

PFMD GOVERNANCE

VERSION HISTORY	DATE	COMMENTS
V1	17.01.21	Update of 2019 document with insights of Board meeting December 2020
V2	12.05.21	Update based on approval of key sections by the Board and with comments of Next level task force
V3	08.06.22	Update PFMD Board and Executive Committee
V4	21.03.23	Update election process, standing committees and nomination committee
V5	23.06.23	Update Executive Committee mandate
V6		

Table of contents

1.	Purpose of this document	4
2.	Preamble	4
3.	Key principles of PFMD	4
3.1.	Governance for inclusion and agility	4
3.2.	Commitment and expertise	4
3.3.	Collaborative leadership	5
4.	PFMD's purpose: make systematic patient engagement happen	5
4.1.	Nature of the organization	5
4.2.	Organization structure	6
5.	Membership	6
5.1.	Eligibility criteria to become PFMD member	7
5.2.	PFMD members' representation criteria	8
6.	PFMD Board, Executive Committee, Independent Experts and Strategic Advisory Board	9
6.1.	PFMD Board	9
6.1.1.	Composition of the PFMD Board	9
6.1.2.	Independent experts	9
6.1.3.	Eligibility and application to the Board	10
6.1.4.	Role of a Board Member	10
6.1.5.	Term, election, and rotation of the Board	12
6.1.6.	Meetings	12
6.1.7.	Decision-making Process and Quorum	12
6.1.8.	Resignation, removal, and change in affiliation	13
6.1.9.	Declaration of Interests Policy	13
6.1.10.	Orientation process for Board Members	13
6.2.	PFMD Executive Committee	13
6.2.1.	Composition of Executive Committee	13
6.2.2.	Eligibility and application to become a member of the Executive Committee	14
6.2.3.	Role of the Executive Committee	14
6.2.4.	Term, election, and rotation of the Executive Committee	14
6.2.5.	Meetings	15
6.2.6.	Resignation and removal	15
6.2.7.	Conflict of Interests	15
6.3.	Strategic Advisory Board (SAB)	15
6.3.1.	Composition and Eligibility to the Strategic Advisory Board	15
6.3.2.	Role of Strategic Advisory Board Members	15
6.4.	Determination of Conflict of Interest	
7.	The Synergist	16
7.1.	Role/ mandate	16
8.	PFMD Funding	16
8.1.	Core funding	16
8.2.	Project-specific funding	16
8.3.	Alternative funding	16
9.	Deadlocks	17
10.	Liability of members	17

11.	Intellectual property	17
12.	Withdrawal or exclusion of members	17
13.	Closure – end of PFMD	17
14.	Annex 1 - About The Synergist	19
15.	Annex 2 - Travel & Expenses Policy	19
16.	Annex 3 - PFMD Board Members & Executive Committee	21
17.	Annex 4 - Declaration of Interests Policy	22

1. Purpose of this document

The purpose of this document is to articulate PFMD's governance, the structure, and the systems by which PFMD is directed and controlled. It also depicts how PFMD makes operational and strategic decisions.

Expertise, commitment, and agility are key principles for PFMD; thus, the governance structure should always be interpreted respecting these principles.

2. Preamble

The Patient Focused Medicines Development (PFMD), established in October 2015, is an independent, global collaborative initiative aiming to make qualitative patient engagement the new norm in drug development, digital health, MedTech, and across health systems. PFMD is a not-for-profit organization hosted and managed by The Synergist. Providing a pre-competitive and neutral environment, PFMD seeks to have a balanced representation of stakeholders to ensure transparency, inclusiveness, and credibility. Stakeholders include patients and patient organizations across diverse areas of health, healthcare professionals, the life sciences industry, regulators, payers, and other professional organizations invited to ensure a diversity of perspectives, create synergies, and deliver better public health outcomes.

3. Key principles of PFMD

The following principles are founding principles above any other governing rule or policy.

3.1. Inclusion and agility

Since establishing PFMD, the patient engagement landscape has evolved from considering the potential risks of engagement with patients to a new reality that outlines the risks of NOT engaging with patients. The patient engagement approaches have progressed tremendously over the last five years, which creates an even greater opportunity for the future to connect some still fragmented pieces of the patient engagement landscape. Only a diverse partnership across all major stakeholder groups can effectively leverage this opportunity and reduce fragmentation. Based on this belief, the strategic **expansion/development** of PFMD members' network needs a solid & balanced representation of relevant industries, patient organizations, and other relevant stakeholders (such as regulatory, HTA, academia, medical societies, and NGOs).

PFMD Members invest in a collaborative platform that delivers tools, projects, and methodologies that openly support sustainable, systematic, and meaningful patient engagement beyond the PFMD membership for the entire patient engagement ecosystem.

This approach fits the philosophy that only a balanced & diverse inclusion of all stakeholders and agile operations deliver results. As patient engagement evolves, PFMD must continue to lead by acting quickly and decisively

See [membership representation](#) and [inclusion criteria](#) (art. 5.2 and 5.1, respectively)

3.2. Commitment and expertise

PFMD membership is based on expertise and commitment toward better and meaningful patient engagement within and beyond member organizations. In addition to supporting patient engagement best practices in general, membership in PFMD also represents a commitment to ambassador PFMD practices within one's organization. PFMD Members, by making this transition and demonstrating patient engagement benefits act also as exemplary cases for other organizations and stakeholders to follow.

