What is the Patient Engagement Open Forum

A series of virtual events (in 2020) where we will work together, in a multi-stakeholder context, to turn patient engagement 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.
**Agenda**

**June 25th**
- PE2020 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)

**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 0 (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 CTR)
  - Good Lay Summary Practice, communicating trial results to the general public – how patient engagement can work (organised by EPFIA and EFICIP)

**November 5th**
- THEME: Regulatory

**November 23rd**
- **Plenary session:**
  - PE2020 conclusion session
Let’s work together to spread the word

#PEOF2020

@imi-paradigm
@eupatients
@PFMDwithPatient
Agenda

15h40 – 16h00 Welcome and introduction
Ingrid Klingmann (EFGCP) and Giorgio Barbareschi (EATG)

16h00 – 17h20 Presentation of PARADIGM tools

• Case study based on:
  o Recommendations on how to identify the right match for the right patient engagement activity
  o Raising awareness on managing competing interests in a multi-stakeholder environment

Kay Warner (GSK), Elisa Ferrer and Maria Cavaller (EURORDIS) and Mathieu Boudes (EPF)

• Guidance for Reporting and Dissemination of Patient Engagement Activities

Ana Diaz (Alzheimer Europe) and Stuart Faulkner (University of Oxford)

17h20 – 17h30 Wrap up and end of the session
PARADIGM
Patients Active in Research and Dialogues for an Improved Generation of Medicines
The Consortium’s mission and objectives

**Mission**
Participate to the co-creation of a sustainable framework allowing systematic, meaningful and ethical patient engagement in medicines R&D

**Objectives**
- Develop processes and tools for these three points in the medicine lifecycle
- Develop a sustainability roadmap for patient engagement
The members of the consortium
A work flow towards specific outputs

- Defining stakeholders, preferences, needs and expectations
- Assessment of practices and process
- Development of metrics for monitoring and evaluation
- Co-designed recommendations and resources for patient engagement
- Sustainability strategy
- Dissemination and engagement
- Project coordination and management
Creation of tools: the objectives

- **To increase stakeholders’ preparedness** for patient engagement in the priority areas in the medicines lifecycle addressed by PARADIGM by developing recommendations on the required capabilities for each stakeholder to be better prepared for meaningful and effective patient engagement.

- **To develop guidance** on patient engagement addressing each key stakeholder groups requirements

- **To enhance stakeholders’ capacity** to concretely implement efficient patient engagement policies through the development of a capacity building toolbox targeting all stakeholders.

- **To support communication** in uptake and dissemination of the project’s emerging results, with the aim of promoting adoption of the results by all stakeholders.
<table>
<thead>
<tr>
<th>Topic</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendations on how to find the right match for the right patient engagement activity</td>
<td></td>
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<tr>
<td>Raising awareness on managing competing interests in a multi-stakeholder environment</td>
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<tr>
<td>Enhancement of the EUPATI industry guidance</td>
<td></td>
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<td>Guidance for reporting and dissemination of patient engagement activities</td>
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<tr>
<td>Recommendations on required capabilities for patient engagement</td>
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<tr>
<td>Monitoring and Evaluation framework</td>
<td></td>
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<tr>
<td>Community Advisory Board- Guidance document and templates</td>
<td></td>
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<tr>
<td>Patient engagement agreements explained</td>
<td></td>
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<tr>
<td>Recommendations for HTA bodies to conduct patient engagement activity during early dialogue</td>
<td></td>
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<tr>
<td>Code of conduct</td>
<td></td>
</tr>
</tbody>
</table>
Case study
**Patient engagement in medicines R&D:**
Recommendations on how to find the right match for the right patient engagement activity

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

Kay Warner
GSK

Mathieu Boudes
European Patients’ Forum

Elisa Ferrer
EURORDIS

Maria Cavaller
EURORDIS
The case

• Stakeholders involved

  Sheila works as head of patient engagement at Genius Pharma. She is planning a patient engagement activity to help identify relevant rheumatoid arthritis endpoints for the design of a clinical trial.

  Rick is a volunteer at Arthritis Patients’ Group, an international patient organisation. He coordinates patient engagement in the organisation and provides support to patients throughout the process.

• The activity:
  Identify patient-relevant endpoints for the design of a clinical trial.
**STEP 1:** Outline the patient engagement activity on shared purpose

### Recommendations

Diagram 1 below sets out the steps to follow when finding the right match for the right activity. Each step is then further explained in this section. (PO stands for patient organisation(s) and CoI for Conflict of Interest)

<table>
<thead>
<tr>
<th><strong>DIAGRAM 1: Process steps</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>STEP 1</strong> By the engaging partner</td>
</tr>
<tr>
<td><strong>STEP 2A</strong> By the engaging partner</td>
</tr>
<tr>
<td><strong>STEP 2B</strong> By the engaging partner</td>
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<tr>
<td><strong>STEP 3</strong> By the engaging partner and the relevant PO(s)</td>
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<tr>
<td><strong>STEP 4A</strong> By the relevant PO(s)</td>
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<tr>
<td><strong>STEP 4B</strong> By the engaging partner</td>
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<td><strong>STEP 5</strong> By the engaging partner and the relevant PO(s)</td>
</tr>
<tr>
<td><strong>STEP 6</strong> By the engaging partner and the relevant PO(s)</td>
</tr>
</tbody>
</table>

