

# Collaborative Patient Engagement: Mapping the Global Landscape



made  
with  
patients



***A first step in co-creating an  
action-orientated framework  
for patient engagement***

*Participate in the landscape mapping  
project, share your experience and  
join the PE global network*



# Mapping the patient engagement landscape across the lifecycle of medicines development

## Introduction

Medicines are developed to improve the lives of patients. Serving patients in the best way possible requires a deep understanding of their medical conditions, needs and priorities. This can be gained only through direct, sustained and constructive interactions with ‘patients’ - a definition that includes those with the medical condition and their family or carers. Health stakeholders agree that broadening patient engagement is key to improving drug development and providing solutions that achieve both clinical and patient-desired outcomes. As a result, there is an encouraging and increasing number of patient engagement (PE) initiatives that aim to integrate the patient voice in medicines development specifically, and in the healthcare arena generally.

However, current PE is sporadic, fragmented and unstructured with no clearly defined framework or agreed process. Without such a framework, the ability of PE activities to meet agreed and desired objectives will be compromised. What is needed is a consistent approach to PE, through development and implementation of an efficient, measurable and reliable meta-framework that involves patients as partners and is accepted and used by relevant stakeholders.

Despite the substantial increase in PE initiatives, there is currently no efficient mechanism for accessing information on what PE activities are ongoing or planned and to identify challenges encountered and lessons learned. Therefore, an essential first step in development of a meta-framework is to identify and ‘map’ existing initiatives and frameworks, allowing a 360-stakeholder view of the PE landscape. This will provide a platform for identifying gaps and synergies from different stakeholder perspectives and allow those committed to effective PE to learn from good practice by actively sharing experience and to connect. It also means not always having to start from scratch each time but instead there is a growth in expertise and knowledge that can be incrementally build upon.

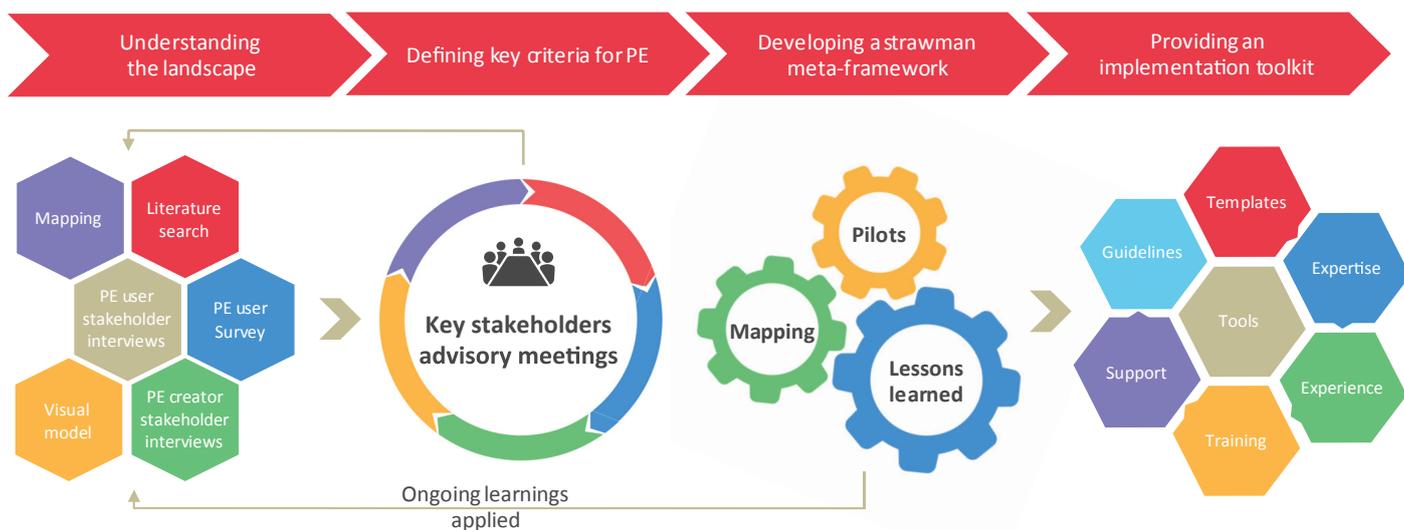
## Patient Focused Medicines Development

The Patient Focused Medicines Development (PFMD) group, established in 2015, is an open, independent multinational coalition based on expertise and commitment to develop and drive implementation of PE. It is a non-profit collaboration whose activities are funded by member organizations – currently patient groups and the pharmaceutical industry.\* PFMD is a truly global partnership and a collaborative platform that synergizes efforts to integrate the voice of the patient across the medicines lifecycle. We aim to transform the way in which we understand, engage and partner with patients globally in the design and development of research and medicines by focusing on unmet patient needs.

