



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	05.12.24	Inclusion of 2024 Governance updates and Conflict of Interest Revision



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1. Preamble

The Patient Focused Medicines Development (PFMD), established in October 2015, is an independent, global collaborative program 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 coalition of members (**Members**) hosted and managed by The Synergist ASBL. Providing a non-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, life sciences industry, regulators, third-party payers and other professional organizations invited to ensure a diversity of perspectives, create synergies and deliver better public health outcomes. This document sets forth our structure, governance, and expectations for how we work together.

2. 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 involve 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 the 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 to co-create methods to help them achieve and maintain their health goals.

2.1. 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 formalised by bilateral contracts between The Synergist and individual Members (The Synergist is described in Annex 1).



2.2. Organization structure

PFMD is governed by a PFMD Board, representing Members and making 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 Program.

The Executive Committee is a subset of the PFMD Board. The Executive Committee acts as advisor and sounding board to the Executive Director.



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 since its foundation, 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 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 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 frameworks principal, 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, their brands, or 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. Sharing resources generates mutual value. 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 Members

PFMD welcomes Members from institutions, organizations, and individuals that 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 and the Membership Committee, who submit a recommendation to the PFMD Board for validation.

4.1 Members' rights

Members' rights include:

1. Participation in the PFMD's Strategic Advisory board;
2. Participation in PFMD's projects and expert committees;
3. Access and use PFMD data, tools, and services before they become publicly accessible;
4. Benefiting from services provided by The Synergist in the framework of PFMD and having the possibility to access specific licences from PFMD (e.g. "labels", certification marks); see [intellectual property and creative common license](#) (art. 11).



4.2 Members' obligations

Members' obligations include:

1. Contributing to the development of PFMD patient engagement good practices, tools, methodologies, and support materials;
2. Upholding and applying the PFMD principles and key commitments ([Section 3: Key Principles of PFMD](#)) within the partnership agreement;
3. Acting as PFMD Ambassadors within their own organizations and externally, by actively contributing to and disseminating PFMD work, tools, and outcomes to help drive patient engagement.

Members' principles include:

- **Duty of Care:** Board Members must use their best judgement 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. They must also demonstrate loyalty by adhering to and defending decisions made collectively by the Board, ensuring unity and consistency in representing the organization's interests.
- **Duty of Integrity:** Board Members must stay true to the organization's mission and applicable laws and regulations when making decisions for the organization.

4.3 Membership Categories

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 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 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.

Independent Experts are individuals who bring unique value to PFMD through their specialized expertise, diverse perspectives, and ability to create meaningful impact. They may act as representatives of an organization or as individuals, contributing to the program's mission without being tied to specific institutional interests.

All types of membership are considered equal within the project work and perspectives of participating



Members are considered regardless of their member status.

4.4 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 (3.3) and respect for every individual's expertise and background (3.1).

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. Organizations 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 standard 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** ([Section 3.3: 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 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.

4.5 Diversity and Representation

PFMD strives for diversity & inclusion in its Members' representation. Therefore five diversity criteria have been identified based on current gaps and good practices, which are monitored closely:

1. Diversity of Stakeholders groups:



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- ❑ 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 and cultural diversity through Members and Board. Geographic diversity should reflect membership composition and PFMD strategy. We are committed to seek 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, 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

5. PFMD Board

Positions on the PFMD Board and Executive Committee, Independent Experts and Members of the Strategic Advisory Board are nominative and should be based on the merits and active participation in PFMD's work, as well as the exemplification of PFMD principles.

5.1 Board Composition

The number of Board Members shall be a maximum of 21 and a minimum of 17, including the Executive Committee (which is a subset of the Board). This number may be changed at any Board meeting by a two-thirds majority vote, provided at least half of the Board Members are present. 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 independent experts who add value to the program through their expertise, diversity, and impact whether acting from an organization, or as individual representatives.



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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”.



5.1.1 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

Primary area of expertise:

1. Independent Patient Expert
2. Independent Industry Expert
3. Independent Other Expert (HTA, Regulatory, academia, public health authority, or with other relevant expertise, e.g. advocacy, executive leadership in a diverse environment , etc.)

5.2 Board Elections

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



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

1. The individual is an employee of a PFMD Member that has a signed commitment to PFMD for at least 3 years, or the individual has proven commitment and value to PFMD, based on their participation in PFMD activities.
4. 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.

