PARADIGM Patient Engagement Tools
Session #1

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

PATIENT FOCUSED MEDICINES DEVELOPMENT

EUPATI
European Patients' Academy on Therapeutic Innovation

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.

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Patient Engagement open forum Into Reality

Agenda

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)

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

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Let’s work together to spread the word

#PEOF2020

@imi-paradigm

@eupatients

@PFMDwithPatient

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Agenda

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

16h00 – 17h20 Presentation of PARADIGM tools

- Case study based on:
  - Recommendations on how to identify the right match for the right patient engagement activity
  - 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

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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

Research and priority setting

Design of clinical trials

Early dialogues with regulators and HTA bodies

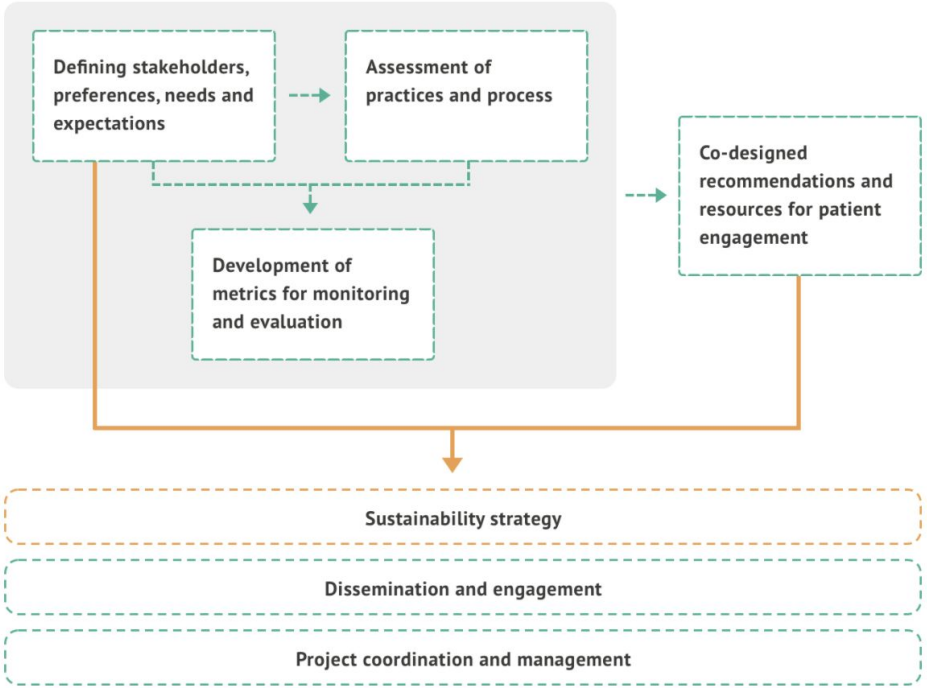
Objectives

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



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.

List of topics with tools post gap analysis

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	Enhancement of the EUPATI industry guidance	Guidance for reporting and dissemination of patient engagement activities	Recommendations on required capabilities for patient engagement
Monitoring and Evaluation framework	Community Advisory Board- Guidance document and templates	Patient engagement agreements explained	Recommendations for HTA bodies to conduct patient engagement activity during early dialogue	Code of conduct

Case study

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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

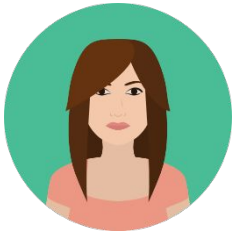
Mathieu Boudes
European Patients' Forum

Elisa Ferrer
EURORDIS

Maria Cavaller
EURORDIS

The case

- Stakeholders involved



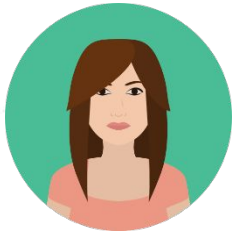
Sheila works as head of patient engagement at Genius Pharma. She is planning a patient engagement activity to help identify relevant rheumatoid arthritis endpoints for the design of a clinical trial

Pharma company

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

Patient representative

- The activity:
  Identify patient-relevant endpoints for the design of a clinical trial



STEP 1:
Outline the patient engagement activity on shared purpose

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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)

DIAGRAM 1: **Process steps**

STEP 1	By the engaging partner	Outline of the patient engagement activity on shared purpose (scope, time, human and financial resources ...)	
STEP 2A	By the engaging partner	Identification of relevant PO to co-create the activity	
STEP 2B	By the engaging partner	If no PO exist, has the capacity nor is interested, use alternative methods to create the activity with the patient community	
STEP 3	By the engaging partner and the relevant PO(s)	Co-definiton of the competencies needed to carry out the patient engagement activity	
STEP 4A	By the the relevant PO(s)	Identification of patients or their representatives that match the needed competencies for the activity	
STEP 4B	By the engaging partner	If no PO exist, has the capacity nor is interested, use alternative methods to identify patients or the representatives that match the needed competencies for the activity	
STEP 5*	By the engaging partner and the relevant PO(s)	Running the engagement activity	The identification of the patients and their rep is the sole responsibility of the relevant POs and CoI checks should be performed by the partners
STEP 6*	By the engaging partner and the relevant PO(s)	Measuring its impact and reporting back the the community	

* Not the scope of these recommendations

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STEP 1: **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[6] 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 hypothesis 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 Annex 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 patients/patient organisations 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

[6] A shared purpose. IPFMD's Patient Engagement Quality Guidance. Available at: https://patientfocusedmedicine.org/pegg/patient-engagement-quality-guidance.pdf

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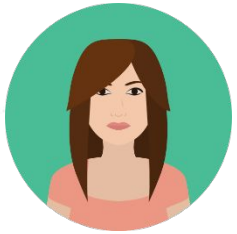
the suitable match are made.

