

From Gaps to Bridges

The Future of Patient
Engagement in Central
and Eastern Europe

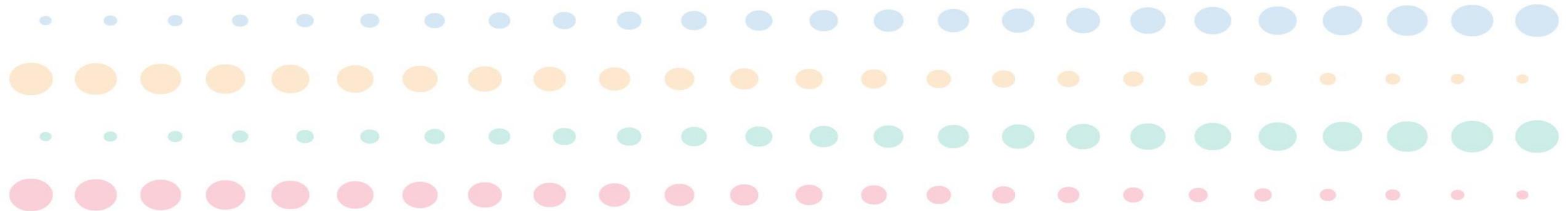


**Capacity and capabilities for patient
engagement workshop
12 May 2020**

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Capability framework for patient engagement: what, why and how we got here?



How easy is it in your country to build a skilled workforce with the right capacities and capabilities to sustain patient engagement in medicines R&D?:

