



# Patient Engagement Quality Guidance for the Medical Device industry

A practical guide to planning, developing and assessing the quality of patient engagement (PE) activities and projects throughout the development and lifecycle of medical devices

- **What is it?** It is a tool that contains **seven quality measures** to plan and assess projects to involve patients. We call this the Patient Engagement Quality Guidance (PEQG). You can also use it to capture the quality of the PE project and the benefit it brings to the stakeholders involved.
- **Why use it?** To increase the quality of your (organization's) PE activities. You can use it as a planning tool before starting a PE project, as an assessment tool at the end of a project, or as a gap-analysis tool to compare projects within the organization.
- **Who is it for?** Any stakeholder (e.g. patient advocate, clinical investigator, researcher, or sponsor) can use it to plan or assess the quality, outcomes and impact of a PE project.
- **When should it be used?** You can use it for a PE project that takes place at any point along the health, drug or medical device research and development (R&D) continuum and beyond.
- **How was it developed?** It was originally created iteratively by a large community of different stakeholders, including patients, researchers, industry and others with experience in the medicines development process.

**This version has been adapted (in terms of terminology, additional resources and examples) to fit the medical device industry's use by a similar multi-stakeholder process.**

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<sup>1</sup>The Patient Engagement Quality Guidance (PEQG) 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](#).



# Definition of patient engagement

While there is no widely-accepted definition or consistent language to describe patients' involvement and engagement in health research, and medical device industries, in this document the term 'patient engagement' (PE) refers to the active and meaningful involvement of patients and carers in activities within these areas. The following definitions should help to explain what we mean.

**Patient** – “those (people) having or at risk of having the medical condition(s) whether or not they currently receive medicines or vaccines to prevent or treat a disease” as well as “the family and those caring for those with the medical condition(s),” patient advocates, and patient groups ([National Health Council](#), 2017). In addition, some patients may require the use of a medical device in order to prevent, treat or maintain a condition.

“**Patient engagement**, in drug development and product review, means **involving patients as active participants** in these processes.

Simply enrolling and following patients as passive research subjects in a clinical trial does not rise to the level of patient engagement. Instead, patients should be treated “as valued and valuable partners whose input, advice, and guidance is sought and implemented” throughout these processes.” [National Health Council](#), (2017)

“INVOLVE defines **public involvement in research** as research being carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them.” [INVOLVE/ NHS](#), (2017)

“By “**engagement in research**,” we refer to the **meaningful involvement of patients**, caregivers, clinicians, and other [healthcare stakeholders](#) throughout the research process—from topic selection through design and conduct of research to dissemination of results.” [PCORI](#) (2015)

“**Patient engagement occurs when patients meaningfully and actively collaborate** in the governance, priority setting, and conduct of research, as well as in summarizing, distributing, sharing, and applying its resulting knowledge (i.e., the process referred to as “knowledge translation”). It is of vital importance as “engaging patients in health care research makes [investments in] research more accountable and transparent, provides new insights that could lead to innovative discoveries, and ensures that research is relevant to patients' concerns.

**The international experience with engaging citizens and patients in research has shown that involving them early in the design of studies, ideally as early as at the planning stage, leads to better results.”** [Canadian Institutes of Health Research](#), CIHR (2014)

# The seven Patient Engagement Quality Criteria

The 7 Quality Criteria (QC) provide an agreed set of principles to improve consistency in PE practices, help you ensure the quality of PE in existing and future projects, and showcase the results and impact of projects in a systematic way.

These 7 QC were created to help you keep in mind the importance of PE in the R&D processes and lifecycle of a medical device product and in the patient’s care journey. These criteria describe the core values for strong, effective PE. The seven criteria are shown below in Figure 1.



Figure 1. Overview of the PE Quality Criteria

We suggest the 7 QC be considered in this particular order. The relevance of each QC may differ from project to project but it is important to review and apply all criteria for all projects.



# How to use this tool and how it is structured

## 1. Use it as a planning tool

If you are starting a new project, you can use the PE Quality Guidance to plan the PE project. You can use the PE Quality Criteria to help you identify and set the PE goals and outcomes you want to reach.

## 2. Use it as an assessment tool

For ongoing or completed projects, you can use it to assess the level and the quality of PE you achieved and to compare different projects and gather learnings in a systematic way

- **Use it for gap analysis**

The tool can help identify what works well and what can be improved, and help you plan for future PE projects. Fill in the tool as best as you can – it will highlight any missed opportunities for PE.

The tool incorporates four sections:

### Section 1

#### Basic information

Here you can define what you are aiming to achieve and the key stakeholder groups with whom you will work or are working.

### Section 2

#### PE Quality Criteria checklists to assess the quality of PE

The lists explore how you propose to implement PE and assesses whether your project has considered the seven PE Quality Criteria ([Figure 1](#)) in terms of operations and core values.