\*See Appendix for details of PFMD membership and governance

PFMD is taking a practical and methodological approach to co-create a meta-framework with all stakeholders. Our approach starts with bringing together and mapping initiatives and good practices that integrate the voice of the patient throughout the lifecycle of medicines development. This will accelerate the creation of an effective, globally standardized meta-framework for PE that can be adopted and implemented by relevant stakeholders. The 4 key steps to development and implementation of a meta-framework are summarized in Figure 1. Step 1 is understanding and mapping the PE landscape. We will be mapping and categorizing PE initiatives, but we do not judge them. Step 2 is defining key criteria for PE. Insights from these two stages will inform Step 3, development of a ‘strawman’ meta-framework that will provide a working model for use and further refinement. Step 4 is the development of an implementation toolkit that will provide participating stakeholders with the practical resources and support needed to implement the meta-framework within their own PE initiatives.

Figure 1: Developing a meta-framework – step-by-step



There is no ‘one size fits all’ approach to PE. As such PFMD has developed an organic and inclusive partnership strategy that encourages evaluation and feedback, review and ongoing refinement of the meta-framework. PFMD’s not-for-profit, inclusive, collaborative and open approach are key success factors for the development of a valuable and adopted framework. This White Paper is being shared as a work in progress and is part of PFMD’s commitment to open and timely collaboration. It focuses on our approach and progress towards a map of the PE landscape. Rather than presenting stakeholders with a ‘fait accompli’, we encourage review and feedback to ensure that tools we develop are not made for but rather made with stakeholders.

## Methodology

### *Preliminary mapping*

We have deployed various methods to conduct a landscape assessment and obtain needed information on current PE initiatives. These are: a preliminary mapping of known initiatives; an extensive literature search; and interviews with stakeholders across healthcare who have partnered with patients and/or provided guidance to partnering with patients. The methodology used in preliminary mapping of initiatives involved a search of initiatives underway in both formal and non-formal publications, journal articles, conference hearings, and word of mouth. The preliminary mapping identified a need to validate data with various organizations given the limited publications on this topic, the inconsistencies that may be presented in anecdotal presentations, and the wide spectrum of how organizations categorize “partnership with patients”.

### *Online Collection Tool*

Much information on PE is not routinely published but instead is shared in meetings and discussions, mandating a need for a pro-active collection process. As such, we are also developing an online collection tool to gather data where there may be no documentation publicly available. The online collection tool will capture quality data using pre-defined standards to allow for consistency in depiction and will also help to ensure that the information collected across various initiatives is credible, consistent, and up to date.

Collecting and understanding initiatives by talking directly with those involved and requesting their input (rather than relying on desk research alone) provides a greater opportunity to understand efforts underway, including their successes and limitations. In addition, it allows identification of potential tools to measure the impact of patient engagement. Good practices of the individual efforts underway will ultimately be integrated into our global meta-framework, if applicable. Finally, this allows a connection or contact with all initiatives, allowing further collaboration from the meta-framework point of view but also the creation of a global network of PE for further practical PE between stakeholders.