When signing up for a membership, organizations commit to co-create, adopt, and adhere to the patient engagement framework principles, activities, and learnings developed with PFMD and help deploy them internally, externally, and across all other stakeholders.

3.3. Collaborative leadership

The Program is non-competitive as a core principle and does not exist to promote the interests of any specific organization, its brands, or its products. Members must always work for the common goal's interest, leaving individual interests at the door.

There should be a balance between what each Member brings to and takes away from the collaboration. Deliverables should be defined in a way that creates value for all participants. Resource sharing is a value exchange. In general, tools and information produced should be open and accessible to anyone.

Finally, in committing to the common goal, Members recognize that PFMD's role is to be a catalyst and support other initiatives working towards the same purpose.

4. PFMD's purpose: make systematic patient engagement happen

PFMD's goal is to improve global health by co-designing the future of healthcare for patients WITH patients. Its mission is to bring together initiatives and best practices that integrate the voice of the patient, thereby speeding up the creation and implementation of a practical, globally standardized framework - that involves patients as partners - as well as the necessary tools, services, and support to allow the adoption of the framework by various stakeholders. To reach this goal, PFMD's strategy is to build demand and create conditions for all stakeholders to implement patient engagement more systematically and with a consistent approach. Partnering with patients to design and develop new solutions means co-create methods to help them achieve and maintain their health goals.

4.1. Nature of the organization

The PFMD membership does not constitute nor is deemed to constitute a legal entity between the Members, nor make a Member the agent or representative of another Member unless expressly stated otherwise. PFMD is hosted by The Synergist and formed by bilateral contracts between The Synergist and individual members (The Synergist is described in Annex 1).

4.2. Organization structure

PFMD is governed by a PFMD Board, representing members and taking the strategic decisions for the organization (see sections [Composition of the board](#) and [Board role & decision matrix](#); art. 6.1.1. and 6.1.4, respectively). Day-to-day operational decision-making is delegated to the Executive Director, who runs the organization.

The Executive committee is a subset of the PFMD Board. The Executive committee acts as advisors and ‘sounding board’ to the Executive Director, with no extra decision-making power.



5. Membership

PFMD welcomes members from institutions, organizations, and individuals who support a better future for patients and society and are willing to invest in such a future through collaboration with the commitment, passion, and expertise to generate better patient and health systems outcomes. To join PFMD membership, an application is sent to the Executive Director, who submits a recommendation together with the Executive Committee to the PFMD Board for validation.

Members' rights include:

1. having the right to participate in the PFMD's Strategic Advisory Board;
2. having the right to participate in PFMD's works streams and expert committees;
3. having the right to access and use PFMD data, tools, and services;
4. having the right to be beneficiaries from services provided by the Secretariat and having the possibility to access specific licenses from PFMD (e.g., "labels," certification marks); see the [intellectual property and creative common license](#) (art. 11)

Members' obligations include:

5. contributing to developing PFMD patient engagement through good practices, tools, methodologies, and support materials
6. upholding and applying the PFMD principles and key commitments within the partnership;
7. acting as PFMD Ambassadors within member organizations and externally, who actively contribute

to and disseminate PFMD work, tools, and outcomes within and beyond their organizations to help drive patient engagement.

For-profit members are considered as funding members and are required to sign a specific bilateral contract with The Synergist and pay a membership fee.

Not-for-profit members are required to sign a memorandum of understanding with The Synergist but are not required to pay a membership fee.

Associate members:

Associate members are organizations that commit to funding (for-profit organizations) or participating in-kind (non-profit organizations) in PFMD's specific projects without being official PFMD members. The commitment of an associate member shall be detailed in the bilateral agreements or MoUs with the Synergist. The general members' obligations apply to associate members within the scope and timeline of the projects they are participating in. The Associate Members shall not participate in the PFMD Strategic Advisory Board, or take part in the governance of PFMD activities.

Associate members participate in the steering committee of one or more specific projects.

All types of membership are considered equal within the project work, and perspectives of contributing members are considered regardless of their member status.

5.1. Eligibility criteria to become a PFMD member

All PFMD members shall demonstrate substantial experience, expertise, and/or commitment in the patient engagement area to collaborate and advance systematic patient engagement. This translates into collaborative leadership that respects the principle of non-competitiveness and respect for every individual's expertise and background.

The following criteria are reviewed when assessing member candidatures.

On organization level

- **Shared vision and values** described in the expression of interest and application form
- **Capacity to contribute:** The applicant should outline broadly the capacity of their organization to participate (describing the level of engagement) in PFMD in tangible terms.
- **Ambassadorship and people empowerment:** When signing up for a membership, organizations commit to co-create, adopt and implement patient engagement frameworks and help champion them across their organization & other stakeholders. Organisations give a clear mandate to their representative to vote and influence decisions.
- **Geographic remit:** PFMD members should normally be global or regional organizations; national umbrella bodies, or organizations, individuals, or institutions with substantial international standing or reputation in Patient Engagement.
- **Signed commitment:** Memorandum of Understanding or contract with a 3-year commitment in order to be eligible for election to the board.

