



PATIENT FOCUSED  
MEDICINES DEVELOPMENT



# The PFMD Book of Good Practices

1<sup>st</sup> edition | 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.

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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



PATIENT FOCUSED  
MEDICINES DEVELOPMENT



HEALTH COLLABORATORY



# Patient/Caregiver Pathway Mapping & Patient Shark Tank®

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Organisation: Health Collaboratory

## The PFMD Book of Good Practices

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

**TO DOWNLOAD THE FULL BOGP, PLEASE VISIT:**

<https://involvement-mapping.patientfocusedmedicine.org/book-of-good-practices>

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# Patient/Caregiver Pathway Mapping & Patient Shark Tank®

Organisation: Health  
Collaboratory



## Basic Information

The objective of these interventions is to understand the path that patients and care/support partners have travelled, with a focus on their challenges, emotional state, and support mechanisms. Proprietary tools were used to translate the patient and care/support stories into quantitative data. The stages across their journey were discussed beginning with the experience of symptoms through long term management. Qualitative semi-structured interviews were conducted utilizing a conversational, narrative, ethnographic approach to allow patients and care/support partners to piece together and share their story in a meaningful way. An interactional exchange of dialogue took place using a biographical, fluid and flexible structure, which provided the opportunity for a co-production of the patient and care/support partner journey map. A participatory storytelling technique was used to provide a safe zone for information exchange with a deeper dive into the following domains:

- Emotions experienced across phases of the care journey
- Challenges and barriers faced
- Main questions across the care journey
- Main channels/sources used for information and support
- Relationship with doctors and care team
- Impact of condition on main aspects of life

### Objectives:

- To provide quantitative and qualitative data on unmet needs and therapeutic burden of patients and care/support partners through pathway mapping, life impact, and emotional journey across disease states
- To empower patients and their care/support partners to provide perspective on healthcare innovations

## The methodology of the patient engagement initiative:

1. Qualitative semi-structured interviews utilizing a conversational, narrative, ethnographic approach were conducted to allow patients and care/support partners to piece together and share their stories and unmet needs in a meaningful way
2. Participatory techniques were deployed providing an opportunity for co-production of patient and care/support partner pathway mapping. Proprietary tools were created to assess some of the following domains and translate unstructured data into quantitative data points. Example domains include:
  - Impact of Condition on Life
  - Challenges and Barriers Faced
  - Triggers and Behaviours
  - Therapeutic Burden
  - Decision Points & Healthcare/ Clinical Trial Experience
3. The Patient Shark Tank® was created to amplify the voice of the patient and care/support partner in the design, development and/or continuous improvement of healthcare innovation, whether it's technology, research design, education, policy, strategy etc. Although there are expert patients and care/support partners who are part of the tribe, the majority of patients and their care/support partners have not intersected with players in the healthcare ecosystem other than their healthcare team. Patients and care/support partners are coached on how to reflect on their personal stories and experiences as they provide perspectives and/or partner on the development of innovations. To ensure diversity in patient and care/support partner populations, emphasis is put on recruiting a balance of those who represent various ethnicities, races, religions, age groups, socioeconomic status, geographies and sexual orientation. To certify innovations a co-designed scorecard is utilized to allow for standard criteria and assessments to be used in the evaluation of innovations resulting in a “Patient Shark Tank Tested” seal. Today, over 18,000 patients and care/support partners across disease states have evaluated innovations globally.

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



Research and discovery phase: including drug discovery, non-clinical and candidate-identification phases

Post-marketing or clinical study phase 4: including post-regulatory approval phase



## Which stakeholders does this PE project involve?



Patients  
and carers



Polymakers



Health technology  
assessment  
organisations



Research funders



Patient advocates,  
patient organisations  
and associations



Regulators



Pharmaceutical  
companies or  
industry



Other



Healthcare  
professionals



Payers



Researchers

Other: Investors



## The quality of patient engagement

### 1. Shared purpose



The initiative was created to ensure that patients and care/support partners have an opportunity to voice unmet needs and therapeutic burden outside of a typical interview session. Pathway mapping was conducted utilizing 1:1 (patient), 1:2 (patient: care/support partner), and 1:many (group of patients) approaches.