## Visualizing the PE landscape through different lenses

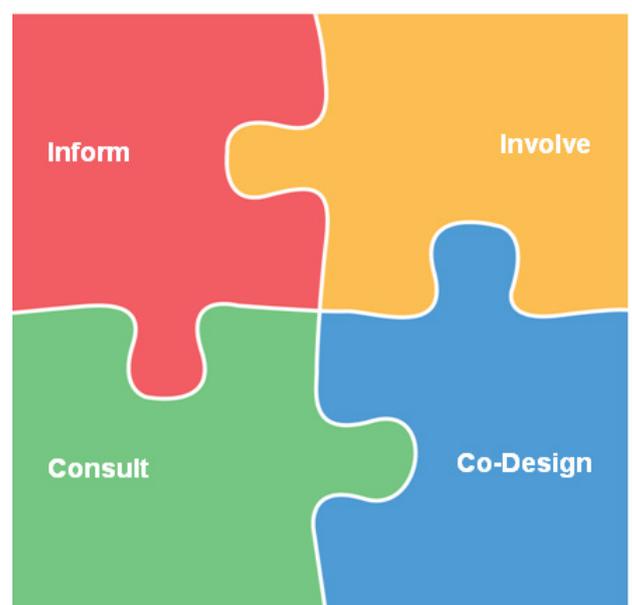
There are various elements of the data being collected that may or not be relevant to different stakeholder groups. Furthermore, as the data is collected it has become evident that no single visual will be applicable to all relevant stakeholders and sectors. To this end, we have produced a preliminary set of **Visual Snapshots** in order to depict the data being collected in a manner that is meaningful to a diverse audience. An overview of these Visual Snapshots and their primary goals are summarized in Table 1.

*Table 1: Overview of Visual Snapshots and their primary goals*

VISUAL MAPPING SNAPSHOT	PRIMARY GOAL
Patient Partnership Map	An overview of the types of patient involvement by sector
Patient Engagement Initiative Spider Chart	A sample of initiatives underway by primary, secondary, tertiary focus
Patient Engagement Landscape Radar	A bird's eye view of initiatives underway by primary focus, sector, geographic scope, initiative timeline/maturity range, and condition of focus
Patient Expertise Matrix	A sample of initiatives underway by type of patient involved, category of patient partnership, and sector
Patient Engagement and Medicines Lifecycle Matrix	A sample of initiatives by phase in the lifecycle of medicine continuum, category of patient partnership, and sector
Patient Experience Lifecycle Matrix	A sample of initiatives by phase in the disease management continuum, category of patient partnership and sector
Patient Engagement Region of Activity	An overview of initiatives by region

### Patient Partnership Map

Preliminary mapping and research has demonstrated that there are various methods of partnering with patients and different types of patients and caregivers with variation in expertise and ability to engage in initiatives that need to be delineated. Currently however, criteria and definitions around partnering with patients have varied. The Patient Partnership Map is being developed as a model to provide a standard classification of PE initiatives, serve as a foundation to a global meta-framework, and provide the community with criteria to incorporate into their work. Four categories have been created (Inform, Involve, Consult and Co-Design) where each category can be coupled with a separate category of “Empower”, which represents those patients trained on how to utilize individual health experiences to amplify their voice and influence future initiatives. This may also include coaching, problem solving skills, and/or the provision of a big picture overview to provide patients with context (Figure 2).



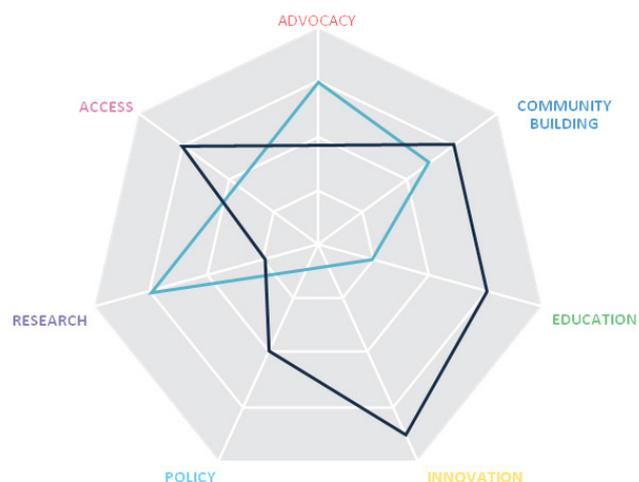
*Figure 2: Patient partnership categories*

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### Patient Engagement Initiative Spider Chart

Our approach begins with understanding individual initiatives and then placing these in the context of the wider PE landscape. Many initiatives are diverse and have more than one focus area that needs to be captured. In response to this need, we are developing the Patient Engagement Spider Chart to showcase the primary focus of each initiative, but also to capture secondary focus, tertiary focus, etc. to provide a more detailed and informative dataset. The Patient Engagement Spider Chart provides a snapshot of each initiative. These are then brought together based on their primary focus/activity to build a bigger picture, as depicted in the Patient Engagement Landscape Radar.



