



PATIENT FOCUSED
MEDICINES DEVELOPMENT



Patient Engagement Quality Guidance Tool

[Planning a 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]



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 planning your project:

- How will you transparently share the starting point or objectives, and the degree to which stakeholder input can influence project directions?
 - If relevant, for each of your objectives or desired outcomes, indicate if and to which extent this has been agreed with the patient(s) or patient group(s) you wish to engage with.
- Consider also involving the relevant internal stakeholders in your PE project, like organisation's internal stakeholders with a key role in defining the project's outcomes, or are key to the success of the project (such as legal and compliance departments, management, etc.).
- How and when will you validate it? For example, you may want to consider implementing checkpoints throughout the project to make sure everyone is still aligned on the common purpose of the project, particularly if things change.
- Can all stakeholder express the shared purpose in their own words? This ensures everyone really understands what the shared purpose is.
 - How will you communicate with and align all stakeholders to achieve clarity on "shared purpose" from the start and throughout the project?
- What processes do you have in place to accommodate ongoing feedback?
- How do you ensure that all stakeholders understand what the project success looks like?
 - In cases of disagreement, how will you respond?
 - How will you respectfully allow the disagreement while coming to plans to move forward?

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)



1. Shared purpose

What will you do to achieve this criterion?

What is your stated "shared purpose"?

How will you confirm with all stakeholders that the purpose is understood, that contributions will influence the original plans and that disagreements will be addressed?

Will you plan to review 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 planning your project:

- What would “respect” look like for the stakeholders involved in your project?
 - Do you know what your partners expect from you or each other in terms of respect?
 - How do you intend to show your respect for the stakeholders?
- Consider having in writing what mutual respect looks like, what is expected from all stakeholders involved and co-defining the “code of conduct” in the project.
- How will you maintain mutual respect across all stakeholders in all interactions and activities?
 - What issues do you need to consider, and how will you overcome these?
 - How do you make sure that everybody’s contribution (whether from individuals or groups) is respected, for example, as a ‘lived’ experience that adds value to the project?
- How do you ensure that you are able to engage with patients and other partners continuously from planning to execution (instead of in a sporadic manner)?
- How do you take into account accessibility considerations for people with health conditions?
 - Have you consulted with them to identify what makes it easy for them to participate?
 - What practical steps will you take to overcome these barriers?
- How will you collect feedback from stakeholders regarding how well (or not) they are respected and how well access needs have been met?

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)



Section 2: The quality of patient engagement

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.



2. Respect and accessibility

How will you address respect and accessibility in this project?

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



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 planning your project:

- Who do you need to engage in this project to have outputs that reflect the needs and interests of end users. Key considerations could include:
 - Gender
 - Ethnicity
 - Sexual orientation
 - Age
 - Knowledge
 - Availability
 - Social circumstances
- What can be done to reach out to, and engage with underrepresented communities or groups to ensure you have a diverse and representative selection of stakeholders and expertise?
- How will you ensure that the PE representation is relevant for the goals and outcomes you are seeking?
- How will you address upfront the importance of PE representatives supporting their views with facts/data/evidence, which demonstrate 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 will you ensure broad, competent, diverse representation of stakeholders?

How will you check that the representation of stakeholders in your project will support 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 planning your project:

- At what stage in your project will roles/responsibilities be formally discussed, agreed and documented?
 - For example, have all the stakeholders involved signed a memorandum of understanding?
- How do you achieve co-creation of roles/responsibility/assignment?
- What mechanisms will you establish to enable regular and open dialogue /overview of partners' roles and responsibilities?
- Are all stakeholders aware and 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 will 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 will you do to achieve clarity and communication as well as regular check-points on roles and responsibilities?



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4. Roles and responsibilities

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

At what frequency will this be 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 supporting questions when planning your project:

- How will you assess the level of knowledge and expertise all stakeholders might need to be able to participate in the project?
- What will you do to ensure all stakeholders (including yourself) are capable and knowledgeable enough to confidently participate in the project? For example,
 - How do 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 do stakeholders identify to improve their capacity for engagement on this specific project?
- How do you make sure that stakeholders are supported to stay involved throughout the project?
- What support in capacity building are you providing?
 - At what frequency will you validate that the approach you provide works for all participants involved throughout 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](#)
- [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)



Section 2: The quality of patient engagement

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5. Capacity and capability for engagement

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

How will 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 planning your project:

- How is knowledge sharing facilitated and information made easily accessible (with a user-friendly format, style and language) to all stakeholders in the project?
- Have you established a communication and dissemination plan including timelines for regular updates internally and externally? (e.g. speed of response to emails)
 - Does this plan consider speed of response by and to stakeholders?
 - Does the plan reflect expected behaviours and timelines for communications?
 - Are the methods of communication appropriate for all stakeholders?
 - Is 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 will be accountable for setting up regular phone calls?
 - Who will take notes in meetings?
 - How often will you meet?
 - How much reaction time do you agree upon for a phone call, or an email?
 - What kind of issue or change does each party expect to be immediately reported, and how?
- When communicating externally or when there is a need to release specific type of information, consider the regional and national regulations and requirements if necessary.

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?)

¹ All 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.



Section 2: The quality of patient engagement

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.



6. Transparency in communication and documentation

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

How will you validate that your communication and documentation plans are 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 planning your project:

- How do you plan to ensure continuity of the project and relationships from beginning to end?
- Instead of conducting a “one and done” project, think 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 will you do to achieve this criterion?

How will you gather feedback on what you have done?

How will you check that your planning to secure continuity and sustainability is appropriate also for the stakeholders you’ve involved in the project?



Results, outcomes and collecting evidence

In case you want to use this section for the planning of a project:

- consider expected results, positive impact expected for medicines development phases
- expected impact for patients
- expected impact for stakeholders involved in the project
- give examples of the different methods you will use to collect evidence

Describe the impact you expect this project to achieve.

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



Expected 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.

Expected 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.



Expected 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.