5.3 Terms and Term Limits

The Nomination Committee organizes and monitors the election process. 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 (see section 6.2.4 “Term, election and rotation of 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 signed commitment of at least 3 years with 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 proposed by the Nomination Committee will be presented to the Board to avoid the fear of not being elected as an obstacle to applications;
- 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 Board Composition Matrix.
- The number of applicants is not disclosed: whether there will be a high or low number of candidates stays confidential;

The Nomination Committee will review and interview potential candidates proposed and selected by the Executive Director and the Chair of the Nomination Committee, 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 and the Executive Director. The slate of candidates is then sent to the Board to be confirmed through a vote.



5.4 Onboarding

New PFMD Members and Board Members will follow the onboarding process that has been defined separately and that ensures an appropriate level of knowledge and responsibilities for Members within the Program. The onboarding process includes, but is not limited to:

- a public announcement on social media following confirmation from the new Member or Board Member,
- visibility on the PFMD website, and
- an official orientation meeting which details PFMD's governance, activities, and current events.

The orientation and onboarding meeting should also outline the responsibilities and opportunities for the new Member or Board Member's role. At least one current Board Member should be present at the aforementioned orientation meeting.

5.5 Responsibilities

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. 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.

The Board roles are 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 organization and externally.
- 3. Provide oversight:**
 - Support & evaluate the Executive Director;
 - Monitor that programs are aligned with strategy;
 - Provide financial oversight;
 - Ensure legal and ethical integrity.

5.6 Quorum

The PFMD Board makes decisions (cfr [decision matrix](#)) through a voting process with a quorum of at least half



of the Board Members present, by a simple majority, unless other quorums are provided for a specific decision.

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 validates the initiative’s scope and/or organization and rules.

5.7 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 addressed through bilateral contact between the Executive Director and Board Member who cannot attend pre and post meetings to get views on critical issues.

5.8 Decision-making

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 & Purpose	Approves
Strategic planning	Develop mid and long term strategy (2 to 5 years)	Approves
	Approve high-level strategic planning and authorize Executive Director to execute	Approves
Ensure Resources	Members & Resources	
Build a competent board	Change PFMD Governing bodies structure, including appointing 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 Executive Committee Members of PFMD	Approves
Provide Oversight	Monitoring	
New projects	New projects above 10% of the annual budget	Approves
Provide financial	Annual high-level Operating Budget	Approves



oversight	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	The Executive Committee oversees the Executive Director's support and evaluation on performances, driving the process based on insights and input gathered from the full Board. The evaluation is finalized through a consensus-building process with the Board.	Endorses

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

5.9 Task Forces and Committees

The PFMD Board may appoint ad-hoc task forces and standing committees as outlined in the Board decision matrix. Ad-hoc or special committees of the board, as may from time to time be deemed necessary, may be created to serve a limited amount of time or for the duration of a particular program or project for which they were created.

All committees, both standing and ad-hoc, should have a designated Chairperson. The Chairperson of a committee should be nominated by the Executive Committee taking into account suggestions from the Executive Director.

5.10 Nomination Committee

The Nomination Committee drives the election process of the Board and Executive Committee members (details in the section 5.2 focused on the election process).

The Nomination Committee is composed of five Board Members, of which a maximum of two Executive Committee Members. Candidate Board Members shall be proposed by the Executive Director and the Executive Committee based on a list of volunteer Board Members; they are then appointed by a simple majority vote by the Board. 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.



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5.11 Governance Committee

The Governance Committee is responsible for enhancing and adapting PFMD's bylaws to meet the evolving needs of the organization.

It is composed of a minimum of three members and a maximum of five, with the committee being chaired by a member of the Executive Committee. Candidate Board Members are proposed by the Executive Director and the Executive Committee from a list of volunteer Board Members, and they are then appointed by a simple majority vote of the Board. The Governance Committee aims to reflect a diverse selection of Board Members.

5.12 Membership Committee

The Membership Committee oversees the election process for new PFMD members (details can be found in Section 4 on PFMD Members). The Committee receives the applications, assesses the validity of the Eligibility Criteria (Section 4.4), and submits its recommendation to the PFMD Board for a vote.

The Membership Committee is composed of a minimum of three members and a maximum of five, and is chaired by a Board Member. Candidate Board Members are proposed by the Executive Director and the Executive Committee from a list of volunteer Board Members, and are then appointed by a simple majority vote of the Board. The Membership Committee aims to reflect a diverse selection of Board Members.