Seven categories have been created to classify the primary focus of the initiatives, recognizing that there may be more than one focus per initiative. These categories include:

- **Research** - focused on science of investigation into study of materials (e.g. medicines) and sources to establish facts and reach new conclusions
- **Policy\*** - focused on advancing a course of principle of action adopted or proposed by government and/or other sectors in healthcare
- **Innovation** - focused on creation of new ideas, devices and/or methods
- **Education** - focused on imparting health care knowledge and/or behavior change
- **Community Building** - focused on the provision of support and services for the patient, caregiver and/or other members of care team to allow for connections across continuum of care
- **Advocacy\*** - focused on public support for/recommendation of a certain cause and/or individual support of a patient/caregiver navigating healthcare
- **Access** - provision of patient assistance in obtaining appropriate health care resources and services

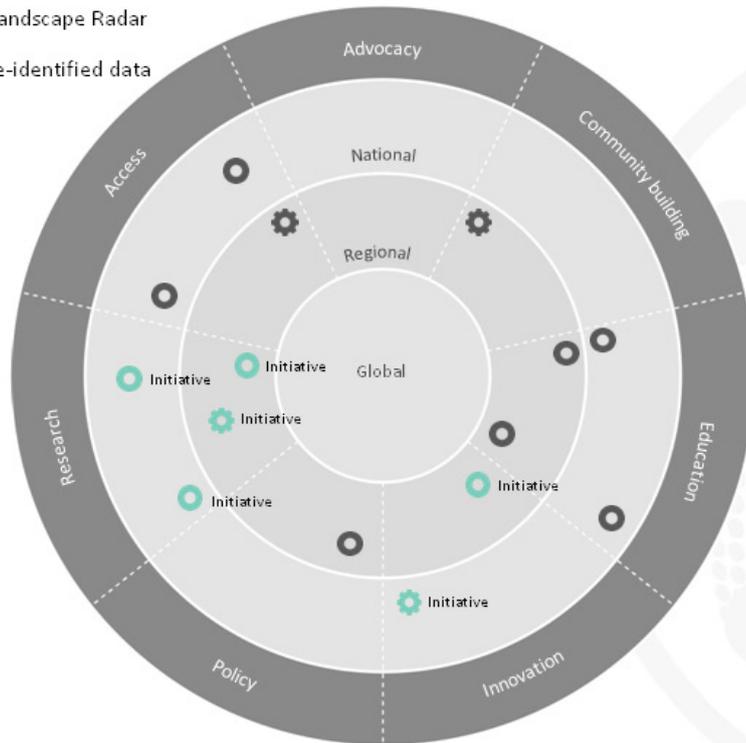
\*Note there may be overlap between the 'Policy' and 'Advocacy' categories.

### Patient Engagement Landscape Radar

Patient involvement and PE is appearing across different sectors in healthcare, but efforts vary and are not solely specific to research. There are learnings that can be incorporated into a global meta-framework but first there is a need to recognize and understand the different pathways to PE. We aim to showcase the various types of initiatives underway by sector and primary focus area with a drill down into geographic region, timeline, and therapeutic area. This snapshot incorporates the primary focus areas where initiatives have been color coded by type of organization that has involved patients. There are 3 different views: a depiction of the local, regional, global focus (geographic scope); a depiction of initiative timeline (maturity range); and depiction of the condition of focus (medical scope). These are illustrated in Figure 3, shown with the geographic scope radar populated as an example.

Figure 3: Depiction of initiatives by geographic scope, maturity and medical scope

Patient Engagement Landscape Radar  
Geographic Scope  
Logged in view with de-identified data



- Key
- Organization X Initiatives
  - Other Initiatives
  - ★ Initiatives that empower patients
  - Initiative about guidance on PE
  - ⚙ Initiatives doing the work

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Patient Engagement Landscape Radar  
Medical Scope