Group and 1:1 feedback was obtained from patients and care/support partners to ensure they felt their specific needs were being addressed. In addition, scorecards that were used as part of the Patient Shark Tank® were co-designed with patients and their care/support partners.

### 2. Respect and accessibility



All patients and care/support partners received coaching during the Patient Shark Tank® to ensure they were comfortable interacting with various stakeholders. In addition, we created a process to provide patients who were not comfortable participating in a group setting, and those with limited mobility to also participate. Patients were compensated for their time.

Benchmarking of fair market reimbursement vs. expectations was also conducted. There were also frequent 1:1 touchpoints.

### 3. Representativeness of stakeholders



Different ethnicities, races, religions, age groups, socioeconomic status, geographies, sexual orientation, and stages of disease were incorporated into the selection of our patient/caregiver partners using our database, which consists of ~18,000 patients and care/support partners representing various patient and care/support partner segments across disease states.

To ensure the activity represented varied demographics and was fair balanced, we set criteria with specific goals that were documented to also ensure the right patient and care/support partner was aligned with the right project.



## 4. Roles and responsibilities



Patients and care/support partners were clear on their role in the pathway mapping and how the data would be used to determine trends in unmet need. Patients and care/support partners were also provided direction on how their Patient Shark Tank® participation would be used with feedback loops built in throughout.

Commitment documents were developed with patients and care/support partners. A scorecard co-designed with patients and care/support partners was used during the assessment.

## 5. Capacity and capability for engagement



All patients and care/support partners received training and coaching during the Patient Shark Tank® to ensure they were comfortable interacting with various stakeholders. Not all patients and care/support partners that were interviewed were used in the Patient Shark Tank®, thus comfort level and boundaries were determined in advance.

Each patient and care/support partner completed an assessment on their engagement preferences and overall experience in the activities.

## 6. Transparency in communication and documentation



Some interviews were recorded and notes taken throughout. Feedback was captured in Patient Shark Tank® scorecards that were co-designed with patients and care/support partners.

## 7. Continuity and sustainability



All patients and care/support partners that participated were kept abreast of developments and continuous improvement of the initiative through frequent updates, even as other patients and care/support partners rotated through different parts of the project.

We used various communication channels to ensure continuity throughout the project.

## Results and outcomes

Patient Shark Tank®:

- **>18,000 patients and care/support partners across the globe**
- **~900 innovations evaluated**
- **Patient Shark Tank® compensation assessment conducted in alignment with expectations**
- **12 Different Assessment Models Created**
- **Virtual Build Underway**

Pathway Mapping Initiative led to the following (measured) outcomes:

- **1,800 patients/1,200 caregivers**
- **Short term and long term unmet needs of patients and care/support partners were identified (traditionally from KOL perspective)**
- **Trends in burden of therapy were identified**
- **Co-design of potential research questions**
- **5 innovations were evaluated using Patient Shark Tank® during [this project] utilizing 300 patients and caregivers**

Improvement in understanding unmet needs and therapeutic burden.

Evolution from KOL perspective of patient/caregiver burden.

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### Positive impact for specific medicines development phases

- Co-design of research question
- Opportunity for non-traditional voices to be heard
- Diverse representation of patient and care/support partner populations
- Quantified patient stories and unstructured data through various proprietary tools to translate qualitative data into quantitative data points that could be used in submissions

