



PATIENT FOCUSED
MEDICINES DEVELOPMENT



Patient Engagement Quality Guidance Tool

[Assessing an ongoing or completed PE project]

[See the Patient Engagement Quality Guidance main document here](#)

Insert the name of the PE activity/ project below:

Section 1: Basic information

PE project description (suggested to be filled out by project leader)

Short summary that describes the background and need for the project; the project objectives including anticipated benefit and/or expected outcomes; the methodology used/proposed and the project itself; stakeholders involved (including level or type of involvement as relevant).



Which phases of research, medicines development, lifecycle or disease management does your PE project cover?

[Tick the boxes that apply.]

Research and discovery phase

(including (1) unmet medical needs identification, (2) disease understanding [patient experience of the disease], (3) drug discovery, non-clinical and candidate-identification phase)

Pre-clinical phase

(including non-clinical, pre-clinical research, safety and efficacy tests)

Clinical study phase 1

Clinical study phase 2

Clinical study phase 3

Health technology assessment

Regulatory review and approval

or registration phase (including submitting for market authorisation request and approval)

Post-registration / -launch activities

clinical study phase 4,
drug safety monitoring and pharmacovigilance,
Pricing and reimbursement
real-world evidence generation,
adherence,
patient education,
patient and carer support programmes,
disease management,
public health,
marketing insights

Other

[Please provide details]

Which stakeholders does this PE project involve?

[Tick the boxes that apply.]

Patients and carers (including caregivers, and family members)

Patient advocates, patient organisations and associations

Healthcare professionals (including clinical investigators, general practitioners, specialists, pharmacists and nurses)

Policymakers

Regulators

Payers

Health technology assessment organisations

Pharmaceutical companies or industry (including medical devices and biotech companies)

Researchers (academic researchers and investigators)

Research funders

Other (for example, contract research organisations (CRO) and hospitals)

[Please provide details]

Consider the Patient Engagement Quality Criteria that apply to your project. Each criteria can help you identify new ways to increase the level of PE and to improve the quality of PE in your project.



1. Shared purpose

This refers to the project's aims and outcomes that all stakeholders taking part should agree on before starting the project. Consider putting in place processes to help facilitate discussions between all stakeholders to identify each other's values, expectations and objectives, and review and discuss priorities in the planning of the project. It can be valuable to enable stakeholders to exchange views openly to understand the scope and objectives of the project, acknowledging that some of their objectives may differ. All parties concerned should also have a shared written description of the common goals of the project.

Consider these supporting questions when assessing your project:

- Have all stakeholders understood the aims of the project the same way and with least possible ambiguity?
- How and when did you validate it? For example, you might have considered implementing checkpoints throughout the project to make sure everyone was still aligned on the common purpose of the project, particularly if things changed.

Useful resources to consider:

- [The PFMD Book of Good Practices](http://im.pfmd.org/bogp) (<http://im.pfmd.org/bogp>):
 - [Example 1](#)
 - [Example 2](#)
- [Purpose is good. Shared purpose is better](#) (Boncheck, 2013)
- [A shared purpose drives collaboration](#) (Nayar, 2014)
- [National Standards for Public Involvement](#) (Standard 2 Working together, Standard 5 Impact)

What did you do to achieve this criterion?

What is your stated "shared purpose"?



Section 2: The quality of patient engagement

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1. Shared purpose

How have you confirmed with all stakeholders that your purpose is understood, that contributions have influenced the original plans and that disagreements have been addressed?

Have you reviewed the shared purpose and its understanding among stakeholders?

At what time points?



2. Respect and accessibility

This refers to (1) respecting each other, and respectful interactions within the project to be established among partners, and (2) openness to and inclusion of individuals and communities (to the project) without discrimination. Considerations to ensure good conditions to implement the project should be made from the beginning. For example:

- simplification of wording
- budget and payment considerations
- cultural adaptations to procedures
- practicalities such as meeting timing, location and format
- accessibility of project materials
- written co-developed rules of conduct

Accessibility to participate may be facilitated by enabling multiple ways to involve stakeholders who could benefit from and/ or contribute to the project. For example, patients with cognitive impairment might need more time to go through project material, or need printed versions rather than electronic documents or PDFs for easier reading.