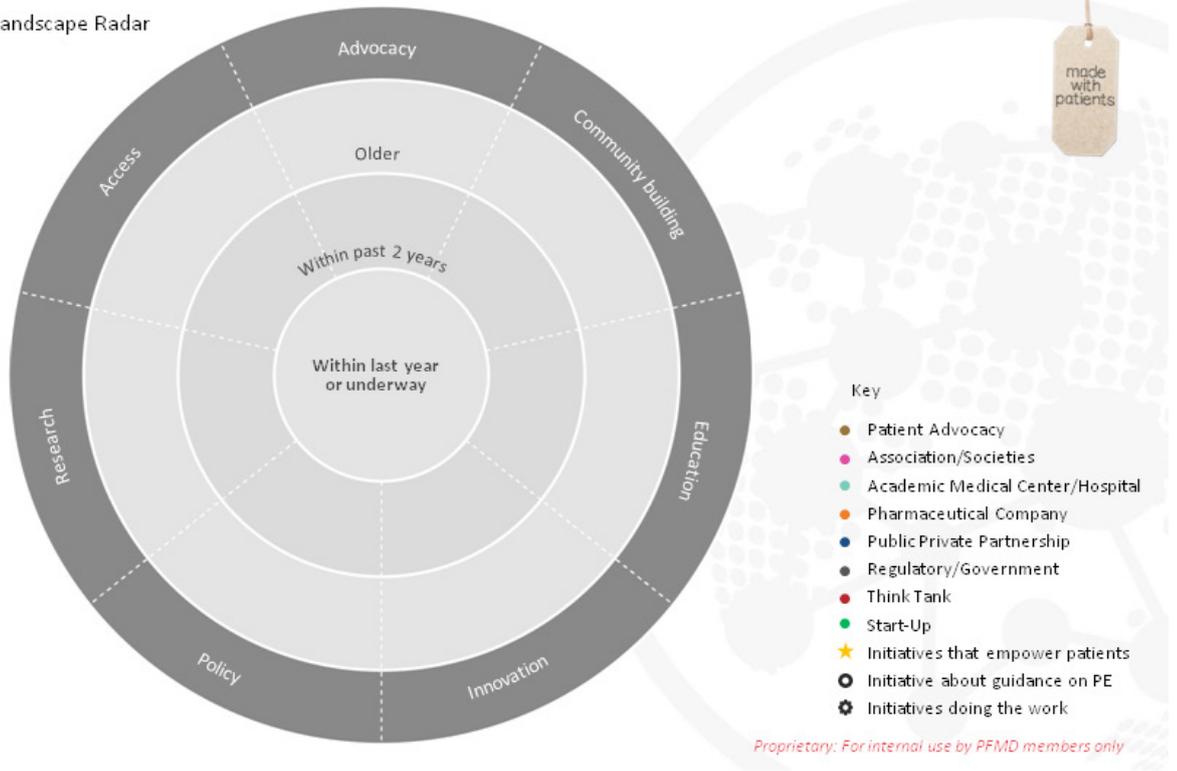


- Key
- Patient Advocacy
  - Association/Societies
  - Academic Medical Center/Hospital
  - Pharmaceutical Company
  - Public Private Partnership
  - Regulatory/Government
  - Think Tank
  - Start-Up
  - ★ Initiatives that empower patients
  - Initiative about guidance on PE
  - ⚙ Initiatives doing the work

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**Patient Engagement Landscape Radar**  
Maturity Range



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## Patient Expertise Matrix

There are different types of patients partnering in the research to care continuum and variations in skills or expertise can affect the level of patient involvement. Understanding and mapping this patient diversity can allow us to capture trends, identify gaps, and define good practices. Several categories have been defined to capture patient diversity based on information available from existing initiatives. These will be further validated through focus groups and additional research and will be refined as more information and insight is gained. The Patient Expertise Matrix categorizes each initiative by type of patient involved and level of involvement and also captures different levels of patient partnership across an initiative.

	Newly Diagnosed, Non Expert Patient	In treatment, Non Expert Patient	Patient advocate affiliated with an organization	Expert patient not affiliated with an advocacy organization	Caregiver
Inform					
Consult					
Involve					
Co-Design					

## Patient Engagement and Medicines Lifecycle matrix

Many initiatives are aligned with a particular phase in the medicine lifecycle while others span several phases. The Patient Engagement and Medicines Lifecycle Matrix uses the levels of partnership as a building block to align initiatives with the corresponding phase (or phases) in the medicine lifecycle matrix. These initiatives will be represented by sector along the continuum. The Medicines Lifecycle represented in this visual has been adapted from a variety of sources including CTTI’s “Best Practices for Effective Engagement with Patient Groups around Clinical Trial”, which was originally adapted Parkinson’s Disease Foundation materials for CTTI’s Patient Groups & Clinical Trials Project, and the continuum depicted in University of Maryland’s report “Assessing Meaningful Patient Engagement in Drug Development: A Definition, Framework, and Rubric”.