On individual level

- Individuals representing their organization on PFMD Board or SAB shall **demonstrate substantial experience and/or commitment** in the patient engagement area.
- **Commitment to collaborative leadership:** This translates into a clear motivation to practice collaborative leadership that respects the principle of non-competitiveness and every individual's expertise and background.
- **Complementarity** of the candidature profile **to the current PFMD diversity** (CFR. PFMD members representation criteria). Each candidature will be assessed against PFMD diversity criteria (5.2.1 below) to provide value to PFMD and ensure a balanced representation.
- **Transparency and synergy:** The applicant is expected to be transparent about their participation in similar initiatives and commit to connecting any relevant initiatives in which they may or may not be involved.

5.2. PFMD members' representation criteria:

PFMD strives for diversity & inclusion in its members' representation. Therefore 5, diversity criteria have been identified based on current gaps & good practices, which will be monitored closely:

1. Diversity of Stakeholders Groups:

- Balanced representation from the patient community and from the pharmaceutical/life sciences industry;
- HTA, Regulatory, academia, public health authority, and experts who add value to the program through their expertise, diversity, and impact, whether acting from an organization or as individual representatives.
- Looking for a broad spectrum of industry representation: Integrating members from the Device and Digital world

2. Geography, culture & race:

- Increase racial diversity through members and the Board. Geographic diversity should reflect membership composition and PFMD strategy. Strategy 2025 aims to extend to Asia. We are committed to seeking a broader representation of race through our members, particularly given the importance of race as a principal determinant of health outcomes.

3. Gender:

- Sustain the current good gender balance at the Board and the Exco, and continue to monitor & report gender balance throughout overall PFMD membership

4. Skills:

- Commitment to increase connection with champions that can support the implementation of the PFMD 2025 Strategy Goals in areas such as Digital, HTA, and Device.

5. Patient organization (or industry) size and scope:

- Aspiration to build the membership with organizations with more specified or focused impact and scope (still with substantial international standing or reputation in Patient Engagement) that strategically align with PFMD's Goals

6. PFMD Board, Executive Committee, Independent Experts, and Strategic Advisory Board

Positions on the PFMD Board and Executive Committee are nominative and should be based on the merits and active participation in PFMD’s work, as well as the exemplification of PFMD principles.

6.1. PFMD Board

6.1.1. Composition of the PFMD Board

The number of Board members shall be a maximum of 21, including the Executive Committee (which is a subset of the Board). This number may be changed at any annual Board meeting by a simple two-thirds majority vote. The PFMD Board shall be composed according to the following principles:

- Min. 30% to max 50% of representatives from the patient community;
- Min. 30% to max 50% of representatives from the pharmaceutical/life sciences industry;
- Target 20% HTA, Regulatory, academia, public health authority, and experts who add value to the program through their expertise, diversity, and impact, whether acting from an organization or as individual representatives.

As a guiding principle, the PFMD Board shall be composed respecting the principles of representation in gender, geography, race, skills, and different stakeholder communities according to the “PFMD Representation Criteria”



6.1.2. Independent experts

Principle: PFMD looks for independent experts who add value to the program through their expertise, diversity, and impact, whether acting from an organization or as individual representatives.

Nomination/Election: Same election process for individual representatives, as for members representing an organization.

Criteria for selection: Applicable Members' selection criteria are applicable for individual representatives

Seat at the Board: Individual representatives, elected to the board, have a seat at the board, as any other board member.

Vote at the Board: Individual representatives, elected to the board, have the same voting rights at the board as any other board member.

Seat at the Executive Committee: Individual representatives may be elected and serve as members of the Executive Committee

Titles:

- Independent Patient Expert
- Independent Industry Expert
- Independent Other Expert (HTA, Regulatory, academia, public health authority, etc.)

6.1.3. Eligibility and application to the Board

Members apply to the PFMD Board by submitting interest to the Executive Director and the Executive Committee, who will assess the eligibility based on the criteria below.

Individuals are eligible for the PFMD Board upon fulfillment of the following criteria.

- The individual is an employee of a PFMD member organization that has a signed commitment to PFMD for at least 3 years, or the individual is an independent expert fulfilling the eligibility criteria and committing to support and promote PFMD’s activities in one’s network for at least 3 years.
- The Member organization/individual has proven commitment and value to PFMD, based on their participation in PFMD activities.
- The individual has the approval and a mandate of the organization she/he represents to take an active part in PFMD and to devote appropriate time on PFMD activities.

6.1.4. Role of a Board member

PFMD is governed by a PFMD Board representing the members and taking the organizational strategic decisions detailed in the “Board decision matrix”. The Board mandates the Executive committee to advise the Executive Director in implementing the strategy. Operational and day-to-day decision-making is mandated to the Executive Director by default. The Executive Committee has no decision-making power beyond the other Board members.

PFMD Board members are elected to make decisions in PFMD’s best interests ahead of their role as representatives of their respective organizations.

Board role is to:

1. Establish Organizational identity:

- Determine mission & purpose and advocate for them
- Develop long term strategy & ensure effective strategic planning

2. Ensure Resources:

- Participate in building a competent board
- Ensure adequate financial resources
- Enhance PFMD’s position, perception, and reputation in their role as ambassadors within their own organisation and externally.

