



PATIENT FOCUSED  
MEDICINES DEVELOPMENT



# Piloting Manual for the Patient Engagement Quality Guidance

## Scope of this document

This document is for anyone who is interested in testing the PE Quality Guidance (PEQG) within a patient engagement (PE) initiative and providing their feedback to help improve its usability and impact to all stakeholders.

Within this “user manual”, you will find all needed information for piloting the PEQG in your initiatives, supported with links to the relevant feedback forms and templates for assessment. You will also find communication material to help you introduce the PE Quality Guidance to your initiative partners.

### How to read this manual

This manual is meant to be your first-hand instructions when starting your piloting process. As with any manual, please feel free to read only those parts that are relevant for you. *We do recommend that you check at least the following three sections: “How to get started” section on page 2, “Stakeholders involved, roles and responsibilities” section and “Which forms to fill out and when” section, both on page 3 in order to provide the expected feedback during your piloting process.* You can find all forms and templates needed from the appendix.

If you are missing some information or have a suggestion to improving these instructions, please send us an email with subject to [pfmd@thesynergist.org](mailto:pfmd@thesynergist.org)

## Glossary

With **patient engagement (PE)**, we mean the meaningful engagement and involvement of the patient community (patients, caregivers, patient experts, patient advocates, patient organisations, and the public) in the co-creation, co-design, and/or co-lead of various activities, initiatives, functions, products, etc. in the research, development, delivery and lifecycle of medicines. The level of engagement might differ from initiative to initiative, but in this context, patient engagement is more than surveying patients. In other words, it’s a 2-way collaboration, a direct and constructive interaction and partnering with patients in various important roles.

With **“initiative”** we mean patient engagement programmes, projects and activities in almost any scope or length.



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## Basics

### Why is piloting important?

Piloting the guidance is a critical milestone to pursuit our ambition to provide instructions and guidelines that are comprehensive to the majority of stakeholders committed to deliver excellence in PE activities.

As with any type of guidance, the highest risk remains weak adoption and uptake to real activities in PE. The consequence with limited usage is that there is little feedback generated in result and opportunities to improve current work will be limited.

### Who should pilot?

As the PE Quality Guidance targets the entire community of stakeholders working in PE in different phases of medicines research and development continuum, our ambition is to collect robust feedback on initiatives where multiple stakeholders (at least 2 groups<sup>1</sup>) are involved. This will be a prerequisite to be enrolled for the piloting

### What type of initiatives to pilot?

**Piloting the PE Quality Guidance is open to multiple types of PE initiatives:**

- those in the planning phase that will be planned and completed with the PEQG,
- those initiatives that have already ended and evaluation will be done as a retrospective assessment or gap analysis from the PEQG perspective.

For some special instances, it might be valuable to evaluate the quality of PE in an ongoing initiative as well. Although we do not list it here as one of the types for piloting, you may test it and send us feedback for consideration.

The initiatives can be anything from academic research, authoring a publication, clinical trial design, to organising patient engagement activities in any phase of the research, development or delivery and lifecycle of medicines.

### How to get started?

**Piloting is divided into two categories:**

- **“PFMD supported piloting”** will be agreed with specific set of initiatives to ensure there is enough diversity to give us enough feedback for the improvement of the guidance after the piloting period. We are open to consider additional initiatives that can help us demonstrate tangible impact from the use of the PEQG. If you'd like to suggest your project for PFMD supported piloting, please contact PFMD team at [pfmd@thesynergist.org](mailto:pfmd@thesynergist.org). Information about these initiatives will be communicated publically and PFMD team will provide updates and some aggregate interim results for the community to follow the progress and experiences of these pilots.
- **“Independent piloting”** can be done by any organisation, group, collaboration or company by registering through the registration link (see Appendix 1). We will ask you for your consent in using your feedback from your piloting experience in our analysis and communication about the results from the whole piloting period. This is open to anyone who is already using or is planning to test the PEQG in their PE projects. We encourage you to use the feedback forms to send us your periodic feedback of the usability and impact the PEQG helps you achieve. Due to limited resources, PFMD does not provide hands-on support for these projects, however, we might be able to answer some questions if needed.

<sup>1</sup> Patient community as a priority group to involve



## Piloting timeline, evaluation & feedback frequency expected

Piloting can start any time between 2018 and Q2/ 2019, but will need to have the final assessment (regardless of the initiative timeline) by end of September 2019. This means that your initiative can be ongoing already and can end after 2019, but for capturing your experience in piloting the PEQG, we would need your assessment by end of September 2019.

Feedback is requested from your piloting experience at different timepoints depending on your initiative timeline (see table 1).