## Patient Experience Lifecycle Matrix

The Patient Experience Lifecycle Matrix has been developed to map initiatives based on phase across the care journey, type of patient involvement, and sector. This view closely aligns with the phases a patient experiences as they manage a condition and provides a different lens that align with diverse stakeholder needs. The origin of the disease management continuum represented here is “Prescription to Learn”®, an educational platform to help patients/caregivers navigate the care journey in partnership with their healthcare teams, developed by CANCER101 Foundation and the Health Collaboratory.



## Patient Engagement Region of Activity

The final visual provides a geographical map of initiatives by region. This will allow stakeholders a global overview of the different PE initiatives underway promoting an opportunity for stakeholder collaboration and learning across regions.

## Visual mapping progress and next steps

PFMD has developed the tools and infrastructure to allow understanding of the PE landscape analysis as described in this White Paper. However, our approach is not restricted to simply mapping but incorporates mapping, validating and promoting an exchange of learning. We have used publically-available information

as a starting point and this will be augmented with active data collection through an Online Collection Tool. This is essential if we are to capture and include the diverse range of PE initiatives and learnings that will inform development of the meta-framework for PE. From a practical perspective – and understanding the potential sensitivity of PE initiatives that may be a ‘work in progress’ rather than completed projects, there will be options for anonymizing data and organization information, and for control and ownership of the data including editing or removing.

We are on track to launch the Collection Tool by the end of May (2016) and urge all stakeholders to take part in this important initiative. There is an encouraging range of PE initiatives that all share a common purpose – to put patients and their needs at the heart of medicines development and lifecycle. Only by working together in an open, collaborative and inclusive way can we make this purpose a global reality.

*Participate in the landscape mapping project, share your experience and join the PE global network*

Email [PFMD@TheSynergist.org](mailto:PFMD@TheSynergist.org) to share feedback or receive an alert when the online tool is launched.

## Appendix

### PFMD Membership

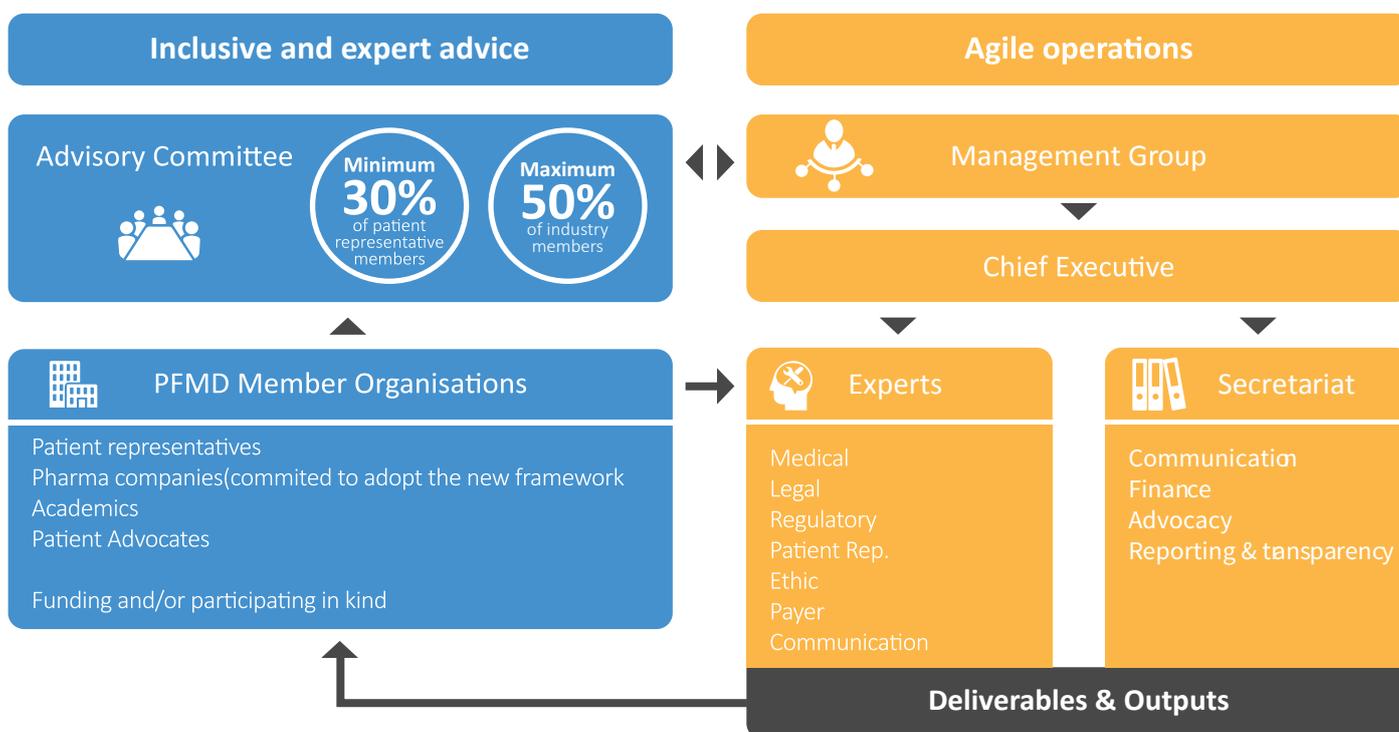
PFMD seeks to have a balanced representation of stakeholders to ensure transparency, inclusiveness, diversity and credibility. PFMD welcomes membership from institutions, organizations and enterprises that support a better future for patients.

