adherence to this Code of Conduct ensures an open and fruitful interaction of engaging partners with patients and their representatives to optimise the development of medicines suitable for use by the patients to be treated
- **The commitment** of the patient engagement community to voluntarily integrate the rules of this Code of Conduct into their collaborations and to insist on adherence to it in case a partner shows deviation

Thank you for joining us today!

- The next session on the PARADIGM tools is on September 10th
- Meanwhile, please participate to the Public consultation
www.imi-paradigm.eu/tools-consultation

Enjoy the rest of the PEOF2020