Consider these supporting questions when assessing your project:

- Did you have in writing what mutual respect looks like, and what was expected from all stakeholders involved?
 - Was the “code of conduct” in the project co-defined?
- How did you maintain mutual respect across all stakeholders in all interactions and activities?
 - What issues did you face and how did you overcome these?
 - How did you make sure that everybody’s contribution (whether from individuals or groups) was respected, for example, as a ‘lived’ experience that added value to the project?
- How did you ensure that you were able to engage with patients and other partners continuously from planning to execution (instead of in a sporadic manner)?
- How did you take into account accessibility considerations for people with health conditions?
 - Did you consult with them to identify what made it easy for them to participate?
 - What practical steps did you take to overcome these barriers?

Useful resources to consider:

- [The PFMD Book of Good Practices](http://im.pfmd.org/bogp) (<http://im.pfmd.org/bogp>):
 - [Example 1](#)
 - [Example 2](#)
- [Influence culture of respect](#), by Legacy Business Culture
- [National Standards for Public Involvement](#) (Standard 1 Inclusive opportunities, Standard 2 Working together)



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2. Respect and accessibility

How have you addressed respect and accessibility in this project?

How have you assessed with stakeholders that they acknowledge mutual respect, and that access to engagement has been optimised?

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3. Representativeness of stakeholders

This refers to the mix of people you involve, which should reflect the needs of the project, and the interests of those who may benefit from project outputs (for example, target population). Consider diversity in expertise, experience, demographics, and other relevant criteria for inclusion. When selecting PE stakeholders, patients, attention will be given to awareness of the diversity required to achieve visible representative voice.

Consider these supporting questions when assessing your project:

- Who have you engaged with in this project to have outputs that reflect the needs and interests of end users. Key considerations would include:
 - Gender
 - Ethnicity
 - Sexual orientation
 - Age
 - Knowledge
 - Availability
 - Social circumstances
- Which actions have you taken to reach out to, and engage with underrepresented communities or groups to ensure you had a diverse and representative selection of stakeholders and expertise?
- How did you ensure that the PE representation was relevant for the goals and outcomes you were seeking?
- How did you address upfront the importance of PE representatives supporting their views with facts/data/evidence which demonstrated representation of stakeholder group in addition to expressing individual opinions.

Useful resources to consider:

- [The PFMD Book of Good Practices](http://im.pfmd.org/bogp) (<http://im.pfmd.org/bogp>):
 - [Example 1](#)
 - [Example 2](#)
- On [Patient Representativeness](#), by NHC
- [National Standards for Public Involvement](#) (Standard 1 Inclusive opportunities)

How have you ensured broad, competent, diverse representation of stakeholders?

How did you check that the representation of stakeholders in your project supported achieving project outcomes?



4. Roles and responsibilities

This refers to the need for clearly agreed, and ideally co-created roles and responsibilities, in writing, addressing that all aspects of project needs will be established upfront and revisited regularly.

Consider these supporting questions when assessing your project:

- What mechanisms did you establish to enable regular and open dialogue /overview of partners' roles and responsibilities?
- At what stage in your project were roles/responsibilities formally discussed, agreed and documented?
 - For example, have all the stakeholders involved signed a memorandum of understanding?
- How did you achieve co-creation of roles/responsibility/assignment?
- Were all stakeholders aware and did they understand their own and others' roles and responsibilities? For example:
 - Who is the go-to person for each topic?
 - What is each stakeholder responsible for?
 - How does change in roles/responsibilities be discussed and communicated?
 - Do they know how to access this information on roles and responsibilities during the project?

Useful resources to consider:

- [The PFMD Book of Good Practices](http://im.pfmd.org/bogp) (<http://im.pfmd.org/bogp>):
 - [Example 1](#)
 - [Example 2](#)
- About roles and responsibilities: [Collaborate across teams, silos and even companies](#) (Newton, 2014)
- [National Standards for Public Involvement](#) (Standard 2 Working together)

What did you do to achieve clarity and communication as well as regular check-points on roles and responsibilities?