3. Provide Oversight:

- Support & evaluate Chief Executive
- Monitor that programs are aligned with strategy
- Provide financial oversight
- Ensure legal and ethical integrity

Board decision Matrix:

Board Roles requiring a decision	Topics to be decided by the Board	Board Decision
Establish Organizational identity	Strategy & Strategic Planning	
Mission & purpose	Review, update and approve Mission	Approves
Strategic planning	Develops mid and long term strategy (2 to 5 years)	Approves
	Approve high-level strategic planning and authorize Exec Director to execute	Approves
Ensure Resources	Members & Resources	
Build a competent board	Change PFMD Governing bodies structure, including naming and dissolving ad-hoc and standing committees and/or working groups	Approves
	Criteria for governing bodies composition	Approves
	Criteria for membership composition	Approves
	New Members to PFMD	Approves
	New Board Members of PFMD	Approves
	New ExCo Members of PFMD	Approves
Provide Oversight	Monitoring	
New projects	New projects above 10% of the annual budget	Approves
Provide financial oversight	Annual high-level Operating Budget	Approves
	Financial reports 2x/year	Approves
Manages major crisis	Validates action plan in case of major crisis (eg. reputation damage putting PFMD at risk)	Approves
Appoints Executive Director	Appointment of Executive Director	Approves
Support & Evaluate Executive Director	Chief Executive Director support and evaluation run through Exco representatives based on performance	Approves

All other decisions are under the responsibility of the Executive Director.

Individual Board members commit to upholding the following as part of their role:

- **Duty of Care:**
Board members must use their best judgment in all dealings with the organization by, for example, preparing for and attending board meetings, raising questions, and providing careful oversight.
- **Duty of Loyalty:**
Board members must be faithful – avoiding conflicts of interest when making decisions affecting the organization.

- **Duty of Integrity:**

Board members must stay true to the organization's mission and applicable laws when making decisions for the organization.

6.1.5. Nomination committee: role, composition, appointment by the board, and rotation

The nomination committee drives the election process of the Board and Executive Committee members (details in the following chapter related to the election process).

Every two years, the Board votes by a simple majority on a delegation of four volunteer board members proposed by the Executive Director and Executive Committee to compose the Nomination Committee. The nomination committee will reflect a diverse selection of board members, including a minimum of one executive committee member.

The Nomination Committee appoints a chairperson.

To ensure continuity and transfer of knowledge, members of the committee shall rotate a maximum of two members every two years (the duration of the role at the Nomination Committee can therefore fluctuate from a minimum of two years to a maximum of four years as needed).

Any Nomination Committee member applying to be reelected to the board will recuse himself/herself from the Nomination Committee.

6.1.6. Term, election, and rotation of the Board

The Nomination Committee organizes and monitors the election process. Every year, there are a minimum of three members rotating off the PFMD Board on a voluntary basis or based on a recommendation from the Executive Committee if there are no volunteers. As a guiding principle, the Board shall be composed respecting the guiding principles of representation in gender, geography, and different stakeholder groups (see [PFMD members representation criteria](#)).

Board members may serve a maximum of two consecutive 3-year terms, not including time served when appointed to fill a vacancy in an unexpired term. A Board member who has served two consecutive 3-year terms may serve 2 new consecutive terms after at least one year of absence from the Board.

Any Board member serving on the Executive Committee while their second 3-year Board term expires may continue to serve on the Board until the expiration of their term on the Executive Committee.

Board members are elected via a Board vote on a slate of candidates proposed by the Nomination Committee and informed by the representation needs and the diversity criteria principles dictated by the governance.

Any member organization with a 3-year contract with PFMD may apply to the Executive Director or may propose to nominate an individual to serve on the PFMD Board.

The Guiding Principles for the slate of candidates are:

- Applications are anonymous: only the slate of candidates will be known
- Number of applicants is not disclosed: whether there will be a high or low number of candidates stays confidential
- The slate of candidates proposed by the Nomination Committee aims to reflect the best possible composition of the board & executive committee respecting the selection & diversity criteria defined in the bylaws.

The Nomination Committee will review and interview potential candidates proposed by the executive director and will send a final slate of candidates to be appointed by the Board by a single approval or rejection vote.

The results from the selection process will be communicated to the candidates individually by the Nomination Committee members & the Executive director before the slate of candidates is sent to the board for a vote.

6.1.7. Meetings

The PFMD Board meets at least twice a year, of which a minimum of one face-to-face meeting per year. Attendance at meetings is critical; any absence should be exceptional and covered by bilateral contact between the Executive director and board members who cannot attend pre and post-meetings to get views on critical issues.

6.1.8. Decision-making process and Quorum

The Board reviews PFMD's achievements, work in progress, and reporting on a regular 6-month basis and monitors compliance with PFMD's strategic objectives. Upon receiving the Executive Director's proposal, the PFMD Board revalidates the initiative's scope and/or organization and rules.

The PFMD Board makes decisions (cfr [decision matrix](#)) through a voting process with a quorum of 10 members, by a simple majority.

