



PATIENT FOCUSED  
MEDICINES DEVELOPMENT



# Patient Engagement Quality Guidance

A practical guide to planning, developing and assessing the quality of patient engagement activities and projects throughout the development and lifecycle of medicines.

The Patient Engagement (PE) Quality Guidance has been co-developed with different stakeholders through an iterative process, building on existing PE knowledge. For the background on the project and more details, please visit our [website](#).

## Contents

<b>Purpose of the PE Quality Guidance Tool</b> .....	<b>2</b>
How the tool is structured .....	3
<b>PE Quality Guidance Tool</b> .....	<b>4</b>
1. Shared purpose .....	5
2. Respect and accessibility .....	6
3. Responsibility and accountability .....	7
4. Representativeness of stakeholders .....	8
5. Capacity and capability for engagement .....	9
6. Documentation and transparency in communication .....	10
7. Continuity and sustainability .....	11



## Purpose of the PE Quality Guidance Tool

**The PE Quality Guidance Tool is a practical guide which will help all stakeholders (for example, pharmaceutical industry, researchers, patient organisations and others) improve the quality of their PE<sup>1</sup> activities. You can use the tool in:**

1. Planning and development;
2. Quality and impact assessments; and
3. Gap analysis.

Once completed, you can use the tool to measure the level and quality of PE activities within your organisation, and to compare different PE projects and their impact. Section 4, 'Lessons learned' gives you the opportunity to share your knowledge with your organisation or team.

The guidance introduces seven PE Quality Criteria [co-created draft] to assess PE practices. These have been developed from published PE frameworks and co-developed further by PFMD Contributors<sup>2</sup>. The Quality Criteria describe the core values that a good PE practice should consider including in its processes.

We do not expect you to be able to fully put into practice every Quality Criteria, as not all criteria will be relevant to all projects. The tool is intended as a practical guide to help you plan and put in place the most appropriate level of PE for your project and organization.

## How the tool is structured

**The PE Quality Guidance Tool (Figure 1) incorporates the following four themes.**

1. The basic description of the project – what you are aiming to achieve
2. The quality of PE in the project – how you will achieve these aims
3. Your assessment of the outcomes and results
4. The lessons you have learned from completed projects

### Section 1

Covers the basic details of the PE project. Here you can define what you are aiming to achieve and the key stakeholder groups you will work, or are working, with.

### Section 2

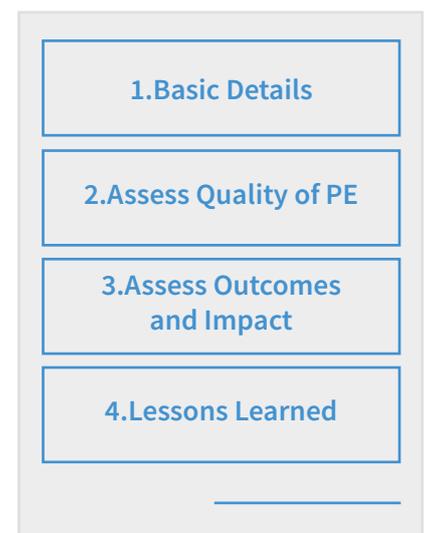
Deals with the quality of PE – it explores how you have used PE to assess whether your project has considered some of the seven PE Quality Criteria in terms of operations and core values (Figure 2).

### Section 3

Covers the outcomes and results of your PE project. If your project is at the planning stage, you will be asked to think about its expected outcomes and impact, or the benefits you expect it to bring to your processes and the medicines development lifecycle, or to the stakeholders taking part. You can use these expectations as comparison points for the assessment you carry out once you have completed the project. For ongoing or completed projects, you will be asked to think about the actual (and measurable) impact the project has had in the medicines development continuum, or the benefits it has brought to stakeholders.

### Section 4

Allows you to share the lessons you have learned – it will help you identify opportunities for future improvement and will help others in your organisation learn more about your project and learn from your experiences.



**Figure 1.** PE Quality Guidance Tool

<sup>1</sup>Throughout the PE Quality Guidance, we use the term 'patient engagement' (PE) to refer to the active and meaningful engagement and involvement of patients in the medicines research and development process, lifecycle of medicines and care continuum.

