



Planning Patient Engagement



Enhancement EUPATI industry guidance: Suggested working practices checklist

Contents

What is this tool?	3
Suggested working practices checklist	4

What is this tool?

This checklist has been designed as a practical tool which may be used during pre-engagement planning of patient engagement activities and addresses the PARADIGM defined recommendations on the required capabilities for patient engagement¹. These recommendations can be matched with the PFMD Patient Engagement Quality Criteria² and are referenced for further information.

Individuals responsible for coordinating patient engagement activities should use this checklist to enable the activity. For example individuals in a patient engagement role, groups directly organising the activity, legal and other support functions should be aware of these recommendations and the checklist.

It defines specific actions that may be appropriate to the activity and can aid discussions to ensure mutually beneficial interactions with adequate preparation.

A column is included for organisers if they wish to self-assess the quality of their preparedness and identify areas for improvement.

It is important to note that patient engagement does not only occur within the area of a specific disease; there will be interest in obtaining patient input/collaboration in areas unrelated to a disease. The checklist should be considered for all interactions.

This tool is complemented by one other document:

- Enhancement EUPATI industry guidance: suggested working practices³

¹ https://imi-paradigm.eu/wp-content/uploads/2019/11/M17_D4.1-Recommendation-on-stakeholders-required-capabilities-for-PE-in-RD.pdf

² <https://patientfocusedmedicine.org/the-patient-engagement-quality-guidance/>

³ Enhancement EUPATI industry guidance: suggested working practices, <http://imi-paradigm.eu/PEtoolbox/enhanced-eupati-guide>

Suggested working practices checklist

This checklist has been designed as a practical tool which may be used during pre- engagement planning of patient engagement activities. It defines specific actions that may be appropriate to the activity and can aid discussions to ensure mutually beneficial interactions with adequate preparation. Organisers can use the rightmost column to include comments addressing considerations such as: “What is the activity?”, “who/what will it affect?”, “what impact will it have?”, “What is the benefit to the patient/community in participating?” and self-assess the quality of their preparedness and identify areas for improvement.

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

Action & associated description	Yes	No	Comments & self assessment (good, moderate, poor, Not applicable) (Aim to reach at least "moderate")
<p>Do you need support to facilitate the patient engagement activity?</p> <p>If the activity involves vulnerable groups, has the support of a caregiver, legal guardian or a professional (such as the facilitator of young person's advisory groups) been requested? In this scenario if involvement of a supporter within a group discussion with other individuals is not feasible, it is important to consider how this support can be provided during the planning of the activity.</p>			
<p>Is there a feedback system in place to inform patient about the outcomes/on the final output?</p>			
<p>To aid identification and prepare for outreach, is the type of patient and level of expertise the activity requires described?</p> <p>Recommendation:</p> <ul style="list-style-type: none"> Consider representativeness of typical patient population, diversity by age; demographics, geographies, socio-economic status, disease experience/status; stigma associated with the illness, substance use, etc.; time from diagnosis; specific symptoms experienced; gender (where applicable), knowledge about the topic to be addressed (e.g. basic or advanced knowledge about R&D processes incl. regulatory). Would the activity benefit receiving views from someone who has a community role and/or can represent a broader patient population? Consider if disease progression and/or if patient experience in previous research or training courses is a factor In some cases the contribution of carers is essential to provide a more holistic view of the disease and treatment burden. Has this been considered? Is it understood what is needed to be able to engage the carers? Is the patient population truly represented? Is the outreach unbiased and does it include patients from all walks of life? Are there any "invisible" patient groups? Are skills such as public speaking, negotiation, diplomacy, creative thinking, etc., required? 			

Action & associated description	Yes	No	Comments & self assessment (good, moderate, poor, Not applicable) (Aim to reach at least "moderate")
<p>Have the roles and responsibilities of all individuals involved been defined and agreed?</p> <p>Provide in a clear and accessible manner, in writing including a plan to be maintained throughout the project/timeframe of interaction.</p>			
<p>Have rules of engagement been defined in terms of format?</p> <p>For example face-to-face, online meetings etc., frequency, and time commitment (including payment when/if possible)</p>			
<p>Is there agreement on what can be shared between the different participants involved?</p>			
<p>Have conditions for patient interaction with each other and other patients outside of the group been agreed?</p>			
<p>Has sufficient budget been secured to cover the full activity to include payment to patients (e.g. expenses and time (where allowed))?</p> <p>Don't forget to allow for any patient organisations costs, audio/visual recording, transcription services, service providers, etc.</p>			
Respect and accessibility			
Action & associated description	Yes	No	Comments & self assessment (good, moderate, poor, Not applicable) (Aim to reach at least "moderate")
<p>Is the PE activity established as an equal partnership, with mutual trust, respect and transparency?</p>			
<p>Has consideration been given to where patients are acting as consultants?</p>			
<p>Does the activity consider the diversity, rights and autonomy of the individuals involved?</p>			

Action & associated description	Yes	No	Comments & self assessment (good, moderate, poor, Not applicable) (Aim to reach at least "moderate")
<p>Is the written information / material adapted to use respectful plain language?</p> <p>Content reflects the patients' age and specific condition / disease limitations with technical terms explained</p>			
<p>Does a definition and explanation exist of what is appropriate (or not) to ask and expected from patients and how to ask relevant questions?</p> <p>Note: Training is being developed for Pharma professionals by PFMD & EUPATI. Also refer to Transcelerate P-PET which has a question bank developed with patients.</p>			
<p>Are participants hosting the activity prepared to answer questions asked by the patients with relevant information?</p>			
<p>If the engagement with patients is face-to-face, has consideration been given to accessible venues and facilities at the venue and those issues beyond physical and practical barriers such as patients' ability to travel to certain locations / countries?</p> <p>Refer to enhanced EUPATI guidance on events and hospitality</p>			
<p>Has consideration been given to adapting the time and duration of activity to patients' needs of care and abilities?</p>			
<p>Do the patients/patient organisations require subject matter training prior to the engagement activity? If yes, consider if this could be provided by a patient organisation or sourced via EUPATI toolkit.</p>			
<p>Is it possible that patients can receive training or support to develop new subject matter skills and knowledge during the engagement activity? If so, think about how this will be provided whilst not compromising conflict of interest</p>			

Representativeness

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

Transparency in communication and documentation

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

Action & associated description	Yes	No	Comments & self assessment (good, moderate, poor, Not applicable) (Aim to reach at least "moderate")
If discussing a medicine early in development to gain patient input, can the features of the medicine such as dosage, target organ(s), mode of action, method of administration, etc., be described in lay language?			
Has an after-action review linked to the aim of the PE practice been planned with all involved?			
Is it clear to all involved how findings from the activity will be released?			
Is a thank you letter to patients planned and will this include a summary of findings and the impact described?			
Has it been determined if the impact of the activity will be measured?			
<p>How will information about the activity be shared as an example of meaningful patient engagement?</p> <p>For example, submission through PFMD (Synapse), via EUPATI or a peer-reviewed publication? Multiple options can apply at the same time.</p> <p>Refer to PARADIGM guidance to facilitate report and dissemination of patient engagement activities</p>			