- 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 EUPATI industry guidance: suggested working practices[7].

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).

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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)

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STEP 5*	By the engaging partner and the relevant PO(s)	Running the engagement activity	The identification of the patients and their rep is the sole responsibility of the relevant POs and CoI checks should be performed by the partners
STEP 6*	By the engaging partner and the relevant PO(s)	Measuring its impact and reporting back the the community	

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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 organisations 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) POs 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[8]:

[7] IMI PARADIGM's Enhancement of PARTNER industry guidance: suggested working practices. Available at: http://imi-paradigm.eu/#/Toolbox/enhanced-eu-patient-guide

[8] Adapted from: Roche's and Novartis' internal materials

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(The list below does not intend to capture the entire set of elements of a complete landscape analysis)

- **Overview of the community**
  - 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, as 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 POs. The recommended topics and the check list below can be downloaded as a stand alone tool here[9].

[9] Available at: http://imi-paradigm.eu/#/Toolbox/identification-of-patient-representatives

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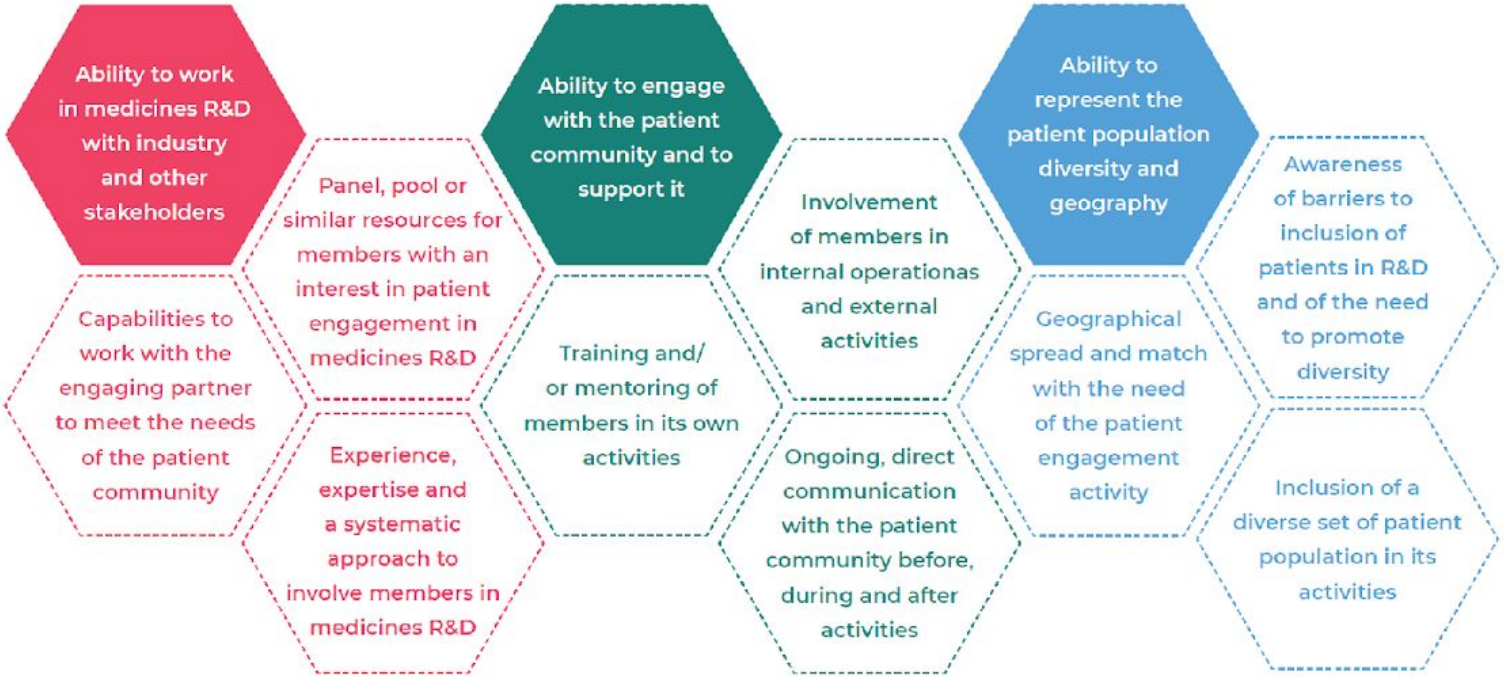
How to find the best suitable patient organisation?