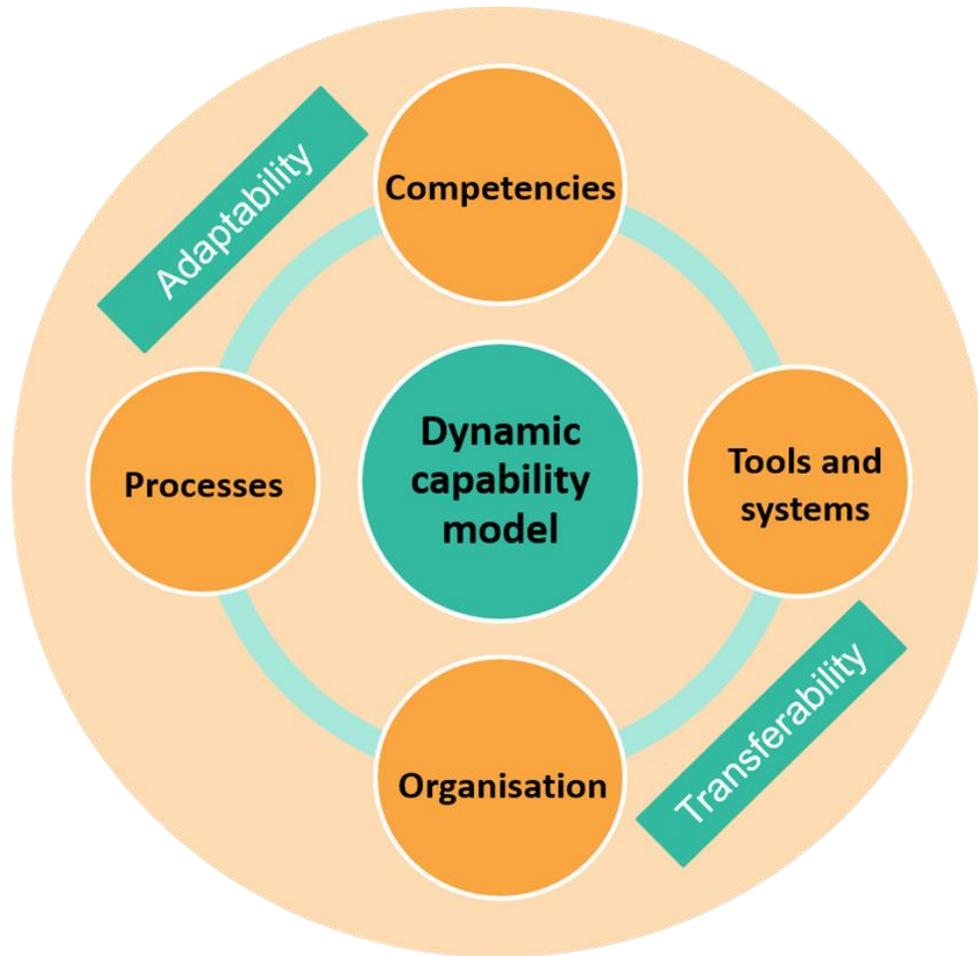


Recommendations on the required capabilities for patient engagement

Purpose

- To provide recommendations on a **set of capabilities** that each stakeholder should aspire **to have in place in their respective organisation** in order to be able to undertake the planning, implementation and reflection of patient engagement activities across the medicine's life-cycle.
- It **DOES NOT** cover the capabilities of the patients participants in patient engagement activities

Patient engagement capability framework



Competencies: Combination of knowledge, skills and behaviours of an individual

Processes: Processes define how things can be done. They can change in accordance with internal policies, regulations, technologies and other influences.

Tools and systems: Instruments necessary to perform a specific task, from technological tools to the ability to use certain systems.

Organisation: Refers to the organisational structure (functions) of each stakeholder group and also to an organisational culture that enables ethical and meaningful engagement.

Patient engagement capability framework

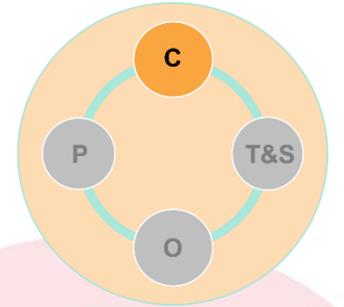
- Organised following [PFMD's patient engagement quality criteria](#)
- The PFMD quality guidance was used as a method to divide the recommendations in sections the most relevant aspects of patient engagement in medicines R&D.
 - Shared purpose and roles and responsibilities
 - Respect and accessibility
 - Representativeness
 - Transparency in communication and documentation
 - Codes of conduct and rules of engagement
 - Managing competing interests
 - Legal agreements and confidentiality
 - How to reach out and interact with patient organisations
 - Continuity and sustainability
 - Financial compensation
 - Measuring patient engagement impact

Basic capability model

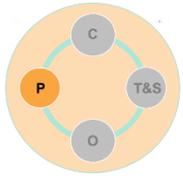
- **Core set of capabilities** that correspond to identified high-priority criteria that should be fulfilled when designing or implementing PE activities:
 1. the aims and objectives of the PE activity are agreed and understandable by all stakeholders
 2. the objectives should be aligned with patients' needs and
 3. the appropriate target population matching the activity objectives should be selected.
- The capabilities related with these high-priority aspects of PE are considered core, from which capabilities specific to other relevant themes can be further elaborated.

Competencies

- Empathy
- Collaborative leadership skills
- Understanding of stakeholders' objectives, structures and conditions
- Knowledge of negotiation techniques to facilitate consensus building
- Knowledge and understanding of the concepts of diversity
- Knowledge of the patients' ecosystem
- Knowledge of the PE ecosystem and of their own stakeholder organisation
- Understanding and being sensitive to patients' accessibility needs
- Ability to reach-out to patient and patient organisations and to build mutually beneficial relationships before the engagement occurs

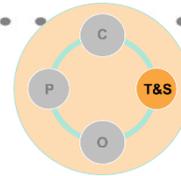


Processes and Tools and systems



Periodical multi-stakeholder meetings/checkpoints to align on objectives and to reassess the roles and responsibilities to identify any deviation.

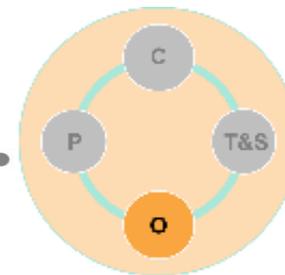
- Feedback-collection methods in place before (to assess needs and expectations), during (to detect and correct any deviations of the agreed upon goals and objectives) and after project completion (to get relevant feedback for future interactions).
- Establishment of procedures to ensure consistency and traceability.
- Policies on inclusion and non-discrimination.
- Guidelines of inclusive and representative patient engagement.
- Flexible and adapted processes to include non-English speaking patients.