* Not the scope of these recommendations
STEPI Outline the patient engagement activity on shared purpose (scope, time, human and financial resources, …)

To facilitate outreach to patients and their representatives, the engaging partner making the request needs to be able to structure their initial requirements:

- Outline the rationale, objective for the collaboration and describe the desired outcomes.
- A shared purpose\footnote{A shared purpose. IPMHD (Individual Patient Medical Quality Guidelines). Available at: \url{https://europeobservatory.org/guideline-patient-engagement-shared}} between the engaging partner and the patients or their representatives who will be involved in the patient engagement activity should be described.
- Describe what the activity is trying to achieve (e.g., inform decision making, build knowledge, assess if hypotheses are meaningful to the patient community, verify understanding or co-create materials to ensure patient friendly language is used, determining inclusion-exclusion criteria in a clinical trial protocol discussion or considering which endpoints are relevant for the patient).
- Describe what is expected from engaging patients, their representatives and their roles in the activity together with the time commitment required. Typically, time commitment will depend on the type of instruments used to capture the insights from patients and their representatives (see Appendix 2).
- Outline interdependencies with other engagement activities planned or ongoing. Always try to limit duplication with other internal activities/projects of similar nature. Combining various activities to meet similar objectives will avoid overburdening patient organisations with numerous requests. Remember many POs rely solely or partly on volunteers, and therefore may have limited resources and capability to react to multiple requests.
- Provide best estimate on timelines including start date and deadline for results or findings from activity; however, include an indication of flexibility with dates (+/- weeks/months). Patient identification may be the most time-consuming part of the project. This can take longer, depending on the disease under discussion, the type of activity, the capacity and capability of patient/patient organisation(s) and other factors. If the engaging partner does not already have a relationship with the chosen patient/patient organisation(s), this must be established to start the process of building trust to foster future collaboration. However, it must be recognised that it will take additional time to build understanding and form a mutually beneficial relationship and this is desirable prior to specific requests for identifying the suitable match are made.
- Indicate what budget is required for the activity. The costs of the activity should be understood, and funding secured before any request is made to patients or patient organisations (or alternatives).
- Detail if the support of a facilitator (or a translator) is needed to perform the patient engagement activities. This is a requirement that we encourage to be mandatory in the case of children and young patients and other target groups where the role of caregiver is essential (e.g., elderly, people living with dementia) and for further guidance, refer to Enhancement EU PAt: industry guidance suggested working practices\footnote{Enhancement EU PAt. Industry guidance suggested working practices.}.

After the engaging partner has drafted the first version of the engagement activity for internal purposes to scope the activity, the co-creation shall begin with the support of the patient community. It appears that the POs - where they exist - are the first and key point of contact to co-create the patient engagement project, to avoid purely transactional elements and to start or consolidate efforts to build trust and collaboration efforts with the patient community.
STEP 2A:
• Identification of a relevant patient organisation to co-create the activity.

STEP 2B:
• Or if no PO exists, use alternative methods (co-creation with the patient community).
STEP 2A & 2B: Identify the right partner(s)—such as patient organisation(s)—to co-create the patient engagement activity

It is important to highlight that, in the case where a patient organisation does not exist, or do not have the capacity or do not wish to collaborate, then the engaging partner shall look for the perspective of the patient community through other means such as patient opinion leaders, online patient communities or, in some cases, patients with lived experience of the specific condition being discussed. The partner will vary according to the goal of engagement.

The engaging partner needs to identify the appropriate (or suitable) PoIs to act as a partner to co-create the activity and support its implementation, by performing a landscape analysis—linked to the activity purposes—of the community that could integrate, as example, the following aspects:

- Number of patient organisations in different countries
- International/regional umbrella organisations
- Patient opinion leaders (both patient organisations leaders or online bloggers)

What is specific about the patient community?

- Core activities
- Connectivity
- Capacity and influence
- Engagement with industry
- Strategic partnership opportunities and areas on which to focus to create the biggest mutual value
- Potential challenges faced in engaging with the community

However, it is clear that not all patient organisations have the same degree of development for a given activity; this may depend on the activities they carry out on a daily basis (e.g., patient and caregiver support vs policy activities) or the main operational focus of the organisation (e.g., multi-stakeholder collaborations vs medical expertise).

Therefore, finding the appropriate partner in this early phase of the activity is important. Diagram 2 below is an example of potential assessment criteria that could be used to identify potential partners and assess the right patient organisation and evaluate in collaboration with the identified PoIs. The recommended topics and the check list below can be downloaded as a stand alone tool here.

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1. (Adapted from Tack M, and Tack N in related materials)
How to find the best suitable patient organisation?

**Diagram 2:** Recommended topics to consider about the patient organisations that could guide the decision about which are the best suitable patient organisations to contact.