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**



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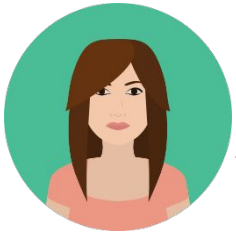

Use the check list of the elements to consider before engaging with a patient organisation

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

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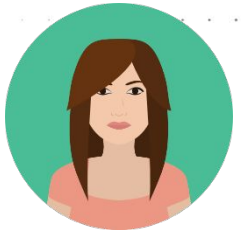
TABLE I: **Check list of the elements to consider before engaging with a patient organisation to work on a patient engagement activity**

Elements to consider before engaging with a patient organisation to work on a patient engagement activity	Yes / No / Partially	Comments
Does the organisation have the experience, expertise and a methodology or a systematic approach about how to involve their members in medicines R&D?		
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?		
Does the organisation have a panel, pool or similar resources which includes their members with an interest in patient engagement in medicines R&D?		
Does the organisation have well-established channels of communications with their members and beyond with the patient community at large?		
Does the organisation involve their members in their own internal operations and external activities?		
Does the organisation have direct contact with their members and the track record of mobilising them?		
Does the organisation have the resources to train and/or mentor their members in its own activities?		
Does the organisation have the geographical coverage that matches the needs of the patient engagement activity?		
Does the organisation address the inclusion of a diverse set of the patient population in its own activities?		
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&D?		



STEP 3:
Sheila and Rick jointly co-define the competencies needed to carry out the activity

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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)
- Databases[10], either open access (e.g. Orphanet[11], PFMD's Synapse[12]) or proprietary (e.g. EMA individual experts' stakeholder database)
- eYPAGnet[13] to engage children and young people through the YPAGs (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 EUPATI (with the limitation that only EUPATI fellows and patients in the EUPATI 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 need 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

[10] IMI PARADIGM's Recommendations on the required capabilities for patient engagement: More information on the Table 8. Available at: http://imi-paradigm.eu/#/toolbox/be-capacity

[11] Orphanet, Available at: https://orphanet

[12] PFMD's Synapse, Available at: https://synapse.pfmd.org/

[13] This network has the recognition of EnprEMA (European Network for Paediatric Research of EMA), Available at: https://www.eypagnet.eu/

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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[14,15,16,17,18]. 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[19].

When conditions exist to prevent co-creation, due to the nature of the activity, external regulations or the capacities of the POs, 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[20].

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[21].

[14] EFPIA's Working together with patient groups. Available at: https://www.efpia.eu/media/412524/working-together-with-patient-groups-27102017.pdf

[15] EFPIA's Code of practices. Available at: https://www.efpia.eu/media/413022/efpia-code-2019.pdf

[16] EURORDIS Charter for Collaboration in Clinical Research in Rare Diseases. Available at: http://download2.eurordis.org.s3-eu-west-1.amazonaws.com/clinical_trials/charter-for-collaboration-in-clinical-research.pdf

[17] EUPATI's Guidance documents on patient involvement in R&D. Available at: https://www.eupati.eu/guidance-patient-involvement/

[18] IMI PARADIGM's Short Guidance 'General and stakeholder-specific considerations to manage competing interests and conflicts of interest'. Available at: http://imi-paradigm.eu/#/toolbox/conflict_of_interest

[19] IMI PARADIGM's Recommendations on the required capabilities for patient engagement: More information on the Table 8. Available at: http://imi-paradigm.eu/#/toolbox/be-capacity

[20] IMI PARADIGM's Recommendations on the required capabilities for patient engagement. Available at: http://imi-paradigm.eu/#/toolbox/be-capacity

[21] The table can be downloaded here as a stand alone tool, Available at: http://imi-paradigm.eu/#/toolbox/identification-of-patient-representatives

TABLE 2: **Competency table**[22] **(downloadable version here)**

Competencies		Definition	1. Low	2. Intermediate	3. High	Patient engagement activity	
						Co-designing the project	Participating in the project
Medical expertise	Basic medical expertise	Medical expertise, anatomic and physiological expertise, knowledge about medicines research and development processes	Basic medical expertise (anatomy, physiology, use of treatments)	Extended medical expertise (medicines development, medical methodology)	In-depth medical knowledge in all aspects		
	Indication specific expertise	Knowledge about the indication/disease, treatments, care and life circumstances of those living with the disease	Basic indication, treatment and care expertise	Extended indication, treatment and care expertise	In-depth indication, treatment and care expertise incl. latest research and treatment expertise		
Systems expertise	Regulatory expertise	Knowledge about the regulatory processes, e.g. evaluation, authorization, reimbursement processes of therapies	Basic knowledge about the medicines approval process, related assesments and reimbursement procedures	Extended knowledge about the medicines approval process, related assesments and reimbursement procedures	In-depth knowledge about the medicines approval process, related assesments and reimbursement procedures		
	Public Health expertise	Knowledge about access and participation in the healthcare system (e.g. social law), knowledge about health policy	Basic knowledge about accessing and participating in the healthcare system	Extended about accessing and participating in the healthcare system; basic knowledge about health policy	In depth knowledge about accessing and participating in the healthcare system and underlying health policy		