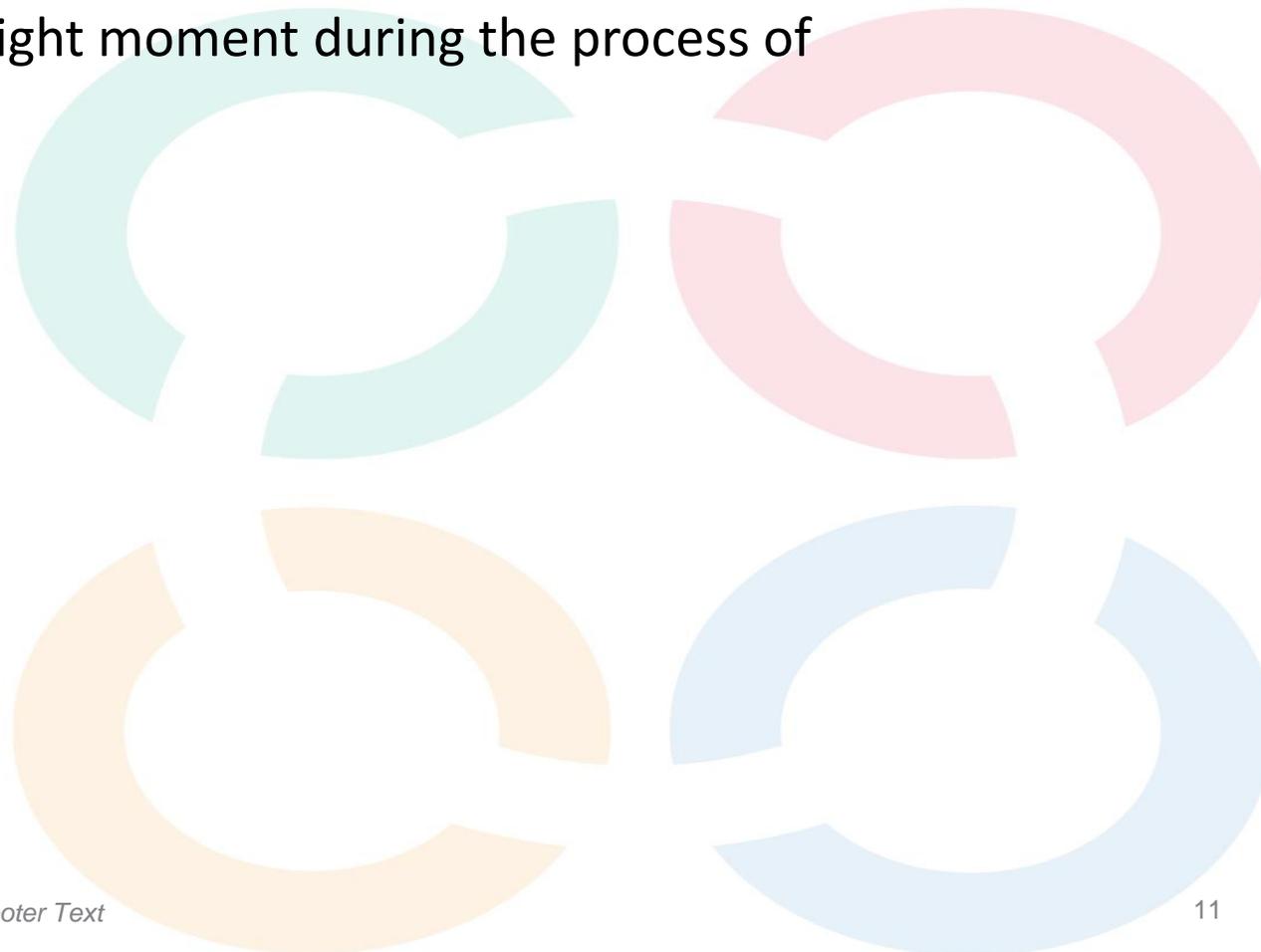
Instruments to collect feedback (e.g. surveys, questionnaires, digital feedback portal).