<sup>2</sup>This is a network of 76 participants that we have named "PFMD Contributors". They have participated in the co-creation of the PE Quality Guidance in an iterative process during 2016 and 2017. For more information, visit our website at <http://patientfocusedmedicine.org/wg-intro/>.



**Figure 2:** Overview of the PE Quality Criteria

## Please note

Not all of the Quality Criteria may be relevant to each specific project, or apply to all projects or organisations. We have designed the seven Quality Criteria to help you keep in mind the importance of including PE in the medicines development continuum and care journey.

The Quality Criteria also provide an agreed set of principles that help keep PE consistent, allow the quality of PE in existing projects to be assessed, and show the results and impact of projects in a systematic way.

[The PE Quality Guidance Tool starts from the next page.]



# PE Quality Guidance Tool

## Section 2: The quality of patient engagement

Consider the PE Quality Criteria that applies to your project. They will help you identify new ways to increase the level of PE in your project and improve the quality of PE within the criteria already included in your project.

There are 7 Quality Criteria, each presented on its own page for clarity.

---

\* For clarity, this consultation document contains only Section 2 of the PE Quality Guidance tool (i.e., the PE Quality Criteria) we are asking for your feedback on.



## 1. Shared purpose

This criterion refers to the project's aims and outcomes that all stakeholders taking part should agree on before starting the project. You may want to consider putting processes in place to help stakeholders identify each other's values, expectations and objectives, and agree on priorities in the planning of the project. Enable stakeholders to exchange views openly to decide on the scope and objectives of the project, acknowledging that some of their objectives may differ.

### Consider these questions when planning or assessing your project:

- How do you make sure patients are engaged throughout the project?
- Are all stakeholders aware of their own and others' roles and responsibilities? Do they know how to access this information during the project?
- Have you considered assigning responsibility to maintain the in-project documentation and/or communications throughout the project?

### Useful resources to consider:

[Provide links to processes or how-to examples]

### What will you do / or did you do to achieve this criterion?

### How will you / or did you check that all participants felt that there was a shared purpose?



## 2. Respect and accessibility

To meet this criterion, your project must be open to individuals and communities without discrimination. You need to consider possible barriers to access the project from the beginning (for example, budget and payment considerations, cultural adaptations to procedures, practicalities and project materials), and ways to lower them. Consider having multiple ways to engage with stakeholders who might need it. For example, patients with cognitive impairment might need more time to go through project material, or need printed material rather than electronic documents or PDFs for easier reading.

### Consider these questions when planning or assessing your project:

- How do you make sure that you engage with patients continuously from planning to execution, instead of in a sporadic manner?
- How do you maintain respect across all stakeholders in all interactions and activities? What issues do you need to consider and how will you/ did you overcome these?
- Did you consider the barriers to engagement with people with health conditions? Have you consulted with them to identify what makes it easy for them to participate? What practical steps will you/ or did you take to overcome barriers?

### Useful resources to consider:

[Provide links to processes or how-to examples]

### What will you do / or did you do to achieve this criterion?

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



### 3. Responsibility and accountability

To meet this criterion, you must clearly define and agree on the roles and responsibilities of all stakeholders, in written. All involved stakeholders should live up to their roles and responsibilities as agreed. Consider having guidelines in place to facilitate stakeholders giving feedback about changes in roles or responsibilities throughout the project timeline. Meetings will encourage concerns to be voiced, heard and responded to.

#### Consider these questions when planning or assessing your project:

- How do you make sure patients are engaged throughout the project?
- Are all stakeholders aware of their own and others' roles and responsibilities? Do they know how to access this information during the project?
- Have you considered assigning responsibility to maintain the in-project documentation and/or communications throughout the project?

#### Useful resources to consider:

[Provide links to processes or how-to examples]

What will you do / or did you do to achieve this criterion?

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



## 4. Representativeness of stakeholders

The mix of people you involve in the project should reflect the needs of the project, and the interests of those who may use or benefit from project outputs (for example, target population). Think about diversity in expertise, experience, demographics, and other relevant (scientific) criteria for inclusion. Differentiate patient input from patient representation that needs to be supported with facts, data or evidence.