5.13 Finance Committee

The Finance Committee oversees and monitors PFMD's financial sustainability, including sources of financing and fundraising, as well as the fee structure and approach.

It is composed of a minimum of one member and a maximum of three, and is chaired by a member of the Executive Committee. Candidate Board Members are proposed by the Executive Director and the Executive Committee from a list of volunteer Board Members, and are then appointed by a simple majority vote of the Board. The Finance Committee aims to reflect a diverse selection of Board Members.

5.14 Audit Committee

The Audit Committee is responsible for reviewing PFMD's financial records for accuracy and providing an annual audit report to the Board for approval.

It is composed of a minimum of one member and a maximum of three, and is chaired by a member of the Executive Committee. Candidate Board Members are proposed by the Executive Director and the Executive Committee from a list of volunteer Board Members, and are then appointed by a simple majority vote of the Board. The Audit Committee aims to reflect a diverse selection of Board Members.

5.15 Resignation, removal, change in affiliation and co-option

Any Board Member may at any time resign by written notice to the Executive Committee and the Executive Director.

If a Board Member is changing professional affiliation or a member organization ending PFMD Membership, her/his Board Membership automatically ends immediately or at the end of the ongoing calendar year. A



longer duration as noted (or co-option) is subject to a simple majority vote by the board. All membership obligations remain unchanged with the member organization.

Any Board Member may be removed for cause by the Board, 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 (the concerned Board Member shall not be taken into account in the presence quorum and shall not participate to the vote). Such causes may include, but are not restricted to, absence from three (3) successive meetings of the Board, prolonged incapacity 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 contradictory to the purposes and policies of PFMD.

Where the numbers of persons on the Board has fallen below [17] or if there is a need to support the PFMD representation criteria (5.2), the Executive Director and/or the Executive Committee 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 by a simple majority vote.

A person appointed to the Board by co-option 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. Any period spent as a co-opted member of the Board shall not count as part of their permitted term of office.

6. Executive Committee

The Executive Committee consists of 4 members, a subset of the Board composed of maximum 21 members.

6.1 Composition and role of the 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.

Role of the Executive Committee

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.



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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
Collaborate with the Board to identify potential candidates for Board membership to recommend to the Nomination Committee
Members Meeting Management and Facilitation
Oversee and Co-Chair the PFMD Board meetings
Assist Executive Director in preparation of Board meetings, including agenda-setting
Call special meetings as necessary
Relationship Management and Board Support
Assist in managing relationships among Board Members and their engagement
Facilitate the relationship between Board Members and the Executive Director
Consult with Board Members on their roles and support them to assess their performance individually and through any potential Board self-assessment formats
Act as spokesperson for the PFMD Program
Hold regular alignment meetings with the Executive Director
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 Meetings

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

6.3 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.

6.4 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, after at least one year off.

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.

6.5 Resignation, removal and co-option

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

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

When a Board Member is co-opted to the Executive Committee they will be expected to serve until the next scheduled Executive Committee elections, where 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.

7. 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 PFMD Member has the right to participate in the SAB. Any organization which has an elected representative at the Board may choose a different individual and representative member for the SAB.

With the SAB, PFMD has a collaborative platform for PFMD Members to bring their unique input, 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.

7.1 Composition and Eligibility to the Strategic Advisory Board

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

7.2 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. The SAB meets quarterly, every year. Members must stay true to their duties and obligations and to the program's mission when bringing insights.

8. Policies

8.1 Declaration of Interests Policy

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. In consequence, 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.

8.1.1 To whom it applies



Conflict of interest arises when individuals in positions of authority or influence, such as PFMD Executive Committee, Board and Strategic Advisory Board Members, face situations where their personal interests or affiliations may compromise their ability to prioritize and act in the best interests of the organization.

Conflicts of interest 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, have commercial or regulatory interests, or other reasons.

8.1.2 Disclosure requirements

All PFMD Board, Executive Committee, and SAB Members are required to declare their interests on an annual basis by returning the form in [Annex 3](#). This will be provided to the Executive Committee but not made available publicly. Failure to provide the declaration form in due time will result in that person's suspension from the PFMD, meaning he/she shall not be authorized to participate in any meeting until the declaration form has been duly submitted. Non-submission after two consecutive reminders sent by the Executive Director shall result in immediate and automatic removal of that person from the PFMD organization.

If a PFMD Board, Executive Committee, SAB member, Synergist member or external becomes aware of any potential Conflict of Interest involving another member, he or she should report it to the Executive Committee.