	Beginning of the piloting process	Interim (midway through the project)	End/ retrospective
Ongoing initiatives and initiatives in the planning	✓	✓	✓
Completed initiatives			✓

Table 1. Evaluation and feedback frequency

## Guidelines and main considerations for pilots

### Stakeholders involved, roles and responsibilities

**All piloting initiatives need to involve at least 2 stakeholders, one representing the patient community** (except if the initiative is fully owned and conducted by the patient community). The initiative can be “led” by one stakeholder, but the involvement of other stakeholders need to be visible and their roles need to be clear.

- We recommend that one of the initiative partners will take the lead in piloting by making sure that there is time scheduled for the group to make the requested starting, interim and/or final assessments for the quality of PE in the initiative.
- Please note that **the PEQG template should be filled out together and a copy sent to PFMD, and a relevant feedback form should be filled out by each of the partner separately online.**

### Which forms to fill out and when

In order to receive timely and relevant feedback in the piloting projects, we recommend the following feedback process for the three initiative stages identified (planning stage, ongoing, completed initiatives). As initiatives differ from one another, we encourage you to plan out your feedback process based on this recommendation as you see best.



## Feedback process

There are 2 forms to be filled in at each point of evaluation and feedback (see Table 2):

1. **The PEQG tool** in the respective scenario (scenario 1 for planning, scenario 2 for ongoing/ completed initiatives)
2. **The online feedback form** in respective evaluation stages (starting, interim, end/retrospective).

### Example on how to use table 2 (see next page):

#### Initiative in planning stage (PEQG template scenario 1)

A patient organisation and pharma company collaborate to co-create a patient leaflet -the project has not started yet.

- In this case, either or both stakeholders can lead the project and make sure that relevant assessment for the quality of PE is done in requested timepoints.
- The PEQG (scenario 1) is introduced to the project partners in the first planning meeting and is filled out by both partners together. A copy of this is sent to PFMD. Then each partner will complete the relevant feedback form individually online.
- Project will be assessed in the interim and at the end with the same method with template scenario 2 and relevant feedback forms.

## For support and feedback

[PFMD.org](http://PFMD.org) has all needed background information of how the PE Quality Guidance was born, who was involved and what are the next steps in the work stream. For examples of patient engagement initiatives please check out [SYNaPsE Mapping and Networking tool](#).

If you experience difficulties and do not know how to proceed, please let us know by sending us an email to [pfmd@thesynergist.org](mailto:pfmd@thesynergist.org).



Table 2. Feedback forms to complete per project type

	Starting evaluation		Interim evaluation			End/retrospective evaluation		
	Individually	With partners	Individually	With partners	Individually	With partners		
<b>Initiatives in the planning</b>	PEQG scenario 1		x	PEQG scenario 2		x	PEQG scenario 2	x
	First evaluation form (online)	x		Interim evaluation form (online)	x		Final evaluation form (online)	x
<b>Ongoing initiatives</b>	PEQG scenario 2		x	PEQG scenario 2 (if relevant)		x	PEQG scenario 2	x
	First evaluation form (online)	x		Interim evaluation form (online) (if relevant)	x		Final evaluation form (online)	x
<b>Completed initiatives</b>							PEQG scenario 2	x
							Retrospective evaluation form (online)	x



## Appendix 1 - Useful links, forms and templates

### Materials and links

Register your initiative to start piloting	<a href="https://www.surveymonkey.com/r/PEQG-piloting-registration">https://www.surveymonkey.com/r/PEQG-piloting-registration</a>
<b>PE Quality Guidance and scenario templates</b>	
Scenario 1 - planning PE initiatives	<a href="http://patientfocusedmedicine.org/peqg/PFMD_Quality-Guidance_Scenario-1.docx">http://patientfocusedmedicine.org/peqg/PFMD_Quality-Guidance_Scenario-1.docx</a>
Scenario 2 - ongoing or completed initiatives	<a href="https://patientfocusedmedicine.org/peqg/PFMD_Quality-Guidance_Scenario-2.docx">https://patientfocusedmedicine.org/peqg/PFMD_Quality-Guidance_Scenario-2.docx</a>

### Feedback forms (Please read instructions from page 3 in order to choose the right form for your evaluation.)

First feedback form (start of project)	<a href="https://www.surveymonkey.com/r/PEQG-piloting-first-feedback">https://www.surveymonkey.com/r/PEQG-piloting-first-feedback</a>
Interim feedback form	<a href="https://www.surveymonkey.com/r/PEQG-piloting-interim-feedback">https://www.surveymonkey.com/r/PEQG-piloting-interim-feedback</a>
Final feedback form	<a href="https://www.surveymonkey.com/r/PEQG-piloting-final-feedback">https://www.surveymonkey.com/r/PEQG-piloting-final-feedback</a>
Retrospective evaluation feedback form	<a href="https://www.surveymonkey.com/r/PEQG-piloting-retrospective-evaluation">https://www.surveymonkey.com/r/PEQG-piloting-retrospective-evaluation</a>

## Questions?

Please contact PFMD at [pfmd@thesynergist.org](mailto:pfmd@thesynergist.org)