How did you check that all participants understood what their roles and responsibilities are, and what is expected of them?

At what frequency was this checked in?



5. Capacity and capability for engagement

This refers to (1) capacity as having relevant and dedicated resources from all stakeholders (for example, providing a dedicated point of contact by the sponsor and having allocated sufficient time by all stakeholders to allow genuine engagement); and (2) capabilities for all stakeholders to enable meaningful engagement (for example, the level of knowledge, expertise and training stakeholders might need to deliver PE activities throughout the project).

Consider supporting stakeholders to build the required capacity and capabilities for this project in different forms of training both with sponsor organisations and with each stakeholder (for example, helping to understand the context, processes, relevant terminology etc.). Both capacity and capability building are intended to facilitate participation and lower barriers to collaborate. Stakeholders can be given access to learning resources and given dedicated support (if needed). Capability needs may vary depending on the project needs, but also e.g. personal circumstances of PE representatives.

Consider these questions when planning or assessing your project:

- How have you assessed the level of knowledge and expertise all stakeholders might need to be able to participate in the project?
- What did you do to ensure all stakeholders (including yourself) were capable and knowledgeable enough to confidently participate in the project? For example,
 - How did you support partners' capacity (i.e. their ability to be able to contribute to the project such as provision of documents in format most appropriate for use, participation in meetings via Skype, etc.)?
 - What training, resources or support did stakeholders identify to improve their capacity for engagement on this specific project?
- How have you made sure that stakeholders were supported to stay involved throughout the project?
- What support in capacity building have you provided?
 - At what frequency did you validate that the approach you provided works for all participants involved throughout the project?
- How have you checked that the materials for patient engagement were in accessible formats, and written in plain and clear language?

Useful resources to consider:

- [The PFMD Book of Good Practices](http://im.pfmd.org/bogp) (<http://im.pfmd.org/bogp>):
 - [Example 1](#)
 - [Example 2](#)
- [EUPATI training resources](#) (2018)
- [National Standards for Public Involvement](#) (Standard 3 Support and learning, Standard 6 Governance)
- Plain language principles
 - [FDA's plain language principles](#) (FDA, 2018)
 - [The Plain Language Action and Information Network](#) (PLAIN) (2018)
 - [Universal Patient Language](#) (BMS) (2016)



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5. Capacity and capability for engagement

What did you do to support building the required capacity and capability for engagement?

How did you check that all stakeholders have what they need to contribute effectively and meaningfully?



6. Transparency in communication and documentation

This refers to the establishment of communications plan and ongoing project documentation¹ that can be shared with stakeholders. Communication among stakeholders must be open, honest and complete. In addition, adequate up-to-date documentation must facilitate communication with all stakeholders throughout the project. Consider proactively and openly sharing progress updates throughout the project externally. In addition, communicating outcomes of the project to all stakeholders and how their contribution was of value to the success of the project is critical.

Consider these supporting questions when assessing your project:

- How was knowledge sharing facilitated and information made easily accessible (with a user-friendly format, style and language) to all stakeholders in the project?
 - Were materials disseminated with enough time before the activity to facilitate/allow for meaningful engagement?
- Have you established a communication and dissemination plan including timelines for regular updates internally and externally? (e.g. speed of response to emails)
 - Did this plan consider speed of response by and to stakeholders?
 - Did the plan reflect expected behaviours and timelines for communications?
 - Were the methods of communication appropriate for all stakeholders?
 - Was the language used (scientific vs. lay) appropriate for all stakeholders?
- Have you considered assigning responsibility to maintain the in-project documentation and/or communication throughout the project? For example:
 - Who was accountable for setting up regular phone calls?
 - Who took notes in meetings?
 - How often did you meet?
 - How much reaction time did you agree upon for a phone call, or an email?
 - What kind of issue or change did each party expect to be immediately reported, and how?
- When communicated externally or when there was a need to release specific type of information, did you consider the regional and national regulations and requirements?