6.1.9. Resignation, removal, and change in affiliation

Any Board member may at any time resign by written notice to the Executive Committee and the Executive Director. Any Board member may be removed for cause by the Board with the Executive Committee, provided that there is a quorum of not less than a majority of the entire Board present at the meeting at which such action is taken and at least two-thirds of those voting endorse removal. Such causes may include, but are not restricted to, absence from three (3) successive meetings of the Board, prolonged incapacitation due to illness or injury, conviction of a crime involving moral turpitude, failure to maintain good standing of one's organization as a PFMD member, neglect or default of assigned and accepted responsibilities, conflict of interest or actions counter to the purposes and policies of PFMD.

If a Board member is changing professional affiliation or a member organization ending PFMD membership, her/his Board membership automatically ends either directly or no later than the end of the ongoing year. All membership obligations remain unchanged with the member organization.

6.1.10. Declaration of Interests Policy

Members of the Board shall scrupulously avoid any conflict between their respective individual interests and the interests of PFMD in any and all actions taken by them on behalf of PFMD. Any possible competing

interests on the part of such person or persons shall be disclosed in full detail to the PFMD Board and Executive Committee as detailed in the PFMD Declaration of Interest policy¹ and such person or persons shall abstain from voting. In addition, such interested Board members must be absent during the Board's vote on the decisions in question. The disclosure as well as the Board member's abstention from voting shall be made a matter of record within the minutes of the appropriate meeting. Disclosure of interest form can be found in Annex 4.

6.1.11. Orientation process for Board members

New PFMD contributors, members, or board members will follow an orientation process that will be detailed by the end of the year 2021 and that will ensure an appropriate level of knowledge and responsibilities for members within the Program.

6.1.12. Co-option to the Board

Where the numbers of persons on the Board has fallen below [16] or if there is a need to support the PFMD representation criteria (5.2), the Executive Director and/or the ExCo can request the Nomination Committee to select one or more replacement board members who meet the eligibility criteria (6.1.3). Such co-option must be approved by the Board at its next meeting.

A person appointed to the board by cooption will be expected to serve until the next scheduled Board elections, where they have the option to stand for election of a full three year period as a member of the Board. The period of co-option will be disregarded in calculating their length of service.

6.2. PFMD Executive Committee

The Executive Committee consists of 4 members who are recognized experts. The Executive committee is a subset of the Board composed of 21 members.

6.2.1. Composition of Executive Committee

The Executive Committee shall be composed according to the following principles:

- As a guiding principle, the Executive Committee shall be composed respecting the principles of representation in gender, geography, and different stakeholder communities (cfr. [PFMD members representation criteria](#))
- At least one member shall be representative of the patient community and one from the life sciences industry.
- An individual serving as an Executive Committee member should have a good balance of firstly international organizational and/or executive leadership, and secondly, prior patient engagement expertise.

6.2.2. Eligibility and application to become a member of the Executive Committee

Any Board member may apply or nominate an individual to serve on the Executive Committee.

6.2.3. Role of the Executive Committee

With their knowledge and know-how, the Executive Committee provides valuable support for the

¹ See PFMD's Declaration of Interests policy in Annex 4

Executive Director in day-to-day operations and decision-making.

The Executive Committee shall provide oversight functions to the organization ensuring that the Board maintains good governance practices. The Executive Committee shall facilitate communication between the Board and the Strategic Advisory Board.

The 4 members of the Executive Committee will cover specific roles:

- Two Members of the Executive Committee will act as Co-chairs of the Board. The role shall rotate between the Executive Committee members
- A Treasurer

The Executive committee members role and goals as Co-chair:

Executive Committee Role	
Board Governance	
	Initiate and lead the Executive Director's performance review
	Lead the Executive Director succession planning, including the appointment of the Executive Director, to be submitted to the Board for approval
	Act in an advisory capacity on behalf of the Board to the Executive Director
	Provide leadership in applying Board Governance, including creating specialized committees and sub-committees as needed
Members Meeting Management and Facilitation	
	Oversee and Co-Chair the PFMD Board meetings
	Guide the planning of Board meetings
	Call special meetings as necessary
Relationship Management and Board Support	
	Assist in managing Board engagement and relationships among Board Members
	Facilitate the relationship between Board members and the Executive Director
	Consult with Board members on their roles and support them in assessing their performance individually and through any potential Board self-assessment formats
	Work in partnership with the Executive Director to make sure the Board's duties are carried out; These duties include the Board's fiduciary duty where one member of the Executive Committee, "the Treasurer", is accountable for gaining a thorough understanding of the finances of PFMD by discussion with relevant Synergist staff. They will use that understanding to facilitate the Board's fiduciary duty to set the budget and to understand and approve the accounts. They will ensure that any financial issues are brought to the Board's attention promptly and comprehensively.

6.2.4. Term, election and rotation of the Executive Committee

Executive Committee members may serve a maximum of two consecutive 3-year terms. An Executive Committee member who has served two consecutive 3-year terms may serve 2 new consecutive terms at the Board.

Every year, at least one member of the Executive Committee will rotate off unless 2 Executive Committee members rotated off the year before.

The Board members will vote on a slate of candidates to be elected to the Executive Committee and proposed by the Nomination Committee (cfr above section about Nomination Committee). The slate of candidates will be informed by the representation needs and the diversity criteria principles dictated by the governance.

Any Nomination Committee member applying to be elected to the Executive Committee will recuse himself/herself from the process to appoint Executive Committee candidates.

6.2.5. Meetings

The Executive Committee joins all PFMD Board meetings and in addition, meets as often as needed to keep PFMD operations agile and efficient.