### Section 3

#### Results, outcomes, and impact

You will be guided to consider (expected and measurable) outcomes and impact, as well as the benefits your project brings to your processes, (i.e. in the development cycle) and to the partnering or other relevant stakeholders. Compare the expected outcomes from the planning phase to the final outcomes to see how well you have achieved them.

### Section 4

#### Lessons learned (for completed projects)

The final section gives you an opportunity to capture the lessons learned in the project. This section will help you identify opportunities for future improvement and will help others in your organization to learn more about your project and gain from your experiences.

Continue to the PE Quality Guidance on the next page:



# Section 1: Basic information

Choose the best option that applies:

I am planning a new project

I am assessing an ongoing or finalized project

Name of the project:

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 (briefly); the proposed methodology and stakeholders involved (including level or type of involvement as relevant).

Write your responses here

Which phases of R&D, life cycle or disease management does your PE project cover?

Select all that apply.

**Device Discovery and Concept**

(including (1) unmet medical needs identification, (2) disease understanding [patient experience of the disease])

**Product Development**

(including non-clinical, product discovery, safety and efficacy tests)

**Clinical trial phases**

**Device Classification**

- Class I
- Class II
- Class III

**Regulatory Device Review**

**Post-Market Activities**

- Manufacturer inspections
- Reporting problems associated with approved medical devices
- Active surveillance
- Post-Market PE activities & therapy management
- disease awareness programs

**Other** (Please provide details on the next page)



Write your responses here

### Which stakeholders does this PE project involve?

Select all that apply.

**Patients and/or carers**  
(including caregivers, and family members)

**Patient advocates, patient organizations and associations**

**Healthcare professionals**  
(including clinical investigators, general practitioners, specialists)

**Policymakers**

**Regulators**

**Payers**

**Health technology assessment organizations**

**Third party research vendors**

**Medical device companies or industry**

**Researchers**  
(academic researchers and investigators)

**Research funders**

**Other**  
(e.g. contract research organizations (CRO) and hospitals)  
(Please provide details)

Write your responses here

## Section 2: Checklist to Assess the quality of PE

Consider the PE 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.

QUESTIONS TO CONSIDER	Y/N	NOTES/ FURTHER INFO
What will you do to achieve this criterion?		
What is your stated “shared purpose”?		
How will you transparently share the starting point or objectives of the project, and the degree to which stakeholder input can influence project directions?		
<ul style="list-style-type: none"> <li>If relevant, for each of your objectives, indicate if and to which extent this has been agreed with the patient(s) or patient group(s) you wish to engage with.</li> </ul>		





QUESTIONS TO CONSIDER	Y/N	NOTES/ FURTHER INFO
<p>Consider involving the relevant internal stakeholders in your PE project, like organization’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.).</p>		
<p>How and when will you validate the shared purpose and its understanding among stakeholders?</p>		
<ul style="list-style-type: none"> <li>Consider implementing checkpoints throughout the project to make sure everyone is still aligned on the common purpose of the project, particularly if things change.</li> </ul>		
<p>Can all stakeholders express the shared purpose in their own words? This ensures everyone really understands what the shared purpose is with the least ambiguity.</p>		
<ul style="list-style-type: none"> <li>How will you communicate with and align all stakeholders to achieve clarity on “shared purpose” from the start and throughout the project?</li> </ul>		
<p>What processes do you have in place to accommodate ongoing feedback?</p>		



QUESTIONS TO CONSIDER	Y/N	NOTES/ FURTHER INFO
How do you ensure that all stakeholders understand what the project success looks like?		
<ul style="list-style-type: none"> <li>In cases of disagreement, how will you respond? How will you respectfully allow the disagreement while coming to plans to move forward?</li> </ul>		
Add your own questions		
Add your own questions		
Add your own questions		

## 2. Respect and accessibility



This refers to (1) respecting each other, 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, compensation and payment considerations
- cultural adaptations to procedures
- project practicalities such as meeting logistics (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 may need printed versions rather than electronic documents or PDFs for easier reading.

QUESTIONS TO CONSIDER	Y/N	NOTES/ FURTHER INFO
How will you address respect and accessibility in this 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?		