1. **Ability to work in medicines R&D with industry and other stakeholders**
   - Panel, pool or similar resources for members with an interest in patient engagement in medicines R&D
   - Experience, expertise and a systematic approach to involve members in medicines R&D

2. **Ability to engage with the patient community and to support it**
   - Involvement of members in internal operations and external activities
   - Training and/or mentoring of members in its own activities

3. **Ability to represent the patient population diversity and geography**
   - Geographical spread and match with the need of the patient engagement activity
   - Ongoing, direct communication with the patient community before, during and after activities

4. **Awareness of barriers to inclusion of patients in R&D and of the need to promote diversity**
   - Inclusion of a diverse set of patient population in its activities
Use the check list of the elements to consider before engaging with a patient organisation

### Arthritis Patients’ Group has:
- A pool of experts with experience to be involved in medicines R&D
- A dedicated person to organise patient engagement activities/opportunities
- A specific training programme
- Well established channels to reach to the wide arthritis patient community

#### TABLE 1: Check list of the elements to consider before engaging with a patient organisation to work on a patient engagement activity

<table>
<thead>
<tr>
<th>Elements to consider before engaging with a patient organisation to work on a patient engagement activity</th>
<th>Yes / No / Partially</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the organisation have the experience, expertise and a methodology or a systematic approach about how to involve their members in medicines R&amp;D?</td>
<td></td>
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</tr>
<tr>
<td>Does the organisation have the capabilities to work with the engaging partner to ensure that the patient engagement activity is suited to the needs of the patient community?</td>
<td></td>
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</tr>
<tr>
<td>Does the organisation have a panel, pool or similar resources which includes their members with an interest in patient engagement in medicines R&amp;D?</td>
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<td></td>
</tr>
<tr>
<td>Does the organisation have well-established channels of communications with their members and beyond with the patient community at large?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the organisation involve their members in their own internal operations and external activities?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the organisation have direct contact with their members and the track record of mobilising them?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the organisation have the resources to train and/or mentor their members in its own activities?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the organisation have the geographical coverage that matches the needs of the patient engagement activity?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the organisation address the inclusion of a diverse set of the patient population in its own activities?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the organisation demonstrate an awareness of barriers to inclusion and of the need to promote diversity in the context of patient engagement in medicines R&amp;D?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
STEP 3:
Sheila and Rick jointly co-define the competencies needed to carry out the activity.
Once the landscaping exercise is performed, the different approaches available to reach out to the identified potential partnering POs are via:

- Umbrella or disease specific organisation (international, regional, national)
- Database(s), either open access (e.g. Orphanet, EFO’s Synapse) or proprietary (e.g. EMA individual experts’ stakeholder database)
- #YPACOnet to engage children and young people through the YPACO’s (young person’s advocacy groups).
- Local company affiliates (or the headquarters when the engagement activity started)
- Search engines (such as Google)

Alternatives:

- Alumni of training programmes such as EUFATI (with the limitation that only EUFATI fellows and patients in the EUFATI network can be identified as right match in this way)
- Investigators and hospitals who are conducting research with and for patients
- Vendors providing patient engagement services that as part of their portfolio may include support to identify POs willing to engage in medicines R&D activities.
- Country based services provided by public sector organisations for example, the National Institute for Health Research (NIHR) Patient Engagement in Clinical Development service.

It is recommended that outreach to various groups and communities happen in parallel, rather than in sequence, thus avoiding tight timelines and mitigates the risk that patient identification is delayed. Nevertheless, it is important to have anticipated and put in place mitigation measures if and when there are more POs and/or individuals willing to engage. The outreach activity to identify patients and their representatives should be coherent with the engaging partner’s capacity to effectively carry on with the activity. Throughout the process, the engaging partner needs to continuously assess what progress is being made during the outreach phase and adjust the approach as appropriate in consultation with the partner PO or alternatives.

It is recommended both the engaging partners to work together to increase the PO’s capability to support future activities. The capability building shall be initiated and organised by the patient community and medicine developers can financially support these activities, following existing guidance documents 5, 6, 7, 60). More information about the capabilities needed to conduct meaningful patient engagement activities for all stakeholders can be found in the IMI PARADIGM’s D4.1 Recommendations on the required capabilities for patient engagement 2, 8.

When conditions exist to prevent co-creation, due to the nature of the activity, external regulations or the capacities of the PO, the patient community may be involved with less integrated approaches at the most appropriate level and this should be decided between the patient community and the engaging partner.

STEP 3: Co-define the competencies for the patient engagement activity

As described above, patient organisations are usually recommended as a key partner in a patient engagement and should be involved in the co-creation of the PE activity. The engaging partner and the relevant patient organisation should work to drive the definition of the skills, behaviors and competencies of the patients and their representatives who will engage in the activity. More information can be found in the IMI PARADIGM’s D4.1 Recommendations on the required capabilities for patient engagement 2.