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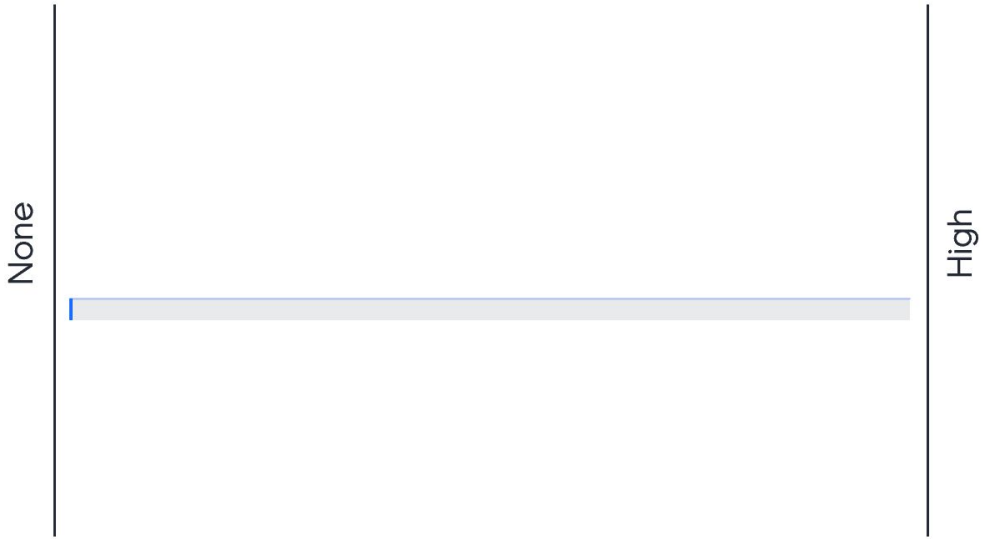
Indication specific expertise

Mentimeter



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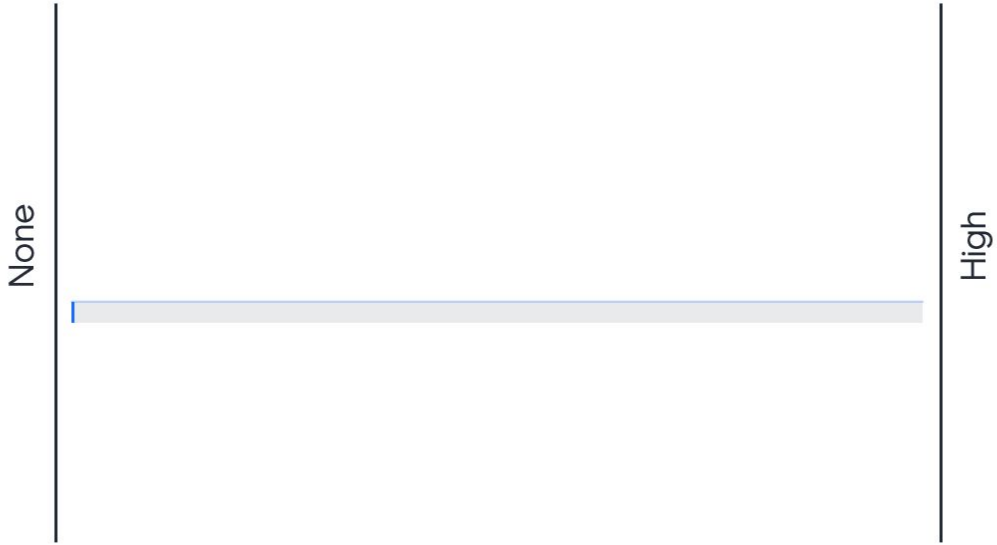
Public Health expertise

Mentimeter



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Methodological expertise	Communication and representation	Well structured and solution oriented communication skills (including digital and social media), and expertise to advocate appropriately for a patient community	Objective communication and appropriate conduct	Clear and focused communication with sound and consistent opinion	High level skills in communication, moderation and group interaction		
	Negotiation skills and political interaction	Expertise in political interaction, negotiation skills	No specific expertise in political interaction	Personal integrity and good negotiating skills	Sensible policy interaction and communication, strong negotiation skills and consistent positions		
Personal framework	Personal experience	Indication-specific expertise based on personal experience	Empathic in relation to those affected	Affected indirectly (e.g. family member)	Direct affected by the condition		
	Community insight and involvement	Involvement in the patient community in a specific indication area. Ability to abstract from personal experience to represent a wider community	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	Structured approach on processes and decision making when interaction with people across specific community. Ability to represent a community		
	Capability to perform the task	Financial means or support to allow to perform a specific role; availability to pewrform specific tasks; Sufficient physical fitness	Ability to engage on a specific task within a strict time and effort limit	Ability to undertake continuous, recurrent interaction	Ability to carry out more complex, long term tasks requiring a considerable commitment (efforts, time and health wise)		