6.2.6. Resignation and removal

The same rules regarding resignation and removal as in the PFMD Board chapter apply here.

6.2.7. Conflict of interests

The same rules regarding conflict of interests as in the PFMD Board chapter apply here².

6.2.8. Co-option to the Executive Committee (ExCo)

Where an elected member of the ExCo is unable to complete their elected period for whatever reason, the Executive Director and the ExCo can request the Nomination Committee to co-opt a member of the Board to serve on the ExCo. Such co-option must be approved by the Board at its next meeting.

When a board member is co-opted to the ExCo they will stand down at the next scheduled Board elections, but they have the option to stand for election, if they choose. Any period spent as a co-opted member of the ExCo shall not count as part of their permitted term of office.

6.3. Strategic Advisory Board (SAB)

The purpose of the SAB is to provide input into most of PFMD activities as well as in the mid-long term strategic direction of the Program. Each member organization will have a seat on the SAB and is thus a way for all members, not only the Board members, to provide input.

With the SAB, PFMD has a collaborative platform for PFMD members to bring their unique insights & perspective into shaping PFMD activities. The SAB provides a forum for all members to gain visibility to be identified as a potential future PFMD Board Member.

² See Declaration of Interests policy in Annex 4

6.3.1. Composition and Eligibility to the Strategic Advisory Board

All PFMD Members (except Associate Members) have a seat at the SAB.

6.3.2. Role of Strategic Advisory Board members

The SAB meetings offer the opportunity to feed the PFMD program with members' insights about the Strategy and the projects. Whilst interacting with the audience and engaging with stakeholders outside of meetings, PFMD members follow the principles of:

- **Duty of Care:**
Members must use their best judgment in all dealings with the PFMD Program by, for example, preparing for and attending meetings, raising questions, and providing careful oversight.
- **Duty of Loyalty:**
Members must be considerate of their commitment and role as a PFMD SAB member and, to their best judgment, aim to avoid conflicts of interest when making decisions affecting the PFMD Program.
- **Duty of Integrity:**
Members must stay true to the program's mission when bringing insights.

7. The Synergist

The Synergist has been appointed to run the operations of PFMD.

7.1. Role/ mandate

The Synergist has multiple mandates encompassing the following items:

Secretariat

The Synergist takes care of all administrative duties linked to PFMD management and membership, including organizing and facilitating the meetings, preparing summary reports, etc.

Host and facilitator according to collaborative leadership principles

The Synergist hosts PFMD. PFMD will not be incorporated at any stage, therefore The Synergist will host the program and will act as a proxy holder on behalf of PFMD, under the Executive Director's guidance.

Project Management

The Synergist organizes and makes its teams available to perform the necessary duties to achieve PFMD's goals as set by the PFMD Board and the Executive Committee.

8. PFMD Funding

PFMD funding shall come from several complementary sources described hereafter.

8.1. Core funding

Core funding of the program shall be provided for by industry (“Industry”) and other for-profit members. Funding raised from Industry and for-profit members shall be unrestricted grants.

Members commit to a 3-year membership and an annual membership fee shall be charged as follows for Industry or for-profit members:

- EUR 100 000.- commitment per year – which may be adjusted as per the PFMD Board’s voted strategy and related budget

8.2. Project-specific funding

Additional funding for specific projects or member-specific products and services is possible.

Organizations can fund a PFMD specific project and thus attain an associate member role. See more under Associate members above.

8.3. Alternative funding

PFMD may raise alternate funding from other sources, including (but not restricted to):

- Foundations
- Public Institutions
- Private donors
- For-profit funding for specific projects

Any exception to the above funding principles has to be approved by the Executive Committee and the PFMD Board needs to be informed.

9. Deadlocks

The governance has been designed to avoid deadlocks. However, should a deadlock still happen, the Executive Director will take the appropriate decision and inform the PFMD Board.

10. Liability of members

PFMD not being incorporated, the program can therefore not be considered liable for anything. All members will be liable for their actions and decisions. Necessary contractual links are enforced by bilateral binding contracts for both contracting parties.

It is therefore not expected that any member would increase or modify its usual liability because of its commitment to PFMD.

11. Intellectual property

As proxy and host for the PFMD, The Synergist shall exclusively own any and all intellectual property rights (IP) arising and/or resulting from one or more Member’s involvement in the PFMD.

In compliance with the philosophy of the PFMD and the rights of all members as defined in this Governance, The Synergist will make the IP available to all eligible members under Creative Commons

licensing terms.

This clause shall survive the end of the PFMD project, including, as described below, should the Executive Team decide to put an end to the PFMD.

12. Withdrawal or exclusion of members

Members can decide to withdraw from the project. Their specific obligations in such a situation shall be provided for by the bilateral contracts to be signed and respect the 3 years commitment.

The Board may decide to exclude members for serious breaches to PFMD's philosophy or to the Governance. The PFMD Board will validate any member exclusion.

13. Closure – end of PFMD

The PFMD Board may decide to put an end to PFMD either because all expected outcomes of the program have been delivered or because serious and objective forecasts show that it will not be possible to deliver these outcomes.