Table 2 below can be used as a tool for individuals to self-assess their own competencies, as well as during the co-design phase to identify the level of competencies required for the activity (between 0 and 3 as per the definition in third column). The scoring can be done between 0 and 3 where 0 means that the competence is not needed and 3 highly desirable. The table can be downloaded here as a stand alone tool.

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7 PHAERA. Chapter 4: Collaboration in Clinical Research in Rare Diseases. Available at: http://www.phaera.org/PHAERA/Chapter4CollaborationinClinicalResearchinRareDiseases.pdf
8 EUFATI. Database of disease specific centres. Available at: http://www.eufati.org/eufatis-guide-to-disease-specific-centres/
10 EMERGO. Chapter 7: Case Studies. Available at: http://www.emergogroup.com/doi/10.1186/s12949-014-0046-4
13 The table can be downloaded here as a stand alone tool. Available at: http://www.emergogroup.com/doi/10.1186/s12949-014-0046-4
<table>
<thead>
<tr>
<th>Competencies</th>
<th>Definition</th>
<th>1. Low</th>
<th>2. Intermediate</th>
<th>3. High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical expertise</td>
<td>Medical expertise, anatomical and physiological expertise, knowledge about medicines, research and development processes</td>
<td>Basic medical expertise (anatomy, physiology, use of treatments)</td>
<td>Extended medical expertise (medicines development, medical methodology)</td>
<td>In-depth medical knowledge in all aspects</td>
</tr>
<tr>
<td>Indication specific expertise</td>
<td>Knowledge about the indication/disease, treatments, care and life circumstances of those living with the disease</td>
<td>Basic indication, treatment and care expertise</td>
<td>Extended indication, treatment and care expertise</td>
<td>In-depth indication, treatment and care expertise incl. latest research and treatment expertise</td>
</tr>
<tr>
<td>Regulatory expertise</td>
<td>Knowledge about the regulatory processes, e.g., evaluation, authorization, reimbursement processes of therapies</td>
<td>Basic knowledge about the medicines approval process, related assessments and reimbursement procedures</td>
<td>Extended knowledge about the medicines approval process, related assessments and reimbursement procedures</td>
<td>In-depth knowledge about the medicines approval process, related assessments and reimbursement procedures</td>
</tr>
<tr>
<td>Systems expertise</td>
<td>Knowledge about access and participation in the healthcare system (e.g., social law), knowledge about health policy</td>
<td>Basic knowledge about accessing and participating in the healthcare system</td>
<td>Extended knowledge about accessing and participating in the healthcare system, basic knowledge about health policy</td>
<td>In-depth knowledge about accessing and participating in the healthcare system and underlying health policy</td>
</tr>
</tbody>
</table>

**TABLE 2: Competency table** (downloadable version [here](#))

<table>
<thead>
<tr>
<th>Patient engagement activity</th>
<th>Co-designing the project</th>
<th>Participating in the project</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

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Indication specific expertise
### TABLE 2: Competency table

**Downloadable version here**

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<td>In-depth knowledge about the medicines approval process, related assessments and reimbursement procedures</td>
<td></td>
</tr>
<tr>
<td><strong>System expertise</strong></td>
<td><strong>Public Health expertise</strong></td>
<td>Knowledge about access and participation in the healthcare system (e.g., social law), knowledge about health policy</td>
<td>Basic knowledge about accessing and participating in the healthcare system</td>
<td>Extended about accessing and participating in the healthcare system, basic knowledge about health policy</td>
<td>In-depth knowledge about accessing and participating in the healthcare system and underlying health policy</td>
</tr>
</tbody>
</table>
Go to www.menti.com and use the code 46 62 27

Public Health expertise

None

High

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<table>
<thead>
<tr>
<th>Methodological expertise</th>
<th>Communication and representation</th>
<th>Negotiation skills and political interaction</th>
<th>Personal experience</th>
<th>Community insight and involvement</th>
<th>Capability to perform the task</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Well-structured and solution-oriented communication skills (including digital and social media), and expertise to advocate appropriately for a patient community</td>
<td>No specific expertise in political interaction</td>
<td>Empathic in relation to those affected</td>
<td>Involvement in the patient community in a specific indication area. Ability to abstract from personal experience to represent a wider community. Financial means or support to allow for unique role and task. Ability to perform specific tasks. Sufficient experience, physical fit, and time.</td>
<td>Ability to engage on a specific task within a strict time and effort limit. Ability to undertake continuous, recurrent interaction.</td>
</tr>
<tr>
<td></td>
<td>Objective communication and appropriate conduct</td>
<td>Personal integrity and good negotiating skills</td>
<td>Affected indirectly (e.g., family member)</td>
<td>Direct interaction with other people living with the disease. Broad insights of different needs of a specific patient community. Frequent interaction with different community members. Ability to represent a community.</td>
<td>Ability to carry out more complex, long-term tasks requiring a considerable commitment (efforts, time, and health wise).</td>
</tr>
<tr>
<td></td>
<td>Clear and focused communication with sound and consistent opinion</td>
<td>Scorable policy interaction and communication. Good negotiating skills and consistent positions</td>
<td>Direct affected by the condition</td>
<td></td>
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</tr>
</tbody>
</table>

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Personal experience

None

High

Press S to show image
STEP 4:
Rick identifies within his PO the representatives that match the needed competencies to identify patient-relevant rheumatoid arthritis endpoints

- Experience of living with the disease
- Knowledge of the R&D process and previous experience in similar activities

Rick also starts checking for competing interests before deciding who could be joining the activity.
considered, with the deployment of Customer Relationship Management (CRM) type software.

