



PATIENT FOCUSED
MEDICINES DEVELOPMENT



The PFMD Book of Good Practices

1st 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.

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



made
with
patients

Building patient centrality into process: clinical development - HILFE FÜR MICH (Patient Navigator)

Organisation: Pfizer

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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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Building patient centrality into process: clinical development - HILFE FÜR MICH (Patient Navigator)

Organisation: Pfizer

Basic Information

HILFE FÜR MICH (Patient Navigator) is an online tool, created for patients as well as their relatives to inform, educate and explore people's needs. The Digital Patient Navigator, first in navigating patients and caregivers through the complex HC system for diseases, initially metastatic breast cancer, stroke and kidney cancer, is patient-led and developed in concept, content and design, leveraging synergies across therapeutic areas in co-creation with external partners.

In a pilot project, a digital service platform that offers quality-reviewed information and patient pathways for people living with illness and their families was developed. With a clear structure with questions, answers, and links, those affected should quickly find the information they need.

- What's unique about this: Through the development of personal "patient pathways" patients also get individual help in dealing with their disease. The patient pathway helps them outline and understand their options and what they can do to stabilize or improve their health. Thus the platform may help the people affected, as well as their families and other members of their support communities, to cope better with their new situation and their own emotions, to deal with the plethora of information, and to make necessary decisions with a sense of confidence and empowerment.

The central impulse for the creation of this internet portal was the idea of a board of patient experts to develop a new information offering for patients with severe chronic disease, which would offer them support and comfort on their path and would help them deal with their new situation, their emotions, and the plethora of information, as well as empower them to make important decisions and to cope better with the disease in their lives.



Patient Navigator is based on patient, physician and the Pfizer expertise:

The experts are represented for metastatic breast cancer (14 experts), stroke (8 experts) and kidney cancer (6 experts) according to their professional background. In these categories, Pfizer colleagues are involved and participate at eye level with the external specialists that support the project. Pfizer's experts on www.hilfefuermich.de are Peter Albiez, CEO Pfizer Germany, and Christina Claussen, Director Alliance Management & Patient Relations Pfizer Germany.

Users find information through more than 250 questions and answers that include links to medical associations, treatment guidelines or journals to make external knowledge available for the users. HILFE FÜR MICH provides links and short descriptions of more than 50 patient organizations and other platforms that offer information and help.

All content goes through a multi-level review process before publication. Checks are performed on the factual correctness of the information, the relevance and currency of the content, and whether the selection and presentation of the topics is suitable for the patient audience. Experts who provide different specialist competencies, such as in the medical, legal, and editorial fields, are involved in the different review processes. Patients also ensure that the patient orientation of the topics and content is guaranteed. Medical specialists check the accuracy of the health topics, while communication experts ensure that the text is easy to read and flows well.

The protection of personal privacy and private data is important to us. We capture, process, and use personal data in compliance with the German data protection laws and its data protection declaration.

Initiative update in August 2019:

- the possibility to create an individual patient pathway has been removed three months ago;
- the number of indications went up from 3 (mBC, stroke, kidney cancer) to 8 (lung cancer, pain, rare disease, ulcerative colitis and smoking cessation) and
- due to this expansion, the number of experts increased as well (lung cancer: 8, pain: 9, rare disease: 13, ulcerative colitis: 9, smoking cessation: 8), and in addition
- the number of questions and answers went up to over 1.050 as well.

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

Medicinal product agnostic, generally intended for newly diagnosed people with illness with potential utility at other times in the journey with that illness.



Other: Care journey (disease/care management)



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

The quality of patient engagement

1. Shared purpose



The concept for the Patient Navigator originated from patients attending a regularly occurring Pfizer-Patient-Dialogue in Germany with patient advocacy groups. Discussions were continued among a smaller group of patient representatives, IT experts, health care professionals, and Pfizer colleagues to co-create the Navigator. The working group confirmed the appropriateness and progress at regularly occurring update discussions.

2. Respect and accessibility



The program was shaped from the start with guidance from patients and in an iterative manner through its development.

Feedback from patients at regularly scheduled discussions verified that these actions were meeting their expectations of engagement.

3. Representativeness of stakeholders



Patient advocates and healthcare professionals involved in the project interact on a regular basis with a diverse group of patients within Germany and strived to integrate those diverse experiences into the project. However, we recognize that individual patient experts cannot be fully representative of all patients who may use the Navigator.

Information is collected by the people using it to help them navigate their care including and not limited to appointments, family and patient resources, medicines, professional and social issues.

4. Roles and responsibilities



The point of contact for the patients involved was a skilled and dedicated Patient Relations Manager (well-versed in Pfizer, EU and Country regulations for interactions with patients) who has developed and nurtured relationships with patients and patient organizations involved.

Feedback from patients at regularly scheduled discussions verified that these actions were meeting their expectations of engagement.

5. Capacity and capability for engagement



The patients involved had the requisite expertise as established advocates and included people with health communications expertise as well as experience as patients.

The selection of the team included patients from the start as well as Pfizer colleagues to ensure the alignment of capabilities with the goals of the project.

6. Transparency in communication and documentation



A transparent communication plan was part of the design and release of the Navigator to the public. In addition the quality process is outlined below:

1. Concept: Co-Development of Concept, Topics and Content together with Patient Organisation
2. Editorial: Defined quality criteria
3. Review I: Check by patients and caregivers
4. Review II: Check by medical and legal external experts

At a glance: How was the content for this website created?