Useful resources to consider:

- [The PFMD Book of Good Practices](http://im.pfmd.org/bogp) (<http://im.pfmd.org/bogp>):
 - [Example 1](#)
 - [Example 2](#)
- [National Standards for Public Involvement](#) (Standard 4 Communications)
- The "New York Times test" (i.e. Would you be comfortable with everything in your emails or documents related to this project to be printed on the front page of an international newspaper, with your name on it?)

¹All in-project material such as project plans, guiding principles, agreement on roles and responsibilities, collaboration and confidentiality agreements, stakeholder contact details and other legal and administrative documents necessary to carry out the project.



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6. Transparency in communication and documentation

What did you do to achieve and implement processes for timely communication and updated documentation throughout the project?

How did you validate that your communication and documentation plans were useful and appropriately implemented?



7. Continuity and sustainability

This refers to the smooth progression of the project, as well as efforts to maintain ongoing relationship with stakeholders. Consideration should be given for the role of stakeholders beyond a single project. When starting the project, consider including in your project plan the actions needed for maintaining expected flow of the project from beginning to end. Create a plan to nurture relationships with your partners and stakeholders involved during the project, and when needed and requested, beyond the project as well. For all stakeholders successful planning and personal and organisational resilience should be anticipated.

Consider these supporting questions when assessing your project:

- How did you plan to ensure continuity of the project and relationships from beginning to end?
- Instead of conducting a “one and done” project, have you thought about how you could share the learnings beyond this project? Can there be broader application of this project or it’s outcomes?
- How can you encourage continuous learning, and how can other teams benefit from patient engagement experiences that were conducted elsewhere in your organisation? For example, you might want to include a “lessons learned” debrief at the end of the project as well as agreeing a communications plan for this.

Useful resources to consider:

- [The PFMD Book of Good Practices](http://im.pfmd.org/bogp) (<http://im.pfmd.org/bogp>):
 - [Example 1](#)
 - [Example 2](#)
- [National Standards for Public Involvement](#) (Standard 5 Impact, Standard 6 Governance)

What did you do to achieve this criterion?



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7. Continuity and sustainability

How did you gather feedback on what you have done?

How did you check that your planning to secure continuity and sustainability was appropriate also for the stakeholders you've involved in the project?



Results, outcomes and collecting evidence

Describe the results and outcomes of your PE project and give examples of the different methods you used to collect evidence.

Describe the impact this has had and provide concrete examples.

[If possible, specify how you would measure this impact.]

- **Positive impact for specific medicines development phases**

For example,

- identifying unmet medical needs,
- accurately prioritised research agenda,
- improved study design (for example, fewer protocol amendments to procedure),
- financial impact due to faster set-up and fewer amendments,
- possible decreased timing to registration,
- patient-driven solutions,
- increased patient adherence to medication and treatment,
- extension of a medicine or treatment to new patient groups or new country/ regions.



- **Direct or indirect positive impact for patients**

For example,

- increased influence or impact on research prioritisation agenda,
- easier access to novel therapeutic options (for example,
- new medicine in clinical trials phase,
- increased awareness of relevant clinical programmes and recruitment procedures),
- improved quality of life for patients,
- better patient-reported outcomes (PROs) and patient-centered outcomes (PCOs), more effective medication.

- **Direct or indirect positive impact for stakeholders involved in the project (other than patients)**

For example,

- more effective research prioritisation efforts, better investments in research and development (R&D),
- faster registration process,
- better understanding of patients' health conditions and expectations,
- patients involved in decision-making process, improved regulatory file,
- more effective medication leading to reduced health services.



Lessons learned

Please describe what you have learned from the project (this can be about your experience of PE, or the project itself). It can be positive or negative, as both provide valuable lessons that can be shared with others in your organisation. If possible, say what other stakeholders have learned from the project.

- What have you learned? What challenges did you face?
- What worked, what would you do again, and why?
- What might you do differently next time, and why?