8.1.3 What Is Expected, What Is Not Expected

The following is a non-exclusive list of potential conflicts of interest and should be disclosed by all Board Members, Executive Committee Members, SAB Members and Associate Members.

WHAT IS EXPECTED (it is not a conflict of interest)	WHAT IS NOT EXPECTED (it is a conflict of interest)
Improper monetary or non-monetary gain	
<p>PFMD Board candidates should undergo a thorough evaluation to ensure no potential for improper monetary gain exists before being elected. PFMD Board Members should disclose their relationship with the organization and properly acknowledge the tools, assets, and resources created by the organization.</p> <p>Examples of what is expected include:</p> <ul style="list-style-type: none"> • A PFMD Board Member has no financial or business relationships with the organization's members that may negatively impact PFMD as an organization. • A PFMD Board Member acknowledges the organization when implementing and/or presenting tools and resources created by PFMD. 	<p>PFMD Board candidates should not be elected if there is a risk of their decisions leading to personal financial benefits at the expense of PFMD's best interests.</p> <p>Examples of what is not expected include:</p> <ul style="list-style-type: none"> • A PFMD Board Member uses the PFMD platform, network, or avenues to promote her/his own services. • A PFMD Board Member uses PFMD's identity, network, or materials to benefit her/his commercial purposes without respecting the Creative Commons licence.
Improper use of influence to impact PFMD processes and safeguards	
PFMD Board Members should uphold transparency and avoid	PFMD Board Members should not misuse their influence to



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using their influence to improperly impact processes and safeguards, ensuring a fair decision-making environment within PFMD.

Example of what is expected:

- A PFMD Board Member maintains a clear boundary between her/his work and decision-making processes within the organization.

manipulate processes or safeguards for personal gain, undermining PFMD's integrity and mission.

Example of what is not expected:

- A PFMD Board Member influences decisions to ensure her/his business is always consulted in a PE process (without legitimate reason that is justified towards better Patient health outcomes)

Reputational Risk

PFMD Board Members should be vigilant in mitigating any actions that may pose reputational risks for PFMD, taking proactive measures to protect the organization's standing.

Example of what is expected:

- A PFMD Board Member consults the PFMD Executive Director or the Executive Committee before taking any public stand that might impact the reputation of PFMD.

PFMD Board Members should not engage in behaviors that could harm PFMD's reputation, whether through personal actions or associations, risking the organization's credibility.

Example of what is not expected:

- A PFMD Board Member taking a public position without prior consultation of PFMD's Executive Director, or the Executive Committee.

Risks of Undisclosed Business Ties

PFMD Board Members should disclose any business relationships with clients and demonstrate independence in decision-making, prioritizing PFMD's interests over external affiliations.

Example of what is expected:

- A PFMD Board Member who works with several clients, including some of PFMD Members, when participating in PFMD's decision-making processes, he/she discloses these relationships (by name if non-confidential) and recuses himself/herself from discussions that could create conflicts of interest.

PFMD Board Members should not allow business relationships with clients to compromise his/her ability to act independently when making decisions for PFMD, potentially leading to biased choices.

Example of what is not expected:

- A PFMD Board Member who has a substantial portion of his/her income, including from management companies, from some of PFMD Members consistently advocates for decisions that financially benefit him/her and his/her clients, rather than putting PFMD's interests first.

Risk of Undermining PFMD's mission and values

PFMD Board Members should always prioritize the organization's interests above all else when making decisions, ensuring the mission and values of PFMD guide their actions.

Examples of what is expected include:

- A PFMD Board Member always puts the organization's mission and values above all else. He/she recuses himself/herself from discussions where he/she has a direct or indirect conflicting interest and acts transparently in all his/her dealings with PFMD.

PFMD Board Members should not allow personal interests or external affiliations to sway their decision-making, undermining the organization's primary mission.

Examples of what is not expected include:

- A PFMD Board Member uses his/her position to push for initiatives that directly benefit personal interest despite it not aligning with PFMD's mission & goals.



8.2 Travel and Expenses Policy

This policy is, to a large extent, inspired by the [World Health organization's staff regulations and staff rules](#), version February 2018. More details available in [Annex 4: Travel & Expenses Policy](#).

9. The Synergist - Role and Mandates

The Synergist runs the Program and, to this end, 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.

More information about The Synergist is outlined in [Annex 1](#).