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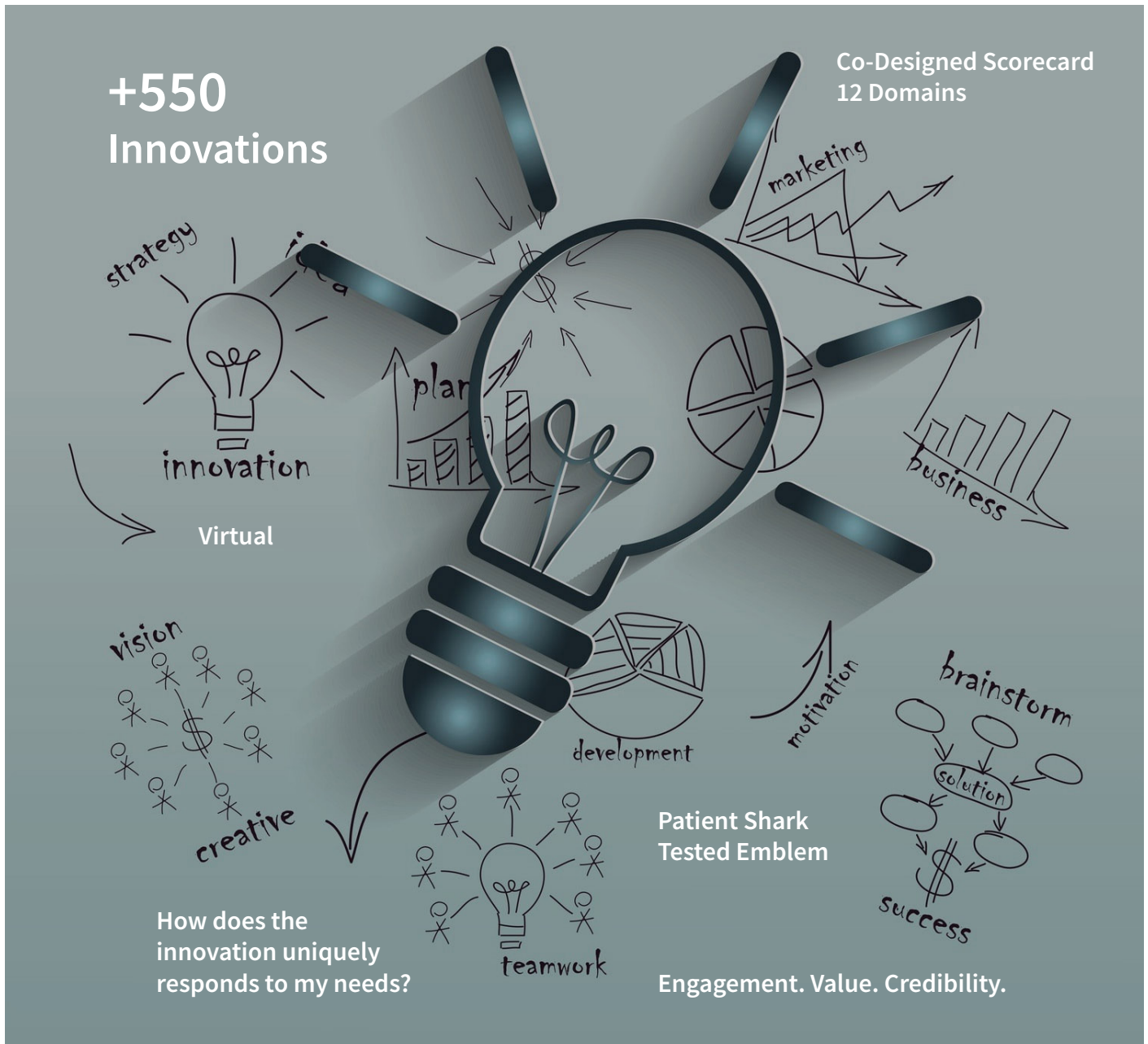
### Direct or indirect positive impact for patients

- Opportunity for patients and care/support partner perspectives to be heard and dimensions of life affected to be measured
- Opportunity to understand how others are also affected through simplified comparative data reports
- Allowed patients and care/support partners to understand how perspectives were utilized through feedback loops



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


- Informed understanding from patient and care/support partner perspective
- Validation against EBM