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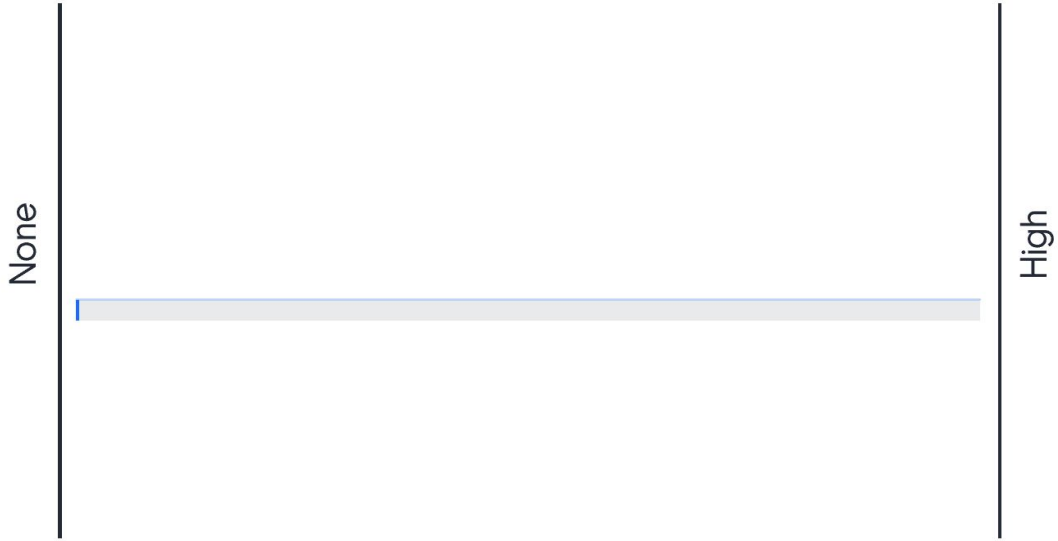
Personal experience



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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

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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)

DIAGRAM I: **Process steps**			
STEP 1	By the engaging partner	Outline of the patient engagement activity on shared purpose (scope, time, human and financial resources ...)	
STEP 2A	By the engaging partner	Identification of relevant PO to co-create the activity	
STEP 2B	By the engaging partner	If no PO exist, has the capacity nor is interested, use alternative methods to create the activity with the patient community	
STEP 3	By the engaging partner and the relevant PO(s)	Co-definiton of the competencies needed to carry out the patient engagement activity	
STEP 4A	By the the relevant PO(s)	Identification of patients or their representatives that match the needed competencies for the activity	
STEP 4B	By the engaging partner	If no PO exist, has the capacity nor is interested, use alternative methods to identify patients or the representatives that match the needed competencies for the activity	
STEP 5*	By the engaging partner and the relevant PO(s)	Running the engagement activity	The identification of the patients and their rep is the sole responsibility of the relevant POs and CoI checks should be performed by the partners
STEP 6*	By the engaging partner and the relevant PO(s)	Measuring its impact and reporting back the the community	

* Not the scope of these recommendations

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STEP 4A & 4B: **Identification of patients or their representatives that match the needed competencies for the activity**

In a member-based PO, qualifying and understanding the membership through development and integration of software that can record the self-assessment of interest, the availability of individuals and their competencies for future engagement with any type of activity could be

[26] Section 3 on Representativeness of stakeholders. Available at: https://patientfocusedmedicine.org/the-patient-engagement-quality-guidance/
[28] Section 7 Representativeness of all stakeholders. Available at: https://imi-paradigm.eu/wp-content/uploads/2019/11/D7.1_Recommendation-on-stakeholders-required-capabilities-for-PE-in-RD.pdf/
[29] National Health Council's Roadmap and Rubric. Available at: https://www.nationalhealthcouncil.org/wp-content/uploads/2019/12/Representativeness%20in%20Patient%20Engagement.pdf

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considered, with the deployment of Customer Relationship Management[28] type software.

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

The IMI PARADIGM's D4.1 Recommendations on the required capabilities for patient engagement[29] states that among others that 'patient engagement functions in the different stakeholder groups may act as a single point of contact either as a nominated person or a department and take responsibility to:

- **Identify the right patients for the patient engagement activity.**
- [...]

Patient engagement functions in both industry and POs can be organised in a number of models (e.g. by types 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 or related functions) in POs 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 POs to identify the patients and their representatives and make a final selection decision based on the results of the identification process (refer to 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 Raising awareness on managing competing interests in a multi-stakeholder environment: Guidance to patients and engaging stakeholders[30].

If the POs 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.

[28] Customer Relationship Management. Available at: https://en.wikipedia.org/wiki/Customer_relationship_management
[26] Section 3 on Representativeness of stakeholders. Available at: https://patientfocusedmedicine.org/the-patient-engagement-quality-guidance/
[30] IMI PARADIGM's 'Raising awareness on managing competing interests in a multi-stakeholder environment: Guidance to patients and engaging stakeholders'. Available at: http://imi-paradigm.eu/#-tool-box/conflict-of-interest

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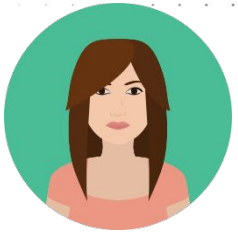
Before the activity starts, Sheila asks herself…



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

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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.