Conception	Editorial Team	Review I: Patients	Review II - Scientific experts
Selection and concept of topics and content in collaboration with experts in patient work	Creation and editorial review of content based on defined quality criteria	Review of the content by external patients and relatives	Review of the content by medical experts on the scientific advisory board

Feedback from patients at regularly scheduled discussions verified that these actions were meeting their expectations of engagement.

7. Continuity and sustainability



The plan included launch in two illness areas with the intent if successful for expansion beyond those areas and in additional geographies beyond Germany. The team including patient experts has been involved in those discussions. A third illness area was launched and more are planned.

Feedback from patients at regularly scheduled discussions verified that these actions were meeting their expectations of engagement.

Results and outcomes

Positive impact for specific medicines development phases

Pfizer's "patients first" approach across the medicines development phases includes creating new alliances and partnerships among stakeholders. Responsiveness to suggestions meeting a need identified through the Pfizer-Patient-Dialogue is but one way Pfizer is demonstrating this commitment.

We are working with other country and global teams to implement this in other countries and adapt it in ways patients feel it will be useful for them.

Direct or indirect positive impact for patients

The Patient Navigator program may help people identify their needs and assist them with navigation through the healthcare system as well as a better understanding of patient health condition and expectations. Metrics below about initial reach and average session duration are encouraging.

Total Number of users (launch 8th May 2017 until 30th August 2019)

	Users total	Session Duration	New Visitors	Returning Visitors
May 2018	221,000	00:00:59	219,600	17,400
2019 update	642,735	00:01:05	641,565	57,992

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

The impact for non-patient stakeholders is the experience of co-creating a tool with patients as experts on the same team. This has not been the traditional approach in the development of healthcare tools for patients.

Lessons learned

Key Learnings:

- 1. A "Patient First" approach is key:** the patient need was at the core of the project and a group of patient experts were involved in developing the program.
- 2. Strong sponsorship and involvement of sponsors along the journey:** sponsorship at senior organizational levels, with involvement throughout the project and at key strategic points.
- 3. Plan carefully with the flexibility to be responsive to potential challenges:** create a project plan, look at all the tasks and dependencies early and get input from all external and internal experts along the way.



 @pfizer

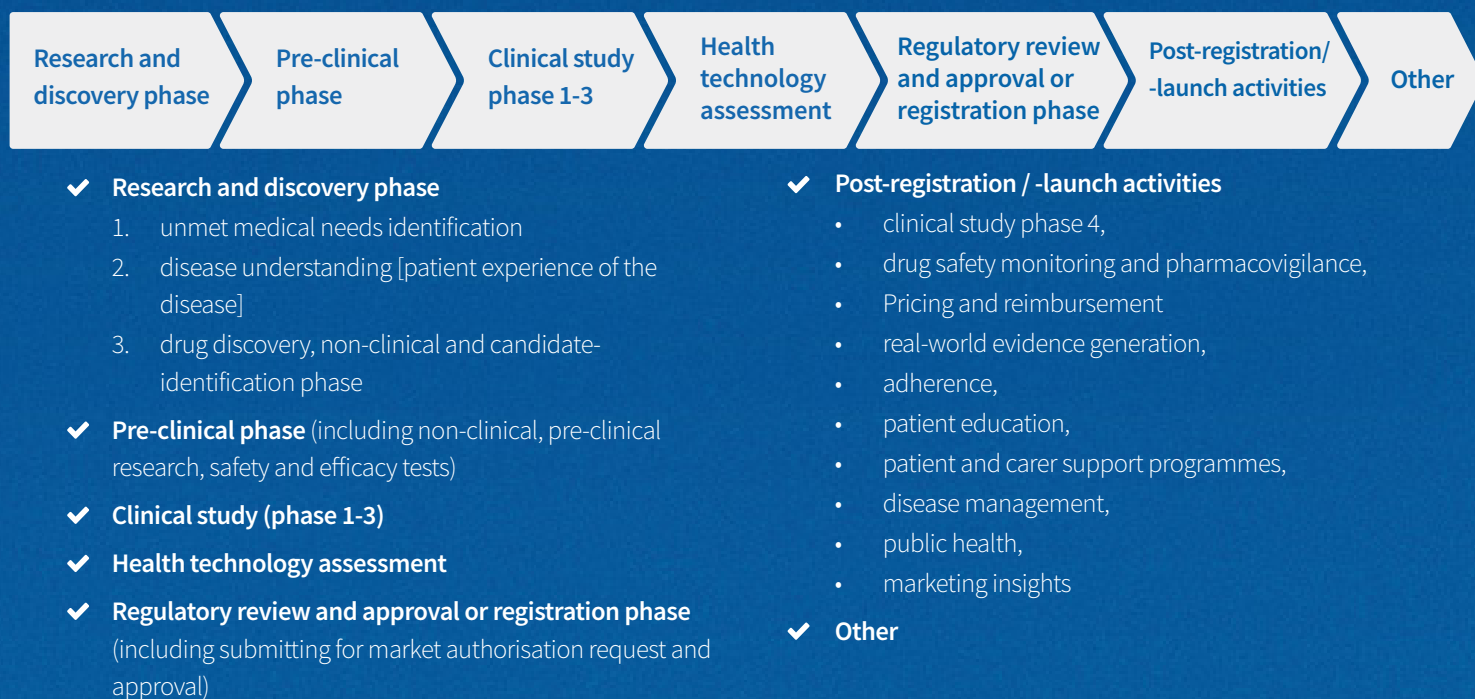
Pfizer's purpose

Our purpose is grounded in our commitment to fund programs that provide public benefit, advance medical care and improve patient outcomes. Our belief is that all people deserve to live healthy lives. This drives our desire to provide access to medicines that are safe, effective, and affordable.

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.