### Consider these questions when planning or assessing your project:

- Who are the people you need to engage in this project to have outputs that reflect the needs and interests of end users or those who might benefit?
- Have you made the effort to reach out to, and engage with underrepresented communities or groups to make sure you have a diverse and representative selection of stakeholders and expertise?
- Is your approach scientifically relevant for the outcome or goals you are seeking? For example, if you are conducting research, are you using a robust, scientific approach?
- Is everybody's contribution (whether from individuals or groups) respected, for example, as a 'lived' experience that adds value to the project?
- Are participants expressing an individual opinion, or are they supporting their view with facts, data or evidence?

### Useful resources to consider:

[Provide links to processes or how-to examples]

**What will you do / or did you do to achieve this criterion?**

**How will you / or did you check that your project's approach is scientifically robust? And how will you/ or did you check that you have enough diversity of participants?**



## 5. Capacity and capability for engagement

To meet this criterion, you need to show that you have assessed the level of knowledge, expertise and training stakeholders might need to meaningfully participate in the project. Think about supporting stakeholders to build the needed capabilities for this project in different forms of training (for example, helping them to understand the process, context, terminology, level or type of involvement, etc.). Stakeholders should be given access to learning resources and dedicated support (if needed).

### Consider these questions when planning or assessing your project:

- How have you assessed the knowledge and expertise all stakeholders might need to be able to participate in the project?
- Do all stakeholders feel capable and knowledgeable enough to participate in the project confidently?
- Do you have checks along the way to make sure that stakeholders can stay involved throughout the project if they can and want to?
- What support in capacity building are you providing? How did you check that your approach is the best for them to build their capacity for this project?
- Did you ask for feedback to make sure the approach you provide works for all participants involved?
- Are the instructions for patient engagement in accessible formats, and are they written in plain and clear language?

### Useful resources to consider:

[Provide links to processes or how-to examples]

### What will you do / or did you do to achieve this criterion?

### How will you / or did you check that all participants have capacity or the capabilities for engagement?



## 6. Documentation and transparency in communication

To achieve this criterion, you need to keep in-project documents\* up to date throughout the project. There should be principles in place to ensure your processes, and the way you interact with patients and the broader community, are transparent and clear. Internal communication within the project should be open, honest and transparent for all stakeholders. External communication about the project and its outcomes should be transparent to the public. Consider also how to share results openly after completing the project.

### Consider these questions when planning or assessing your project:

- Is knowledge sharing facilitated and information easily accessible (with a user-friendly format, style and language) to all stakeholders in the project? For example, this could include the lessons learned along the project.
- When communicating externally, have you taken into account regional and national regulations about releasing information?
- Have you considered creating a communication and dissemination plan to ensure regular updates internally and externally? Are the methods of communication appropriate for all stakeholders or your audience? How about scientific and lay language?
- Do you have a scientific approach or process to capture and analyse the results of your project?
- Do you need a set of principles to manage communication and engagement among stakeholders during the project? Note, that communication needs to be flexible, responsive and reactive.

### Useful resources to consider:

[Provide links to processes or how-to examples]

### What will you do / or did you do to achieve this criterion?

### How will you / or did you check that documentation and (internal and external) communication are / or were appropriately managed for all relevant stakeholders?

\*All in-project documentation such as project plans, guiding principles, agreement on roles and responsibilities, collaboration and confidentiality agreements, and other legal and administrative documents necessary to carry out the project.



## 7. Continuity and sustainability

This criterion refers to the continuity of the project as well as relationship continuity. When starting the project, consider including in your project plan the actions needed for continuity once the project is completed. Create a plan to maintain your relationship with your partners and stakeholders involved beyond the project. If needed, consider creating a transition plan with necessary resources mapped out to carry on the project (for example, in case stakeholders' responsibilities change within their own organisation during the project).

### Consider these questions when planning or assessing your project:

- Do you have a project plan from the beginning to end of the project?
- Do you have a plan to maintain the relationship with stakeholders involved in the project after it ends?
- What are the communication methods stakeholders prefer after the project?
- 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 its outcomes and lessons learned?
- 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 in the project plan a section where you define how the project will be shared internally to raise awareness or share practical tips for conducting similar project(s).

### Useful resources to consider:

[Provide links to processes or how-to examples]

### What will you do / or did you do to achieve this criterion?

### How will you / or did you check that your planning to secure continuity and sustainability are / were appropriate also for the stakeholders you've involved in the project?