This process could be supported by patient engagement managers in patient organisations.

The IMI PARADIGM's CRM type software is designed to:

- Identify the right patients for the patient engagement activity.

Patient engagement functions in both industry and PIs can be organised in a number of models (e.g., by type of activities), in which the engagement of patients is requested (e.g., clinical trial design) or by medical areas (i.e., by disease areas).

Alternatively, patient engagement managers or related functions in PIs could use the outreach power of social media or online communities to identify and recruit patients or their representatives to take part in engagement activities.

Following co-creation of the patient engagement activity and the definition of key criteria (such as competencies, health status, level of availability, language skills...) for the right matches, it is the sole responsibility of the relevant PIs to identify the patients and their representatives and make a final selection decision based on the results of the identification process (see key principles).

A conflict of interest is to be performed by the engaging partner against related criteria as laid out in the IMI PARADIGM's CRM type software is designed to:

If the PIs are not successful with patient identification then the engaging partner may find alternatives, see step 2B. Success can and must only be defined at the co-creation phase between the partners and is best judged after the completion of the activity.
Before the activity starts, Sheila asks herself...

Involving the patients to discuss patient-relevant endpoints for the design of a clinical trial, will this influence the patients’ ability to engage with other stakeholders?

A. No, not at all
B. Yes, it will prevent the engagement of this patient with any other stakeholder
C. Maybe, this depends on the policy for management of competing interests of the other stakeholder and the type of activity in which the patient will be involved
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Ability to engage with other stakeholders

- No, not at all
- Yes, it will prevent the engagement of this patient with any other stakeholder
- Maybe, this depends on the policy for management of competing interests of the other stakeholder and the type of activity in which the patient will be involved

Press ENTER to show correct  Press S to show image
Educational scenarios on competing interests and conflicts of interest

1: You work for a medicines developer and you would like to involve a patient to discuss patient-relevant endpoints for the design of a clinical trial, will this influence the patient’s ability to engage with other stakeholders?

A. No, not at all

B. Yes, it will prevent the engagement of this patient with any other stakeholder

C. Maybe. This depends on the policy for management of competing interests of the other stakeholder and the type of activity in which the patient will be involved

Rationale

A. Patients are in a central position to engage with each and every stakeholder along the medicines research and development (R&D) process and therefore their interests are under scrutiny by the engaging stakeholder. Patients often engage with multiple stakeholders simultaneously and over time. The early identification of potential competing interests is key to effectively manage them upfront in order to avoid or limit the extent of the conflict and the subsequent impact to the patient’s ability for further interaction.

B. Raising awareness about the potential consequences of the engagement, both among medicines developers and the patient community, will help patients to make an informed choice when they engage with a stakeholder, and will help to mitigate the risks of potential conflicts of interest.

C. The type of interaction and the consequences derived from it, may be different depending on the groups involved. Thus, each stakeholder group defines the type of and rules for engagement with their stakeholders. The engaging stakeholder and process of engagement define what represents a conflict of interest.
Why is it important to check potential competing interests?

• Previous interactions with any stakeholder involved in medicines R&D might affect the ability to engage in a given activity

• Early identification of potential competing interests is key for their effective management

Figure 1. Multi-stakeholder approach to patient engagement in medicines R&D
Example of competing interests vs conflicts of interest

<table>
<thead>
<tr>
<th>Competing interests</th>
<th>Company A</th>
<th>Company B</th>
<th>EMA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Declaration of interests and Assessment</td>
<td>Patient is invited by company A to develop multiple sclerosis (MS) PROs. Patient signs an NDA/CA</td>
<td>Same patient offered to join a patient advisory board (PAB) to define MS unmet needs by company B</td>
<td>Same patient is contacted by the EMA to participate in a scientific advice (SA) procedure on a medicine development by company A</td>
</tr>
<tr>
<td>Conflict of interests</td>
<td>Patient has no previous competing interests to declare</td>
<td>Patient declares their activity with Company A to Company B without disclosing any confidential information</td>
<td>Patient declares current engagement with company A and company B</td>
</tr>
<tr>
<td>NO: Company A engages concludes that there is no CoI and the patient engages with company A</td>
<td>NO: Company B concludes that there is no CoI and decides to include the patient in the PAB</td>
<td>YES: EMA concludes that patient has a current direct interest with company A according to EMA policy</td>
<td></td>
</tr>
</tbody>
</table>
Short guidance on managing competing interests and conflicts of interest

Stakeholder-specific considerations when managing competing interests and conflicts of interest

Please review the definitions of relevant stakeholders in the Definitions section.