- Structured feedback sessions (virtually or face-to-face, one-to-one interviews, focus groups, etc.) and other informal mechanisms of personal exchange.
- Databases permissive of identifying the right individual for a specific activity, according to their experience and expertise.
- Tools to reach out to a large number of patients (or other stakeholders), either proprietary or via an intermediary (e.g. via a patient organisation)
- Guidance to stakeholders on the process of engagement

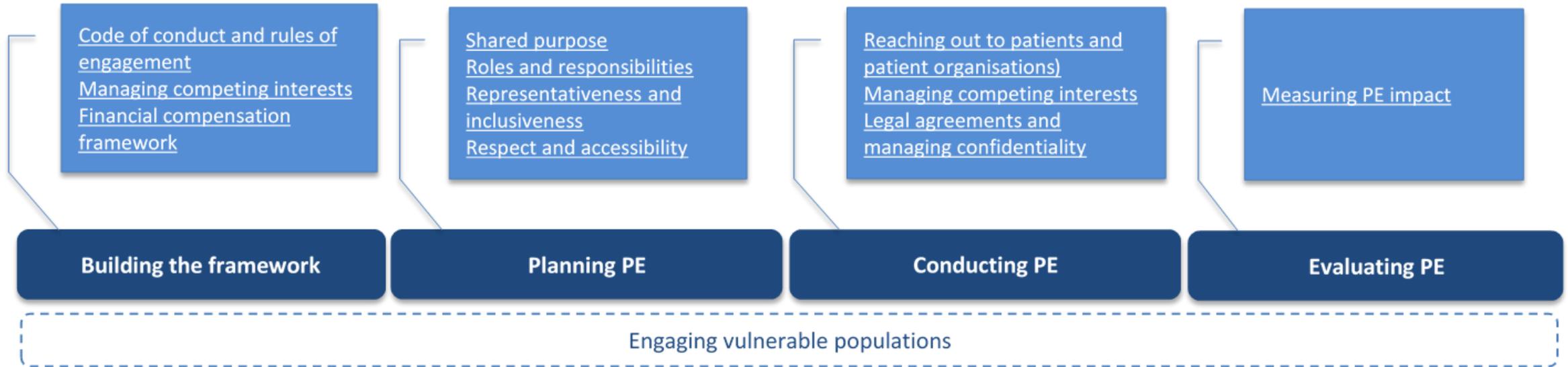
Organisation



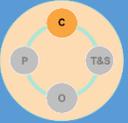
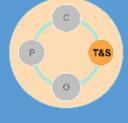
- Patient engagement functions and other organisational functions involved in the activity.
- The right expertise will be brought in at the right moment during the process of engagement.



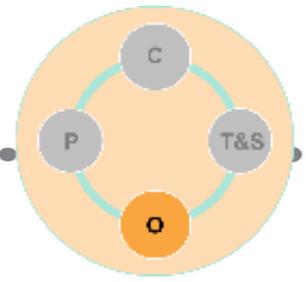
What capabilities are required during the different stages of patient engagement?



Specific capabilities – examples (non-exhaustive list)