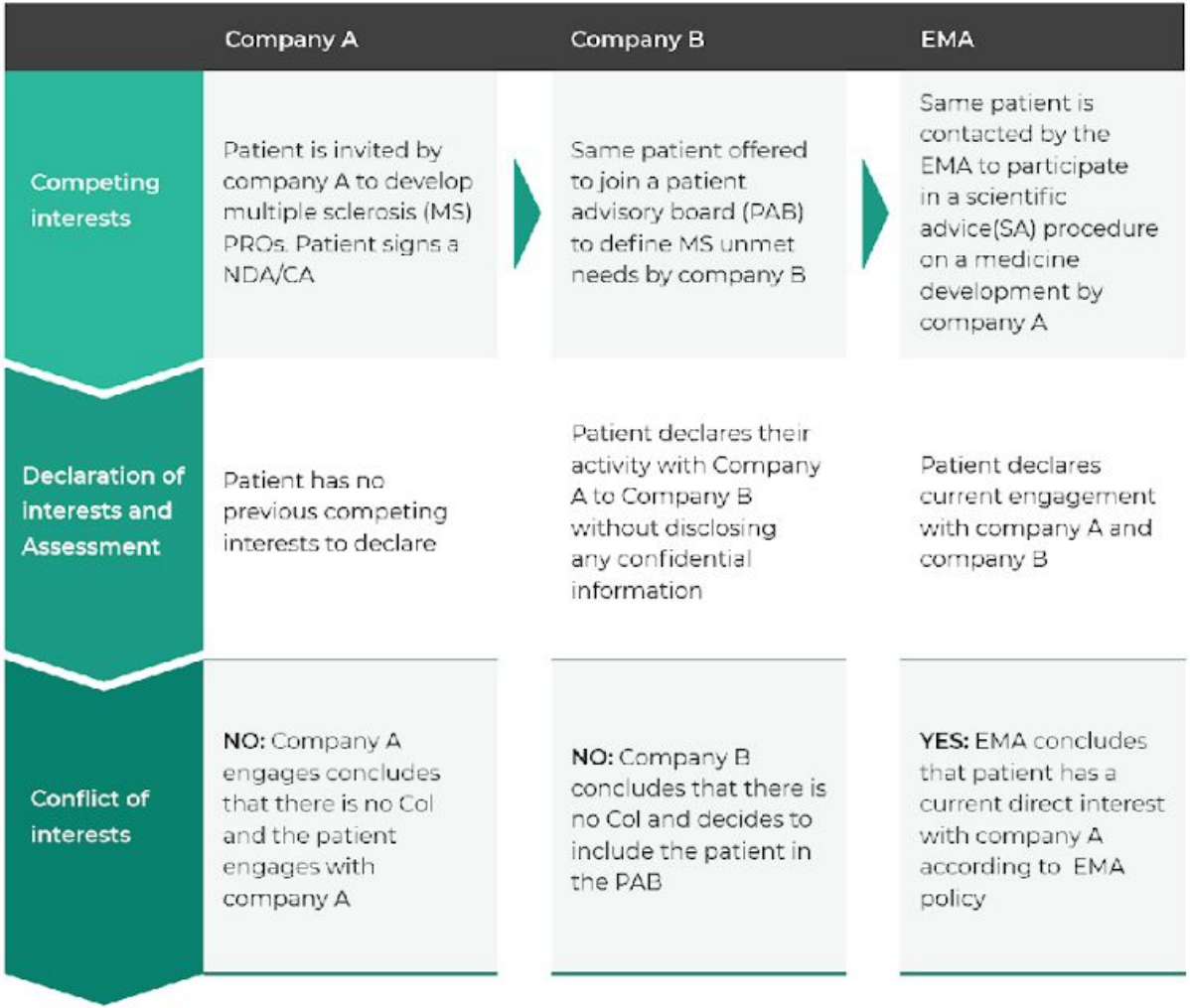
C. The type of interaction and the consequences derived from it, may be different depending on the groups involved. Thus, each stakeholder group defines the type of and rules for engagement with their stakeholders. The engaging stakeholder and process of engagement define what represents a conflict of 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



Short guidance on managing competing interests and conflicts of interest

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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 egagement should take place systematically across the porduct 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 digilence before engaging patients in your activities.
	Mitigation measures should be developed/considerend 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/considerend whenever necessary before any patient engagement activity. Patients and their organisations should be made aware of the existance 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 organisations	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 organisation, 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 CoI

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]

Types of Interest	EMA	Level of restriction in EMA activities
Direct (current or within the last 3 years)	Employed by a medicine developer	No involvement or severely restricted involvement
	Consultancy (regardless of financial compensation)	
	Strategic Advisory Role for a company	
	Financial (e.g. stocks, shares..)	
Indirect (current or within the last 3 years)	Principal Investigator	Involvement permitted but restrictions apply
	Investigator	
	Grant/funding to the patient organisation/ institution	
	Close family member interests	
No interest or interests over 3 years (except executive role or lead role)		Full, unrestricted involvement