### Medicines developers
- Patient engagement should take place systematically across the product lifecycle, and should be conducted by applying foundational principles of respect for and independence of the patient community.
- Set up conflict of interest policy/declaration of interest (DoI) procedure as part of the due diligence before engaging patients in your activities.
- Mitigation measures should be developed/considered whenever necessary before any patient engagement activity.
- Inform patients about potential consequences of the act of engagement (e.g., potential conflict of interest with other stakeholders such as regulatory and HTA bodies, payers).

### Regulators, HTA bodies, payers
- Adapt the processes and documents (e.g., clear and accessible DoI forms, policies) and provide support for patients during the DoI procedure.
- Mitigation measures should be developed/considered whenever necessary before any patient engagement activity. Patients and their organizations should be made aware of the existence of such measures.
- Acknowledge that there might be potential limitations in expertise in the patient community (e.g., rare diseases, underrepresented groups) and ensure that special status is granted where necessary and appropriate.

### Patients and their organizations
- Keep accurate records of your interactions with different stakeholders (e.g., use the log of activities) and disclose before any engagement.
- If you engage with a given stakeholder, prepare your own DoI form and update it periodically.
- If your organization, make sure that engagement and advocacy activities are done by different individuals to ensure that there will be always someone “free from conflict” to engage with other stakeholders.
- Ask about the potential consequences of the particular engagement activity to the engaging stakeholder.
- Be aware of and make use of any accepted mitigation measures in situations that might lead to conflict.

### Annex 2: Examples of levels of restriction in EMA and EUnetHTA activities

#### EMA types of interest and level of restriction
Adapted from EMA policy on handling competing interests [3]

<table>
<thead>
<tr>
<th>Types of Interest</th>
<th>EMA</th>
<th>Level of restriction in EMA activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct (current or within the last 3 years)</td>
<td>Employed by a medicine developer</td>
<td>No involvement or severely restricted involvement</td>
</tr>
<tr>
<td></td>
<td>Consulting (including financial compensation)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Strategic Advisory Role for a company</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Financial (e.g., stock, shares)</td>
<td></td>
</tr>
<tr>
<td>Indirect (current or within the last 3 years)</td>
<td>Principal Investigator</td>
<td>Involvement permitted but restrictions apply</td>
</tr>
<tr>
<td></td>
<td>Investigator</td>
<td></td>
</tr>
<tr>
<td>No interest or Interests over 3 years</td>
<td>Grant/Funding to the patient organization/ institution</td>
<td>Close family member interests</td>
</tr>
<tr>
<td>(except executive role or in-house)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### EUnetHTA types of interest and level of restriction
Adapted from EUnetHTA policy [4]

<table>
<thead>
<tr>
<th>Types of Interest</th>
<th>EUnetHTA</th>
<th>Level of restriction in EUnetHTA activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Major</td>
<td>Employed by a medicine developer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Consulting (including financial compensation)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Strategic Advisory Role</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Principal Investigator</td>
<td>No involvement</td>
</tr>
<tr>
<td>Minor</td>
<td>Being a current member of an association (patient or HCP organization) funded or receiving travel costs or payment for attendance at a conference/meetings sponsored by only one company producing within the technology under assessment, or a competitor, or a relevant technology under development.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Receiving funding for research activities related specifically to the technology under assessment, a competitor, or a relevant technology under development.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Financial (e.g., stock, shares)</td>
<td></td>
</tr>
</tbody>
</table>

Copyright 2020 MIMDGM – Patient engagement in Medicine: R&D Recommendations on how to find the right match for the right patient engagement activity.
Declaration of interests

For example, you will be asked to provide information such as:

• Your affiliations/employment as far as 3 years back from the time of filling the form

• All current and/or past financial interests

• Involvement as an advisor to or a member of an advisory board and/or steering committee for a pharmaceutical company, CRO or another organisation (including non-profit organisations)
Log of activities template

- This tool has been developed for patients and their organisations.
- You will be able to accurately track and declare your interests as required before getting involved in activities along the medicines’ life-cycle.
- You can use this tool as a guidance to set up your own log of activities, or that of your organisation.

<table>
<thead>
<tr>
<th>Log of activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date from/to of engagement (month/year or ongoing)</td>
</tr>
<tr>
<td>Time spent for the activity/or time of engagement (e.g. contract for six months but engagement actual engagement only for one day)</td>
</tr>
<tr>
<td>Country of activity</td>
</tr>
<tr>
<td>Participation Were you participating in your individual capacity or as a representative of your patient organisation?</td>
</tr>
<tr>
<td>Activity What activity did you engage in?</td>
</tr>
<tr>
<td>To complete this field, see Annex 1</td>
</tr>
<tr>
<td>Description of activity (Individual/specific medicine or non-medicine related; disease-related or not) Be mindful not to disclose any confidential information.</td>
</tr>
<tr>
<td>To complete this field, see Annex 1</td>
</tr>
<tr>
<td>Engaging stakeholder organisation(s)</td>
</tr>
<tr>
<td>Type of agreement/contract signed with the engaging stakeholder [5, 6] Have you signed any agreement (e.g. collaboration, consultancy, speaker, advisory board, grant, donation agreement, etc.)</td>
</tr>
</tbody>
</table>
You are keeping a record of your interactions with different stakeholders (in relation to therapeutic development). What type of interactions should you list in your log of activities?