QUESTIONS TO CONSIDER	Y/N	NOTES/ FURTHER INFO
<p>Have you written what mutual respect looks like, what is expected from all stakeholders involved and co-defining the “code of conduct” in the project?</p>		
<p>How will you maintain mutual respect across all stakeholders in all interactions and activities?</p>		
<ul style="list-style-type: none"> <li>• What issues do you need to consider, and how will you overcome these?</li> </ul>		
<ul style="list-style-type: none"> <li>• 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?</li> </ul>		
<p>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)?</p>		
<p>How do you take into account accessibility considerations for people with health conditions?</p>		
<ul style="list-style-type: none"> <li>• Have you consulted with them to identify what makes it easy for them to participate?</li> </ul>		



QUESTIONS TO CONSIDER	Y/N	NOTES/ FURTHER INFO
<ul style="list-style-type: none"> <li>What practical steps will you take to overcome accessibility barriers?</li> </ul>		
<p>How will you collect feedback from stakeholders regarding how well (or not) they are respected and how well access needs have been met?</p>		
<p>How will you assess with stakeholders that they acknowledge mutual respect, and that access to engagement has been optimized?</p>		
<p>Add your own questions</p>		
<p>Add your own questions</p>		



### 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 (e.g. target population).

Consider diversity in expertise, experience, demographics and other relevant criteria for inclusion. When selecting PE stakeholders, including patients, attention should be given to awareness of the diversity required to achieve visible representative voice.

QUESTIONS TO CONSIDER	Y/N	NOTES/ FURTHER INFO
<p>Have you considered who you need to engage in this project to have outputs that reflect the needs and interests of end users? (gender, ethnicity, sexual orientation, age, knowledge, availability, social circumstances)</p>		
<p>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?</p>		
<p>How will you ensure that the PE representation is relevant for the goals and outcomes you are seeking?</p>		
<p>How will you address upfront the importance of PE representatives supporting their views with facts/ data/evidence, which demonstrate representation of stakeholder groups in addition to expressing individual opinions.</p>		



QUESTIONS TO CONSIDER	Y/N	NOTES/ FURTHER INFO
How will you ensure broad, competent, diverse representation of stakeholders?		
Add your own questions		
Add your own questions		



## 4. Roles and responsibilities



This refers to the need for clearly agreed, and ideally co-created roles and responsibilities for the project, in writing. Address all aspects of the project needs upfront and revisit regularly.

QUESTIONS TO CONSIDER	Y/N	NOTES/ FURTHER INFO
At what stage in your project will roles/ responsibilities be formally discussed, agreed and documented?		
<ul style="list-style-type: none"> <li>Have all the stakeholders involved signed a memorandum of understanding?</li> </ul>		
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?		
<ul style="list-style-type: none"> <li>Who is the go-to person for each topic?</li> </ul>		





QUESTIONS TO CONSIDER	Y/N	NOTES/ FURTHER INFO
<ul style="list-style-type: none"> <li>What is each stakeholder responsible for?</li> </ul>		
<ul style="list-style-type: none"> <li>How will change in roles/responsibilities be discussed and communicated?</li> </ul>		
<ul style="list-style-type: none"> <li>Do they know how to access this information on roles and responsibilities during the project?</li> </ul>		
<ul style="list-style-type: none"> <li>At what frequency will this be checked in?</li> </ul>		
<p>Add your own questions</p>		
<p>Add your own questions</p>		

## 5. Capacity and capability for engagement



This refers to (1) capacity as having relevant and dedicated resources from all stakeholders (e.g. 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 (e.g. 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 organizations and with each stakeholder (e.g. 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 (as needed). Capability needs may vary depending on the project needs, but also for personal circumstances of PE representatives.

QUESTIONS TO CONSIDER	Y/N	NOTES/ FURTHER INFO
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?		
<ul style="list-style-type: none"> <li>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.)?</li> </ul>		



QUESTIONS TO CONSIDER	Y/N	NOTES/ FURTHER INFO
<ul style="list-style-type: none"> <li>What training, resources or support do stakeholders identify to improve their capacity for engagement on this specific project?</li> </ul>		
<p>How do you make sure that stakeholders are supported to stay involved throughout the project?</p>		
<p>What support in capacity building are you providing?</p>		
<ul style="list-style-type: none"> <li>At what frequency will you validate that the approach you provide works for all participants involved throughout the project?</li> </ul>		
<p>How did you check that all stakeholders have what they need to contribute effectively and meaningfully?</p>		
<p>How will you check that the materials for PE were in accessible formats, and written in plain and clear language?</p>		
<p>Add your own questions</p>		



## 6. Transparency in communication and documentation



This refers to the establishment of a communication plan and ongoing project documentation\* that can be shared with all 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, where applicable. Lastly, communicating outcomes of the project to all stakeholders and how their contribution was of value to the success of the project is critical.

\*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.

