



PATIENT FOCUSED
MEDICINES DEVELOPMENT



The PFMD Book of Good Practices

1st edition | 2018

 @The_Synergist
@PFMDwithPatient

#PEQualityGuidance
#PEQualityCriteria

 www.PatientFocusedMedicine.org
May 2018

Message from PFMD

Dear reader,

Patient Focused Medicines Development (PFMD) was established in 2015 out of a need that was expressed by many stakeholders in various roundtable discussions. This need was eventually translated into a dedicated organisation that aims to drive systematic patient engagement and involvement forward in the research, development and delivery of medicines.

Today we are very proud that you are reading the Book of Good Practices, as this too was born from a need expressed by many stakeholders. As patient engagement is becoming a norm instead of an exception or a one-off practice, there was a need to share knowledge about

- how other organisations have involved patients in their activities,
- what can be considered as high quality patient engagement, and
- how can different organisations reach the level of patient engagement that is both meaningful to patients but also to the research and development processes so that the output or outcomes will serve the end users better.

The PFMD Patient Engagement Quality Guidance, that was launched in 2018, introduces 7 Quality Criteria for good patient engagement that can be used to plan patient engagement activities, or to assess the level of patient engagement in ongoing or completed activities. Where the Patient Engagement Quality Guidance serves as a tool to help you to do patient engagement, the Book of Good Practices serves as a set of real life cases from a variety of organisations, that illustrate in detail how they have done it. These cases have been chosen from a big pool, assessed by an external group of reviewers and chosen to be included because they exemplify exceptionally well the 7 Quality Criteria. For detailed descriptions of the criteria and explanations for icons used, check the annexes at the end of the book.

The Book of Good Practices will be growing year by year with new cases. To contribute to this work, you can also submit your patient engagement experiences to the PFMD team.

We hope this book will inspire and help you in your patient engagement journey. We encourage you to explore all the tools at your disposal within PFMD and Synapse - the mapping and networking tool, and connect with us for more guidance if needed.

We'd like to extend our thanks to all the reviewers, all case owners and all readers for making the Book of Good Practices possible.

PFMD Team



Understanding patient and stakeholder needs alongside the patient journey*

(*Update in Jan 2018: This project has been discontinued due to internal matters)

Case from a Pharma Company (“Company”)

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THE BOOK OF GOOD PRACTICE INITIATIVES ARE ALSO AVAILABLE IN SYNAPSE.

TO DOWNLOAD THE FULL BOGP, PLEASE VISIT:

<https://synapse.pfmd.org/book-of-good-practices/>

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Understanding patient and stakeholder needs alongside the patient journey*

(*Update in Jan 2018: This project has been discontinued due to internal matters)

Case from a Pharma Company (“Company”)



Basic Information

The Initiative had the goal to understand the needs along the patient journey and to co-develop a solution that helps patients managing their daily life covering the most important needs. As early as possible, stakeholders’ needs alongside the patient journey were collected and matched, so that the most important needs could be identified.

As a second step, based on the prioritized needs, a solution gets co-created and tested. The solution will get implemented after launch. The project itself got stopped due to prioritization of another digital health solution, which was more advanced. However the insights could be used for the other patient solution.

The assessment of the quality of PE practice

Steps towards the Initiative’s solutions in a non-oncology disease setting:

1. Multi-stakeholder advisory board with patients, patient experts, nurses and physicians has been conducted by asking their challenges, needs and feelings alongside the patient journey (please see details on the next page).
2. Results from advisory board have been confirmed with market research and had been matched to internal strategy.
3. External landscape analysis has been conducted to check what solutions are available to patients with the disease.
4. Potential solutions with patients, patient group representatives, nurses and physicians, that were present in the first advisory board, have been co-created. Three ideas were defined to move forward.

- The solutions have been tested with other patients and physicians and revised.
- The solution is going to be implemented within test countries and in collaboration with local patient groups.

Overview of working sessions

Session	Groups	Exercise	Outcome
Working Session I (75 min. plus 15 min. walkthrough during coffee break)	2 mixed groups (collaging is an individual task therefore group composition does not matter)	Collage: select picture and create a collage that reflects how you experience life with the disease (For HCP: create a collage that reflects how you feel about treating patients)	Emotional understanding of: <ul style="list-style-type: none"> The patient's feelings, problems, needs, state of mind The HCP's feelings and emotions when treating patients
Working Session II (60 min. plus 10 min. per group for sharing of key points in plenary)	Separate groups (Patients/PAGs and HCPs)	Needs along the patient journey	<ul style="list-style-type: none"> Talking through patient journey phases (awareness, diagnosis, treatment and adherence) Mapping of needs along the entire patient journey
Working session III (60 min.)	Patient/ PAG group HCP group	Focus - Life with the disease: impact on social life and living with the disease and symptoms Focus - Interacting with patients: typical questions, concerns, dealing with patients' emotions	In-depth understanding of daily challenges, struggles and needs in focus areas that most relevant and actionable for Pharma Company (basis for solution development)
Working session IV (30 min. plus 10 min. per group for results sharing in plenary for III and IV)	Same groups continue from working session III	Solution brainstorming for focus areas: information needs and other solution ideas	<ul style="list-style-type: none"> Longlist of ideas that addresses identified needs in the focus areas Voting and definition of 3-5 ideas

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



Which stakeholders does this PE project involve?



*HCP who were considered as local and/or global TAEs



The quality of patient engagement

1. Shared purpose



Company involved patients and patient representatives as well as other stakeholders from the start until the end of the project, by understanding the needs, co-creating the solution and by implementing it together.

Examples of the questions and topics planned for the advisory board to get discussions started.