A. Only the ones for which you have received compensation and/or remuneration
B. All of them
C. I don’t keep a record of my activities, it is not useful
What type of interactions should be listed in your log activities

You are keeping a record of your interactions with different stakeholders (in relation to therapeutic development). What type of interactions should you list in your log of activities?

A. Only the ones for which you have received compensation and/or remuneration
B. All of them
C. I don’t keep a record of my activities, it is not useful
2: You are a patient advocate and you are keeping a record of your interactions with different stakeholders (in relation to therapeutic development). What type of interactions should you list in your log of activities?

A. Only the ones for which you have received compensation and/or remuneration

B. All of them

C. I don't keep a record of my activities, it is not useful

**Rationale**

A. Only keeping record of the interactions for which you have received compensation/remuneration is not recommended. For some stakeholders (e.g. regulators) paid or unpaid consultancy (i.e. strategic advice) could lead to a conflict of interest.

B. Keeping track of all your engagement activities with various stakeholders, is very important to help you correctly declare your interests to the engaging stakeholder (e.g. regulators, HTA bodies, payers, medicines developers).

C. Not keeping any records may make it difficult to complete the declaration of interest form, as in most cases you would need to declare activities from past years. Failing to keep accurate records increases the possibility of a perceived conflict that may exclude you from some engagement activities.
Reporting and Dissemination of PE activities
The Actors

Ana Diaz
Alzheimer Europe

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University of Oxford

Kay Warner
GSK

Apostolos Kalogiannis
EATG

Laiba Hussain
University of Oxford

Mary Lynne Van Poelgeest-Pomfret
EFGCP
What is the tool?

Structured and timely reporting of objectives and results of a Patient Engagement (PE) activity; not considered confidential, yet sufficiently detailed to permit knowledge gain and transfer between stakeholders and the public with a strong focus on the patient community, as part of a broader and continuous dissemination and communication and change management strategy.
Why is it important?

General lack of structured, detailed and discoverable reporting and **external** dissemination of PE activities

- Enhances collaborative co-production of PE reporting and dissemination materials
- Improves transparency of outcomes of PE activity and learning (not just positives)
- Continuous collective knowledge gain for whole PE ecosystem
- Better continuity - prospective alignment, not retrospective extra effort
How the tool could help

Guiding principles

• Planning and agreeing the **overall goal and timeframe**

• Exploring possible **dissemination mechanisms and channels** for the PE activity

• **Processes planned, agreed and implemented between the respective parties**, capacities and capabilities, roles and responsibilities

• Early involvement of **legal and compliance** departments to reach a mutual understanding on what information can be put into the public domain and when this can occur

• **Meaningful involvement of patients** - joint development and/or dissemination of PE activities being flexible
How the tool could help

- **Content and format of reports** – optimising language, fonts, text, style, and accessible formats

- **Outcomes/outputs** - translation to other languages, continuous learning and knowledge-sharing

- Reporting and dissemination of material, appropriately stored, managed and discoverable for all relevant stakeholders to learn from

- **Flexibility** in the approach using new or existing reporting structures to maximize broader knowledge sharing within available resources
How the tool could help

- Plan dissemination as part of planning for PE activities
- Reflection of your evolving PE approach
- In combination with internal planning and reporting documents
How the tool could help

- Timely dissemination
- Structure and detail
- Maximize learning and discoverability

### Reporting templates

<table>
<thead>
<tr>
<th>Title of the PE activity/ initiative:</th>
</tr>
</thead>
<tbody>
<tr>
<td>When was the activity carried out</td>
</tr>
<tr>
<td>(start date-completion date)</td>
</tr>
<tr>
<td>What stage of medicines research and</td>
</tr>
<tr>
<td>development (R&amp;D) was it most applicable to:</td>
</tr>
<tr>
<td>Date of reporting:</td>
</tr>
<tr>
<td>Organisation(s) who is/are reporting</td>
</tr>
<tr>
<td>and contact details of person to contact</td>
</tr>
<tr>
<td>in case of questions:</td>
</tr>
</tbody>
</table>

**Introduction/rationale:**

- What was the activity about and what did you want to achieve with the PE?