	Competencies 	Processes 	Tools and systems 
Legal agreements and managing confidentiality	<ul style="list-style-type: none"> • Be up-to-date on latest guidance, principles, contract templates and other resources that are available to help create mutually acceptable agreements • Acknowledge that not all stakeholders might have a legal team or any legal support and provide or facilitate access to support. • Ability to write legal documents in easy and understandable language 	<ul style="list-style-type: none"> • Support throughout the agreement signing procedures to the partners by starting early and allowing adjustments in timing if needed by partners to review and understand the requirements and scope of the partnership. • Ensure that all parties involved have the same understanding of the need, scope and implications of confidentiality requirements 	<ul style="list-style-type: none"> • Guidance, contract templates and other resources should be available to help create agreements that are applicable to the stakeholder and to the decision making point. • Provide training to stakeholder organisation’s functions involved in the planning and conducting of the PE activity on pertinent legal processes.
Managing competing interests	<ul style="list-style-type: none"> • Knowledge of medicines R&D, regulatory and post-approval processes • Recognise and proactively manage situations that may result in a conflict of interest (transparency). • Be equipped to advise patients on how to best preserve their independence and avoid potential conflicts of interest 	<ul style="list-style-type: none"> • In-house policies on handling competing interests that should be public or made available upon request and subjected to periodic revision. • Completing a declaration of interests form (by the patient, parent or legal guardian) should be a pre-requisite before engaging in the activity. 	<ul style="list-style-type: none"> • Appropriate forms for the declaration of interests. • Adequate instructions and guidance where needed, should be provided on how to complete the declaration of interest form. • Databases or filing systems to register and track participants’ declarations of interests.
Measuring impact of patient engagement activities	<ul style="list-style-type: none"> • Ability to select or develop evaluation tools and decide which perspectives to capture (e.g. patient partners, industry, researcher, regulators) and what outcomes or impacts to measure. 	<ul style="list-style-type: none"> • Co-creation and co-production of monitoring and evaluation plans in collaboration with all knowledge users. Both quantitative and qualitative measures are recommended. 	<ul style="list-style-type: none"> • Monitoring and evaluation tools with analysis features are needed. Interview guides, questionnaires, log sheets and observation forms are all tools

Organisation



- Patient engagement functions
- Legal and compliance functions within stakeholder groups may have an important role in the definition and application of the rules of engagement and in specific aspects such as the development of reasonable legal agreements and the management of confidentiality and competing interests.
- Finance functions will be involved in developing and applying the financial compensation framework.

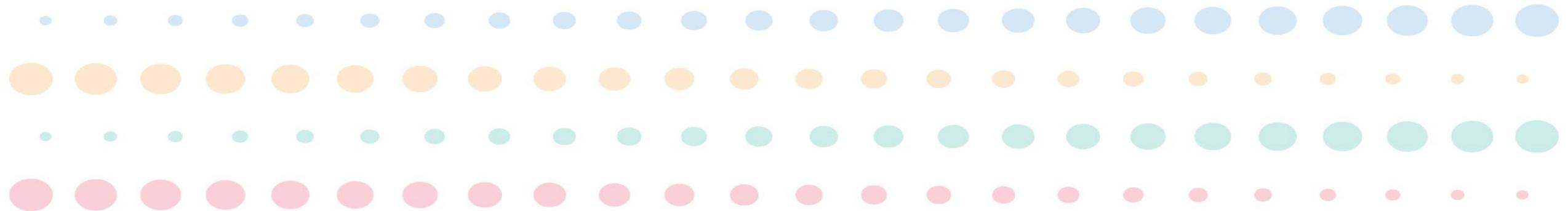
Is this framework relevant for the CEE region?



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Recommendations



Recommendations

- Equip their organisations with **organisational functions holding the core competency set and the core set of processes, tools and systems** to be able to effectively carry out these priority areas
- This **core set of capabilities should be expanded**, where needed, to cover all relevant areas of PE from initially building the engagement framework to evaluating a particular activity for further improvement.
- Across organisations, the **individual competencies should rely on the functions directly involved in the activities and** more specifically will be concentrated **within the functions dedicated to PE**, which will act as the experts on the area of engagement and will act as a single point contact centralising internal and external interactions.
- **Supporting functions** (e.g. legal and compliance, and finance) will be also required to hold certain competencies in the areas of interest related to their specific function (e.g. managing competing interests, establishing a financial compensation framework).
- It is for stakeholder organisations to decide whether other functions require competencies for PE based on their particular involvement, or on the **organisational culture**.

CORE SET

Competencies

- Patient engagement functions
- Functions directly involved in the activity
- Supporting functions (legal and compliance, finance)

Processes

PE PRIORITY ASPECTS

Aims and objectives mutually agreed and aligned to patients' needs
Appropriate patient population included

ALL RELEVANT AREAS

Managing competing interests, rules of engagement, financial compensation of experts and others

Tools and Systems

Organisation

- Patient engagement functions
- Functions directly involved in the activity
- Supporting functions (legal and compliance, finance)

CAPABILITY DEVELOPMENT

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Do you think having a patient engagement function in your organisation would be helpful? Why?