1. Select pictures and create a collage that reflects how you experience life with MS or how you experience to treat MS patients:
 - Why did you use this picture?
 - Why is ... important to you?
 - How do you deal with ...?
 - What is the impact of ... on your daily life?
2. Patient Journey:
 - What was it like for you to go through these steps?
 - What were particular challenges you faced?
 - Why were certain things difficult and what are the implications of that?
 - What are things that went well?
 - What support did you receive?
3.
 - a) What are your (an MS patient's) biggest concerns when getting up in the morning?
 - b) Where do you feel the biggest challenges regarding your social life being an MS patient?
 - c) Where do you struggle most in daily life with the MS disease and the related symptoms?
 - Contracts and track records are in place to meet Company's compliance and legal requirements.
 - After each of the meetings the Company have assessed the quality of interaction with participants.
 - The final solution still needs to be implemented and needs to include metrics to measure the success. (Edit Jan 2018: initiative has been disconnected)

2. Respect and accessibility



- In the workshops a way of verbal and nonverbal communication was used with (for example) pictures, as feelings may be better expressed with images.
- Very strong listening skills as well as moderators who are having the empathy to accommodate all stakeholders have been used.



- There was a follow up in 1:1 meetings to clarify all individual perspectives and to understand if anything in the group was missing .
- HCPs and patients were first split in the workshop. However, the participants wanted to listen to the other perspective, so they handle a joined meeting the following time.
- Participants’ surveys helped to improve the project and the way of working with the stakeholders.

3. Representativeness of stakeholders



The most difficult task was the identification of the right participants*. They were identified via their affiliates and patient group relations people. Qualitative market research was used to complete their findings.

- *1) Patients a) just diagnosed and b) living with the disease for longer time from the 3 pilot countries
- 2) HCPs who were considered as local and/or global TAEs

Company could match the outcomes of the advisory board and the market research very well.

4. Roles and responsibilities



Follow up meetings 1:1 as well as updates via emails informed about the progress. Once the final implementation is done, the feedback loop will be ensured.

This PE project owners used feedback from participants to check if what they did was appropriate to achieve this criterion.

The feedback of the workshop participants was always very good and didn't have a lot of feedback for improvement, other than mixing the stakeholder groups more.

5. Capacity and capability for engagement



In this project, the focus was on questions and solutions for daily life. Therefore, no further skills or knowledge from the participants were necessary. The stakeholders were informed alongside the process of the questions and tasks.

Stakeholders did not look for clinical trial experience, knowledge of drug development. They selected participants on the basis of the following criteria:

- How long they were living with the disease
- Geographical scope
- Female and male ratio

This PE project owners used participants surveys to check if what they did was appropriate to achieve this criterion.



6. Transparency in communication and documentation



Contracts and track records are in place to meet Company’s compliance and legal requirements. As per Company’s guidance, it is mandatory to document any activity with external engagement, e.g. advisory boards. There is a need to work on the share best practice in house and get local approvals for the engagement.

Documents were shared with the workshop participants before, during and after the project. Before the meeting only the objective was shared. After the meetings the outcome and the next steps including the final testing were shared.

7. Continuity and sustainability



The scope of the project as well as the role of each individual involved was always very clearly communicated via the contracts, as well as in the meetings. Whenever questions occurred, they were appropriately addressed.



Results and outcomes

PE practice led to the following measured outcomes:

- Profound understanding of patient and stakeholders needs alongside the patient journey.
- Potential solutions that may impact the life of the patients.
- This Initiative showed Company that there is a very high unmet need in giving the power to patient to live their lives.
- With the co-created solution, which is still in iterations, Company believes that it can help patients to achieve their goal to be proactive in living a normal life.
- The process Company has chosen, is a very solid approach, however, final implementation seems to be more challenging than anticipated due to cost and compliance considerations.

Positive impact for specific medicines development phases

- Improvement of self-empowerment and therefore also clinical care.

Direct or indirect positive impact for patients

- Living a normal life.

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

- Helping HCPs.

Lessons learned

The project was stopped, however the way of working to assess the needs along the patient journey and how to co-create solutions already has been used by other disease areas.

It was very difficult to find the right participants with the right profile and without compliance/ legal restrictions. However, once Company had identified the stakeholders, the biggest learning was, that a multi-stakeholder approach gives the best overview to the questions Company had providing the variety of different perspectives. This made it easier for Company to prioritize the key findings.

Involvement of the stakeholders alongside the project including the multi-stakeholder perspectives.

It's important to give enough time to plan and identify the participants.

Annex 1: How to read the Book of Good Practices

The Book of Good Practices cases are all structured in the same way as the Patient Engagement Quality Guidance. You will find that each case has a basic description, followed by icons to show in which phases of medicines continuum they fit in and which stakeholders they have involved in their work (see description of icons below). In section 2 these cases will describe how they reached each of the 7 Quality Criteria. You will see from the wheel in the beginning, which of the Quality Criteria they exemplified in (judged by an external group of reviewers). Finally, you will find the results and outcomes of each case and the lessons learned.

Which phases of research, medicines development, lifecycle or disease area does this PE project cover?



✓ Research and discovery phase

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 1-3)

✓ 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

Which stakeholders does this PE project involve?



✓ 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)

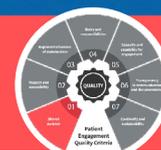
✓ Researchers (academic researchers and investigators)

✓ Research funders

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

Annex 2: Descriptions of the Patient Engagement Quality Criteria

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.

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.

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.

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.

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, involved 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.

6. Transparency in communication and documentation



This refers to the establishment of communications plan and ongoing project documentation 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.

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.