**Who did you involve and how?**

- Who did you involve?
- How did you select the patients?
- Did you train/provide relevant information to them, etc.
How the tool could help

<table>
<thead>
<tr>
<th>completed Template</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Completed Template</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Title of the PE activity/initiative:</th>
<th>RADAR-AD Patient Advisory Board</th>
</tr>
</thead>
<tbody>
<tr>
<td>When was the activity carried out (start date-completion date)</td>
<td>Ongoing - PAB was set up in March 2019. The specific PE activity reported in this template was carried out in June 2019</td>
</tr>
<tr>
<td>What stage of medicines research and development (R&amp;D) was it most applicable to:</td>
<td>Design of clinical trials</td>
</tr>
<tr>
<td>Date of reporting:</td>
<td>March 2020</td>
</tr>
<tr>
<td>Organisation(s) who is/are reporting and contact details of person to contact in case of questions:</td>
<td>Alzheimer Europe. Ana Diaz, Project Officer, <a href="mailto:ana.diaz@alzheimer-europe.org">ana.diaz@alzheimer-europe.org</a></td>
</tr>
<tr>
<td>Timeframe of involvement:</td>
<td>The project started in January 2019. The PAB was set up in March 2019 and will continue until the end of the project. PAB members meet face-to-face at least 3 times a year and keep ongoing written communication in between meetings. A few selected PAB members attend the project Annual General Meeting.</td>
</tr>
</tbody>
</table>
How the tool could help

Completed Template

Who did you involve and how?

- Who did you involve?
- How did you select the patients?
- Did you train/provide relevant information to them, etc.

The PAB is composed of people with dementia, people with Mild Cognitive Impairment (MCI) and carers. Information about the PAB composition and members can be found here: [https://www.radar-ad.org/patient-engagement/patient-advisory-board](https://www.radar-ad.org/patient-engagement/patient-advisory-board)

People with dementia and carers are members of an existing Working Group (information about the WG can be found here: [https://www.alzheimer-europe.org/Alzheimer-Europe/Who-we-are/European-Working-Group-of-People-with-Dementia](https://www.alzheimer-europe.org/Alzheimer-Europe/Who-we-are/European-Working-Group-of-People-with-Dementia))

The PAB members with dementia have different types of dementia, are at different stages of the disease (mild to moderate) and live in different European countries.

People with MCI had participated in a focus group organised by the project and expressed interest in participating long term in the project. Inclusion of people with MCI in the PAB was important as it reflects the type of patients included in the project.

PAB members did not receive any specific formal training. The majority of members have been previously involved in research and PPI activities and in providing feedback to the protocol of the trial. In addition, the consultation is based on their lived experience of the disease. Lay terms are used for all communications, so no previous technical knowledge...
How the tool could help

What worked well and what did not in undertaking the PE activity?

- Careful and detailed preparation of the meeting (e.g. by research team and AE staff)
- Social interactions: PAB members and AE facilitators were already familiar so they felt at ease to participate and there was an atmosphere of trust and openness to share their views.
- Breaks during the day and a relatively long break for lunch. Participants were all in the hotel the night prior to the meeting so no one had to travel on the morning of the meeting.
- The team in the RADAR-AD project was very open to feedback by the PAB and four researchers came to the meeting and helped to facilitate the discussions. It is important that the right people from the team is in the room and can answer questions to the PAB as well as to listen to the feedback first-hand.
- A report was sent to the research team shortly after the meeting and the PAB also received information of the progress of the project.
How the tool could help

Completed Template

What worked well and what did not in undertaking the PE activity?

- What elements of the planning and execution worked well?
- What elements of the planning and execution didn’t work well?

Elements that didn’t work as well:

- It was difficult to find a good balance between the number and length of breaks and time for discussion which works well for all members due to the different types and stages of dementia but also their personal backgrounds.

- This PAB is a large group, which is very valuable for providing diverse opinions and experiences, but it was more challenging to facilitate a large group of members with different needs and to ensure all members have equal opportunities for participating.

- Certain issues ideally would have had more time for discussion.

- Some members of the PAB did not like the vignette activity, however the majority found it very useful.
Which is the most important practical consideration that you face in involving patients in reporting and dissemination?

- Agreeing overall goals and timelines
- Identifying appropriate dissemination mechanisms
- Required writing capacities and capabilities
- Required time and resources
- Involvement of legal and compliance
- Managing confidential material
- Meaningful co-production of material
- Translation of outcomes in other languages
- Flexibility in using existing reporting structures
- Enabling continuous learning and knowledge-sharing
- None of the above
Where does your organisation mainly currently disseminate PE activities?

- 0 Within internal teams
- 0 Own organisation's website
- 0 Websites of the stakeholders involved
- 0 Third party platforms (e.g. EUPATI, PFMD etc)
- 0 Journal or periodical publication
- 0 Forums and conferences
- 0 No external dissemination occurs
- 0 None of the above
How might you get internal buy-in within your organisation to use and adopt this tool?

0 Present to PE teams within your organisation
0 Present to managers or cross functional teams
0 Use it to demonstrate its benefit before seeking buy-in

0 Use it to review and optimise current reporting and dissemination strategies
0 All of the above
Thank you for joining us today!

- The next session on the PARADIGM tools is on July 9\textsuperscript{th}
- The topics covered will be:
  - Community Advisory Boards
  - Code of Conduct
  - Enhancement of the EUPATI Guidance
- Meanwhile, please participate to the Public consultation
  www.imi-paradigm.eu/tools-consultation

Enjoy the rest of the PEOF2020