This decision shall be endorsed by a qualified majority vote from the Members. If a decision to stop the program is made by the PFMD Board, the program's IP and assets can be used by The Synergist to pursue a similar or related mission. (see [intellectual property](#))

Annex 1 - About The Synergist

The Synergist is a not-for-profit organization that offers a symbolic and material neutral platform where all stakeholders can collaborate in a non-competitive environment, understanding that they join forces on an issue which is beyond a single organization's agenda.

The Synergist believes that creating shared value and addressing the common causes that link key concerns is what leads to greater results. The Synergist partners with corporations, influencers, experts, academics, individuals, medical professionals, patients, and NGOs, among others, who share the same philosophy.

The Synergist acts as an incubator and collaboratively leads various projects including implementation of strategy, management, communication, technical development, and fundraising. To learn more about our activities, please refer to www.TheSynergist.org

See The [Synergist One pager](#) to know more.

Annex 2 - Travel & Expenses Policy

This policy is, to a large extent, inspired by the [World Health organization's staff regulations and staff rules](#), version February 2018.

Within this document, the following terms shall be understood as follows:

- The Organization: The Synergist ASBL and any of the hosted programs
- Recipients: Any individual entitled to expenses reimbursement and/or travel reimbursement by The Synergist. Such individuals are employees of The Synergist, members of the Executive Committee, members of the PFMD Board, and members of the SAB from not-for-profit organizations. All other members shall not be considered as Recipients. Delegates or representatives attending on behalf of the Executive Committee or PFMD Board members are not automatically considered as Recipients and therefore will be considered on a case-by-case basis.

Subject to conditions and definitions below, the Organization shall pay the travel expenses of Recipients.

Travel and transportation

The organization shall pay the reasonable travel expenses of Recipients as follows:

- Reasonable travel expenses shall be paid by the organization only if the travel purpose is linked to one of the programs or projects hosted by the organization. Prior approval of the organization is requested, taking into account that travel expenses related to Executive Committee and Board Members (from not-for-profit member organizations) whose attendance to meetings is requested will always be considered approved. The cost to the organization for travel covered by this rule shall not, in any case, exceed that of travel from the Recipient's recognised place of residence to the meeting place.
- For total expenses equal to 500.00€ or more for one meeting - advance approval is requested by the organization.

Travel per diem & expense reimbursements

If a Recipient is paid a travel per diem during any period of authorised travel, the rates of travel per diem and the conditions under which they shall be payable to Recipients shall be established in accordance with the rules published by the Belgian Fiscal Administration. The amount of the per diem is considered to represent an average payment in lieu of reimbursement of a portion of the actual incidental expenses occasioned by travel status.

The Recipient may claim incidental expenses occasioned by travel up to the same amount as a per diem payment per day, through the organization's official expense claim form and attaching the relevant

receipts. Please check with the Organization for details of per diem amounts in different countries if needed.

Route and mode of travel

All travel at the Organization’s expense shall be by a route and mode of transportation determined by the Organization, provided that the Recipient may be permitted to choose a different route or mode of transport on condition that any extra costs are at their charge, and that per diem calculations shall be made on the basis of the route and mode of transport designated by the organization.

Failure to exercise entitlement

In no case shall a Recipient be given any cash payment in lieu of exercising any entitlement under this rule. Any entitlement which is not exercised within one month of the entitlement date shall be forfeited except upon the express approval by the Organization’s management.

Annex 3 - PFMD Board Members & Executive Committee

PFMD Board Members & Executive Committee 2024

Members of Executive committee

(I): Industry

(P): Patients representatives or organization

(O): Others such as HTA's, Research, Regulators, Think Tank

PFMD Board 2024			
1	David Haerry	EATG (P)	M
2	Rebecca Vermeulen	Roche (I)	F
3	Græeme Johnston	Individual Expert Patient (P)	M
4	Randall Rutta	National Health Council (P)	M
5	Derrick Mitchell	IPPOSI (P)	M
6	Esther Krofah	FasterCures/ Milken Institute (Other)	F
7	Anca Toma	EPF (P)	F
8	Jim Elliott	Health Research Authority (Other)	M
9	Bronwyn Lewis	Boehringer Ingelheim (I)	F
10	Lode Dewulf	Individual Expert (I)	M
11	Begonya Nafria	Sant Joan de Déu R. Foundation (Other)	F
12	Neil Bertelsen	HTAi (Other)	M
13	Jan Geissler	Leukemia Patient Advocates Foundation (P)	M
14	Veronica Popa	EURORDIS	F
15	Daniel De Schryver	Janssen Pharmaceuticals (I)	M
16	Marc Boutin	Novartis (I)	M
17	Kate Trenam	UCB (I)	F
18	Mandy Sandkuhler	Mended Hearts (P)	F
19	Leanne West	iCAN (P)	F
20	Liz Clark	King's College of London (Other)	F
21	Rhoyge Traylor	Edwards (I)	M

Annex 4 - Declaration of Interests Policy

PFMD Declaration of Interests Policy and form

Introduction and purpose

Individuals serving on the PFMD Board, Executive Committee, Strategic Advisory Board (SAB) or as Associate members have experience and knowledge about medicines and medical device R&D and health systems and the willingness to drive patient engagement forward and collaborate to make it systematic. This experience and knowledge come from long-term and in-depth involvement with all relevant stakeholders at both a national and international level. As a consequence of that experience, it is inevitable that these individuals will have a number of legitimate ongoing interests with the different public (both government and non-government) and private (e.g. pharmaceutical companies, medical device companies, healthcare providers etc.) organizations. **The purpose of the Declaration of Interests Policy is to protect the individual and PFMD from any suggestion or perception of impropriety.**

Potential conflicts of interest may arise when a person's personal, business, occupational or professional interests' or affiliations may conflict with the discussions held or decisions made in PFMD. This may be because they serve on multiple boards of potentially competing NGOs, may have commercial or regulatory interests, or other reasons.