QUESTIONS TO CONSIDER	Y/N	NOTES/ FURTHER INFO
How is knowledge sharing facilitated and information made easily accessible (with a user-friendly format, style and language) to all stakeholders in the project?		
<ul style="list-style-type: none"> <li>Are materials disseminated with enough time before the activity to facilitate/allow for meaningful engagement?</li> </ul>		
Have you established a communication and dissemination plan including timelines for regular updates internally and externally? (e.g. speed of response to emails)		

QUESTIONS TO CONSIDER	Y/N	NOTES/ FURTHER INFO
<ul style="list-style-type: none"> <li>Does this plan consider speed of response by and to stakeholders?</li> </ul>		
<ul style="list-style-type: none"> <li>Does the plan reflect expected behaviours and timelines for communications?</li> </ul>		
<ul style="list-style-type: none"> <li>Are the methods of communication appropriate for all stakeholders?</li> </ul>		
<ul style="list-style-type: none"> <li>Is the language used (scientific vs. lay) appropriate for all stakeholders?</li> </ul>		
<p>Have you considered assigning responsibility to maintain the in-project documentation and/ or communication throughout the project?</p>		
<ul style="list-style-type: none"> <li>Who will be accountable for setting up regular phone calls?</li> </ul>		
<ul style="list-style-type: none"> <li>Who will take notes in meetings?</li> </ul>		
<ul style="list-style-type: none"> <li>How often will you meet?</li> </ul>		
<ul style="list-style-type: none"> <li>How much reaction time do you agree upon for a phone call, or an email?</li> </ul>		



QUESTIONS TO CONSIDER	Y/N	NOTES/ FURTHER INFO
<ul style="list-style-type: none"> <li>What kind of issue or change does each party expect to be immediately reported, and how?</li> </ul>		
<p>When communicating externally or when there is a need to release specific types of information, are you considering the regional and national regulations and requirements if necessary?</p>		
<p>What will you do to achieve and implement processes for timely communication and updated documentation throughout the project?</p>		
<p>How will you validate that your communication and documentation plans are useful and appropriately implemented?</p>		
<p>Add your own questions</p>		
<p>Add your own questions</p>		



## 7. Continuity and sustainability



This refers to the smooth progression of the project, as well as efforts to maintain ongoing relationships 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 workflow 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 organizational resilience should be anticipated.

QUESTIONS TO CONSIDER	Y/N	NOTES/ FURTHER INFO
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?		
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.		



QUESTIONS TO CONSIDER	Y/N	NOTES/ FURTHER INFO
<ul style="list-style-type: none"> <li>Can there be a broader application of this project or it's outcomes?</li> </ul>		
<p>How can you encourage continuous learning, and how can other teams benefit from patient engagement experiences that were conducted elsewhere in your organization?</p>		
<ul style="list-style-type: none"> <li>Have you included a "lessons learned" debrief at the end of the project as well as agreeing a communications plan for this.</li> </ul>		
<p>Add your own questions</p>		
<p>Add your own questions</p>		





## Section 3: Results, outcomes and impact

### Describe the results, outcomes, measurements and evidence collection

(Note: If you are planning a PE project, write about the expected outcomes, metrics to measure success, impact, etc.)

- the results and positive impact expected in your medical device R&D phases or operations
- impact for patients and/or the patient community
- impact for stakeholders involved in the project
- give examples of the different methods you will use to collect evidence

Write your responses here

### Describe the project’s impact that you expect to achieve in the four categories below.

(If possible, specify how this impact can be monitored and evaluated/measured)

#### 1. Expected or achieved positive impact for specific R&D phases

For example:

- identifying unmet medical needs
- accurately prioritized research agenda
- improved study design (e.g. fewer protocol amendments)
- financial impact due to -effective study start-up, improved retention rates
- possible decreased timing to registration
- patient-driven solutions
- increased patient adherence to treatment
- extension of a device or solution to new patient groups or new countries/regions
- better understanding of the patient experience

Write your responses here



## 2. Expected or achieved direct or indirect positive impact for **patients or patient community**

For example:

- increased influence or impact on research prioritisation agenda
- easier access to novel therapeutic options
- increased awareness of relevant clinical programs and recruitment procedures
- improved quality of life for patients
- better patient-reported outcomes (PROs) and patient-centered outcomes (PCOs)
- more effective device

Write your responses here

## 3. Expected or achieved direct or indirect positive impact for **stakeholders** involved in the project (other than patients)

For example:

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

Write your responses here

## 4. Any other expected or achieved impact overall

Write your responses here



## Section 4: Lessons learned (for completed projects)

### 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 organization. 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?

Write your responses here

# Additional Information

## 1. Annex 1: Other useful resources to consider

## 2. Sources

## 3. Abbreviations and glossary

<b>NHC</b>	National Health Council (US)
<b>PCORI</b>	Patient-Centered Outcomes Research Institute (US)
<b>PE</b>	patient engagement
<b>PFMD</b>	Patient-Focused Medicines Development initiative
<b>PRO</b>	patient-reported outcome
<b>Stakeholder</b>	all parties, organizations or individuals relevant to medicines research and development and care continuum; for example: patients, patient advocates, patient organisations, healthcare providers, device companies, healthcare researchers, payers, regulators, health technology assessment bodies, etc.