### Current PFMD Membership

Society for Participatory Medicine	Parkinson's Disease Foundation	European Patients Forum	European Patients' Academy on Therapeutic Innovation
Cancer101	National Health Council	Pfizer	UCB
Amgen	MSD	GlaxoSmithKline	AstraZeneca

### PFMD Governance

PFMD has from inception been formed as an equal collaboration among patient groups, patients and pharmaceutical industry. The governance model adopted by PFMD ensures at least equal or greater share of voice for patient group members.



Structure	Mandate and role
Advisory Committee	<p>Elected by members and takes the major strategic decisions for the organization</p> <ul style="list-style-type: none"> <li>• Minimum 30% of patient representative members</li> <li>• Maximum 50% of industry members</li> <li>• 12 members allowing participation of current and new members</li> <li>• Quorum of 7 maintains agility and responsiveness</li> <li>• Focus on diversifying the representation of other stakeholders</li> </ul>
Management Group	<p>Supervises execution of the strategy of the Advisory Committee. Also supervises and delegates day-to-day operational decision-making to the Chief Executive who runs the Secretariat</p> <ul style="list-style-type: none"> <li>• Renewable 3 year appointment</li> </ul>
Member organisations	<p>Open to all stakeholders upon recommendation of the Management Group and based on the approval of the Advisory Committee</p> <ul style="list-style-type: none"> <li>• Commit to adopt and adapt the patient engagement meta-framework developed by PFMD and help deploy it across all other</li> <li>• Support PFMD's activities through funding and operational expertise as well as active participation to the projects</li> <li>• Annual membership fee for commercial organisations (for-profit)*</li> <li>• 2-year commitment with renewal on a yearly basis thereafter</li> </ul>
Secretariat	<p>Responsible for the day-to-day management of the initiative and delivery of outputs</p> <ul style="list-style-type: none"> <li>• Hosts the initiative and its administrative processes</li> <li>• Program management and interaction/communication with internal and external stakeholders</li> <li>• Remains neutral and transparent, as a representative of all members</li> </ul>
Experts	<p>Provide technical expertise and recommendations</p> <ul style="list-style-type: none"> <li>• Act as consultants and represent all major technical fields including clinical, regulatory, legal, and patient</li> <li>• Interact with initiatives on an ad-hoc basis on request from the operational team</li> </ul>

\*In order to lower the barrier to entry, the membership fee is kept affordable. Members are invited to fund specific projects additional to the annual fee.