## Lessons learned





 @sarahkrug1

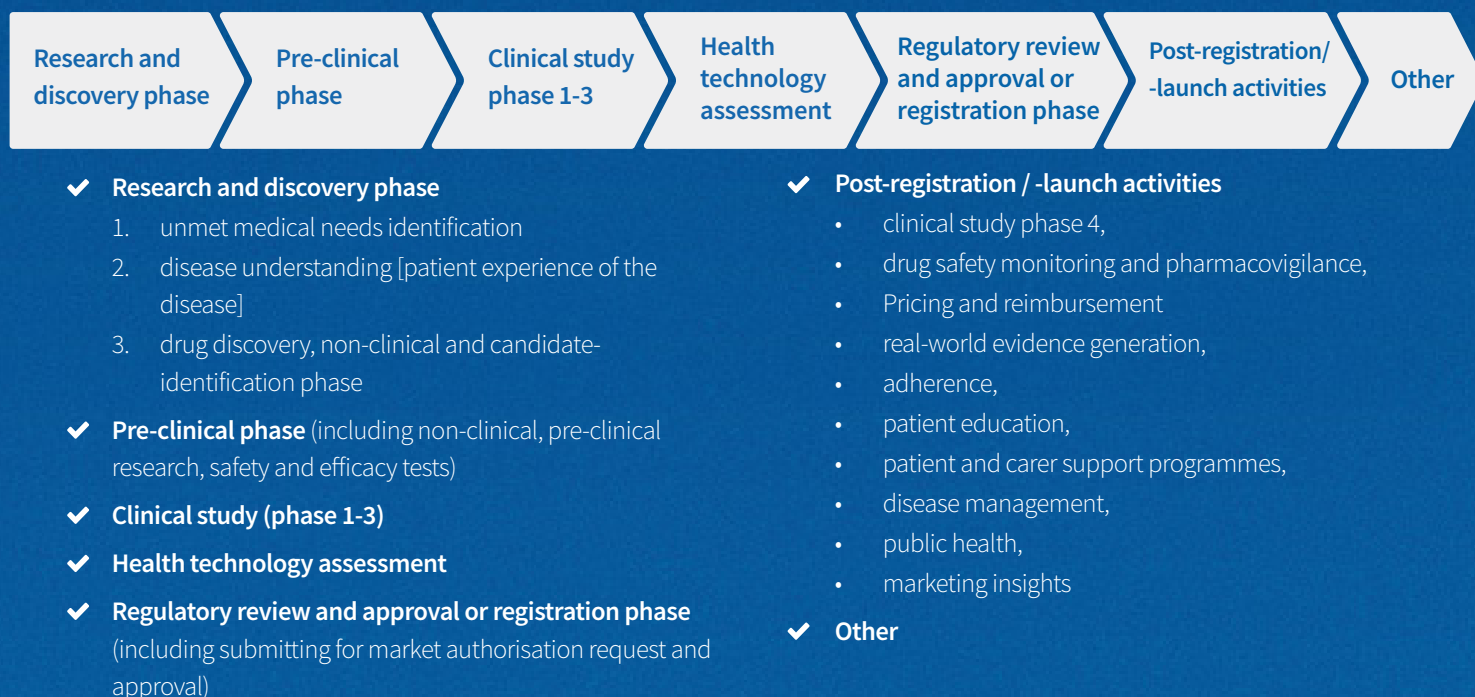
## About the Health Collaboratory

The Health Collaboratory™ is an innovation hub, founded in 2011, that amplifies the voice of patients and their families in healthcare innovation, creating impact through co-designed solutions that advance collaboration across the healthcare ecosystem. As a change agent in advancing participatory medicine, the Health Collaboratory™ is at the intersection of innovation, research, education and advocacy, revolutionizing the way in which we impact and improve health. The Health Collaboratory™ has empowered over 18,000 patients and their care/support partners globally to co-design and provide perspective on the design, development and continuous improvement of healthcare innovations.

# 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?



## Which stakeholders does this PE project involve?



# 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.



# Annex 2: Descriptions of the Patient Engagement Quality Criteria

## 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.