PFMD does not want to limit or influence in any way Board members', Executive Committee's, SAB's or associate members' involvement with other organizations. This disclosure is to provide transparency and help understand whether a potential conflict of interest exists.

In the light of the above, all PFMD Board, Executive Committee, and SAB members are required to declare their interests on an annual basis by returning the form on the next page. This will be provided to the Executive Committee but not made available publicly.

Please complete and return this Declaration of Interests form (form only) to the Executive Director (nicholas.brooke@thesynergist.org) AND the PFMD admin office (office@thesynergist.org) during the first 3 months of the beginning of your term and annually thereof.

Process of determination

Determinations of Potential conflict of Interest

A Board, Executive Committee or SAB member who has declared or has been found to have a conflict of interest shall refrain from participating in the Board or Executive Committee meeting while the determination of a conflict of interest is discussed and voted upon, unless for special reasons the Board requests information or interpretation from the person or persons involved or determines that the interested person may remain in the room. He or she shall not vote on the matter in question and shall not be present at the time of the vote unless the Executive Committee and/or Board determines that the conflict is insignificant or immaterial to the issue at hand. More detailed procedure of determination and

addressing conflicts of interest are laid out in the *Determination of Potential Conflict of Interest procedure*-document³.

³ <https://docs.google.com/document/d/1RGxZX4JSZ2E21UCYn5eV-S1bw5WugH6Q1PN9fCnyMtg/edit#>

PFMD Declaration of Interests-form

Your Name: _____

Position: _____

Organization(s): _____

Email: _____

Date: _____

Other than my involvement in the abovementioned organization(s) I declare that, to the best of my knowledge, the only interests that are relevant to my role on the (*highlight an option*) PFMD Board/ PFMD Executive Committee / Strategic Advisory Board in companies and organizations are those listed below.

[All current and/or past interests from the last 3 years should be declared.]

Employment

Employment with a life sciences company means any form of occupation, part-time or full-time, paid or unpaid, in the company. This includes also companies relating to medicinal products, e.g. contract research organizations (CROs), but not academic institutions.

Enter text below. If there is nothing to declare, add "Nothing to declare".

Consultancy and/ or Strategic advice

Consultancy means provision of advice to a life sciences company, public institution or healthcare organization, regardless of contractual arrangements or any form of remuneration or provision of pro-bono services.

Strategic advisory role means participation (with a right to vote on/influence the outputs) in an advisory board or steering committee with the role of providing advice, expressing opinions on the (future) strategy, direction or activities of a pharma company, public institution or healthcare organization, regardless of contractual arrangements or any form of remuneration or provision of pro-bono services.

Enter text below. If there is nothing to declare, add "Nothing to declare".

Financial interests

Current or potential ownership, investment interest or holding of stocks and shares, stock options, equities, bonds and or partnership interest in the capital of any entity with which the PFMD has or is negotiating a transaction or arrangement (with the exclusion of an investment fund, pension fund and/or similar arrangements).

Current intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medicinal products or healthcare service owned by you or of which you are directly a beneficiary.

Current or potential compensation arrangement (including direct and indirect remuneration as well as gifts or favors that are substantial in nature) with PFMD or with any entity or individual with which PFMD has or is negotiating a transaction or arrangement.

Current position as an officer or board member, employee, or former employee of any entity with which PFMD has or is negotiating a transaction or arrangement.

Enter text below. If nothing to declare, add "Nothing to declare".

Grant, funding to organization(s) and institution(s)

Current grants or other funding (other than compensation for services provided e.g. for consultancy) received from a life sciences company, healthcare organization or governmental institution by an organization/institution to which you belong, or for which you perform any kind of activity, and which is used to support any of your activities whether or not they are related to your work. Any other funding received from a life sciences company by an organization/institution to which you belong, or for which you perform any kind of activity, do not need to be declared.

Enter text below. If nothing to declare, add "Nothing to declare".

Any other interests or facts

Provide information on involvement with additional organizations, institutions, initiatives or projects that may create a potential conflict of interest, e.g.:

- *Academic and/or publicly funded research initiatives in healthcare*
- *Officer, director, trustee, employee, or consultant to any other professional society, research organization, non-profit organization or corporation in healthcare, which may be funded in full or in part from unrestricted grants from life sciences companies or governmental bodies, or may have potential conflicts of interest with PFMD*
- *Employment, consultancy, strategic advisory role and financial interests of first-line family members (i.e. spouse or partner, children and parents)*

Enter text below. If nothing to declare, add "Nothing to declare".

Should there be any changes to the above due to the fact that I acquire additional interests, I shall promptly notify PFMD and submit an updated Disclosure of Conflict of Interests detailing the changes.

Date, place and signature: _____