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

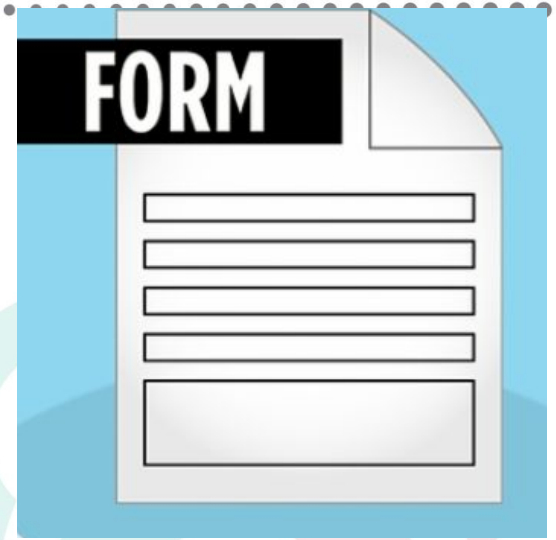
Types of interest	EUnetHTA	Level of restriction in EUnetHTA activities
Major	Employed by a medicine developer	No involvement
	Consultancy (regardless of financial compensation)	
	Strategic Advisory Role	
	Principal Investigator	
	Being a current member of an association (patient or HCP organisation) funded mainly by the industry (>40 % of association budget)	
	Covering/subsidising travel costs or paying an honorarium for delivering a presentation or attending conferences/meetings sponsored by only one company producing either the technology under assessment, a comparator, or a relevant technology under development.	
	Receiving funds for research activities related specifically to the technology under assessment, a comparator, or a relevant technology under development.	Involvement can still occur if interests are no longer existing
	Financial (e.g. stocks, shares..)	

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.

Log of activities	
Date from/to of engagement (month/year or ongoing)	
Time spent for the activity/or time of engagement (e.g. contract for six months but engagement actual engagement only for one day)	
Country of activity	
Participation Were you participating in your individual capacity or as a representative of your patient organisation?	
Activity What activity did you engage in?	
To complete this field, see Annex 1	
Description of activity (Individual/specific medicine or non-medicine related; disease-related or not) Be mindful not to disclose any confidential information. To complete this field, see Annex 1	
Engaging stakeholder organisation(s)	
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.)	

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

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What type of interactions should be listed in your log activities

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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

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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.

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Reporting and Dissemination of PE activities

The Actors

Ana Diaz
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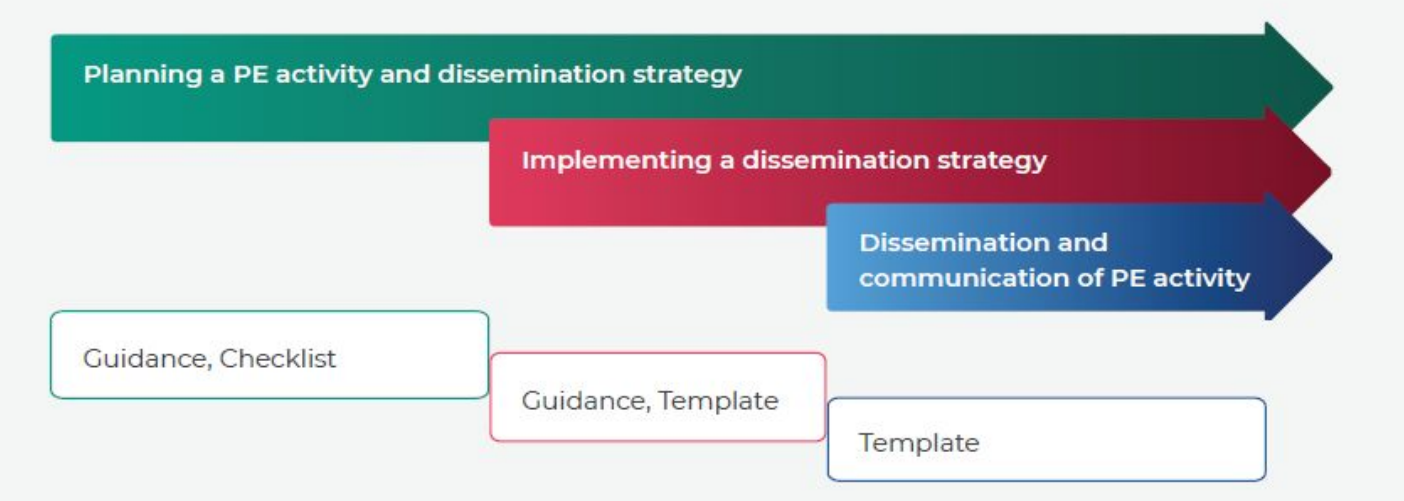
What is the tool?

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

Guiding principles

- **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

Planning checklist

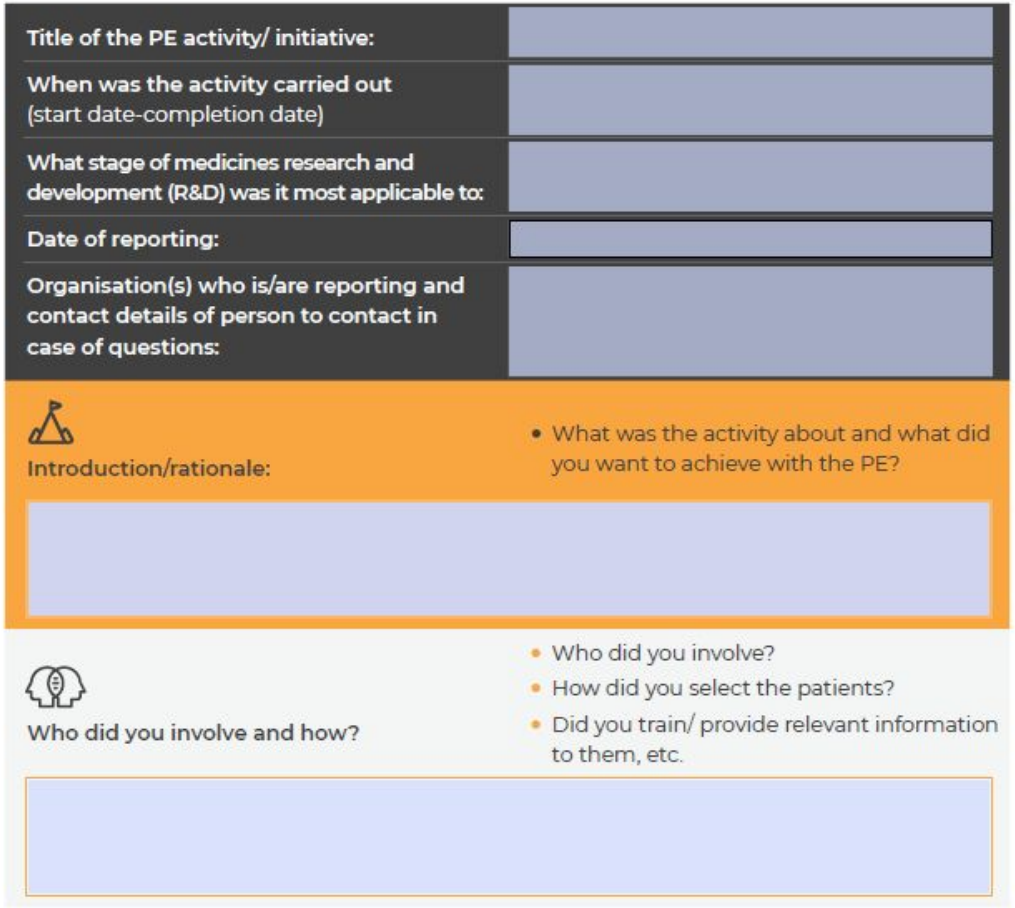
- Plan dissemination as part of planning for PE activities
- Reflection of your evolving PE approach
- In combination with internal planning and reporting documents

Key Principles to consider when reporting and disseminating PE activities			
Process	**Yes**	**No**	**Comments**
Do all stakeholders involved have a clear understanding of the benefits and challenges for timely reporting of this specific PE activity?			
Are existing reporting styles, structures and templates being streamlined across different teams, partners, and stages to reduce duplication and redundancy in content?			
Is there a plan to involve legal and compliance departments early in the planning and implementation phases to help manage potentially confidential material generated between the involved stakeholders?			
Meaningful involvement of patients	**Yes**	**No**	**Comments**
Is it confirmed that patients will be involved jointly in decisions about the reporting and dissemination of the activity?			

How the tool could help

Reporting templates

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



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

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

Completed Template

Title of the PE activity/ initiative:	RADAR-AD Patient Advisory Board
When was the activity carried out (start date-completion date)	Ongoing - PAB was set up in March 2019. The specific PE activity reported in this template was carried out in June 2019
What stage of medicines research and development (R&D) was it most applicable to:	Design of clinical trials
Date of reporting:	March 2020
Organisation(s) who is/are reporting and contact details of person to contact in case of questions:	Alzheimer Europe. Ana Diaz, Project Officer, ana.diaz@alzheimer-europe.org
Timeframe of involvement:	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.

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

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)

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

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 worked well were:

- 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.

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Which is the most important practical consideration that you face in involving patients in reporting and dissemination?

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0 Agreeing overall goals and timelines	0 Identifying appropriate dissemination mechanisms	0 Required writing capacities and capabilities	0 Required time and resources
0 Involvement of legal and compliance	0 Managing confidential material	0 Meaningful co-production of material	
0 Translation of outcomes in other languages	0 Flexibility in using existing reporting structures	0 Enabling continuous learning and knowledge-sharing	0 None of the above

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Where does your organisation mainly currently disseminate PE activities?

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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

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How might you get internal buy-in within your organisation to use and adopt this tool?

Mentimeter

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

0

Thank you for joining us today!

- The next session on the PARADIGM tools is on July 9th
- 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