10. PFMD Funding

PFMD funding shall come from several complementary sources described hereafter.

10.1 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 either an annual or 3-year membership and an annual membership fee shall be charged as follows for Industry or for-profit Members:

Companies Yearly Gross Revenue USD (\$)		Membership Fee (EUR)
Tier 1	> 10 billion	125 000 EUR commitment per year
Tier 2	5 b. < x < 10 b.	100 000 EUR commitment per year
Tier 3	1 b. < x < 5 b.	75 000 EUR commitment per year



Tier 4	< 1 b.	45 000 EUR commitment per year
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Annual membership fees and fee structure may be adjusted as per the PFMD Board's voted strategy and related budget.

10.2 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.

10.3 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.

11. 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.

12. 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 with The Synergist.

It is therefore not expected that any member (organization and/or individual) would increase or modify its usual liability because of its commitment to PFMD.

13. Intellectual property

As proxy and host for the PFMD, The Synergist shall exclusively own any and all intellectual property right (IP) arising and/or resulting from PFMD.

In compliance with the philosophy of 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 PFMD Board decide to put an end to the PFMD.

14. Withdrawal or exclusion of Members

Members can decide to withdraw from the Program. Their specific obligations in such a situation shall be provided for by the bilateral contracts to be signed with The Synergist.

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.

15. 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 Board Members, provided at least half of the Board Members are present. 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 incorporated under Belgian law 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.

PFMD has no distinct legal personality and is hosted by The Synergist. As a consequence, PFMD Membership is formalized by bilateral contracts between The Synergist and individual Members.

Annex 2 - Board Committee and List of Current members

Nomination Committee

BRONWYN LEWIS - Boehringer Ingelheim

GRAEME JOHNSTON - Patient advocate

ESTHER KROFAH - Milken Institute

REBECCA VERMEULEN - Roche



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PFMD Board Members & Executive Committee 2025

Members of Executive committee

(I): Industry

(P): Patients representatives or organization

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

PFMD Board 2025			
1	David Haerry	EATG (P)	M
2	Rebecca Vermeulen	Roche (I)	F
3	Graeme Johnston	Individual Expert Patient (P)	M
4	Randall Rutta	National Health Council (P)	M
5	Derick Mitchell	IPPOSI (P)	M
6	Esther Krofah	Milken Institute (Other)	F
7	Anca Toma	EPF (P)	F
8	Naho Yamazaki	Health Research Authority (Other)	F
9	Bronwyn Lewis	Boehringer Ingelheim (I)	F
10	Nikul Bakshi	Parkinson's UK (P)	M
11	Nicolas Garnier	Servier (I)	M
12	Neil Bertelsen	HTAi (Other)	M
13	Jan Geissler	Leukemia Patient Advocates Foundation (P)	M
14	Emma Andrews	Pfizer (I)	F
15	Daniel De Schryver	Johnson & Johnson (I)	M
16	Wendy Erler	Alexion/AstraZeneca (I)	F
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	Jennifer Austin	Globalskin (P)	F



Annex 3 - Declaration of Interests Policy

Introduction and purpose

The purpose of the Declaration of Interests Policy is to protect the individual and PFMD from any impropriety (real, suggested or perceived) and to provide clarity and remove bias in the process of determining a Conflict of Interest. All PFMD Board, Executive Committee, and SAB Members are required to declare their interests on an annual basis by returning the form below. This form will be provided to the Executive Director but not made available publicly. The Executive Director will work directly with the Executive Committee to carry out the evaluation of the potential conflict as stated below.

Evaluation of Potential Conflict

After disclosing all material facts and discussing any potential conflicts of interest with the interested person, the Executive Committee serves as a filter and recommend to the Board when an actual conflict exists.

Board Members will evaluate and determine on a case-by-case basis whether the disclosed activities constitute an actual conflict of interest through formal vote during the next Board meeting. The outcome of the deliberation about whether a conflict of interest exists will be recorded per Chatham House Rules in the minutes of the appropriate deliberative meeting.

The minutes of the Board shall contain:

- The names of the persons who disclosed or otherwise were found to have a financial or personal, familial, or professional interest in connection with an actual or possible conflict of interest, the nature of the financial or other interest, any action taken to determine whether a conflict of interest was present, and the Board's decision as to whether a conflict of interest in fact existed.
- The names of the persons present for discussions and votes relating to the transaction or arrangement will be recorded, along with the content of the discussion—maintained under Chatham House Rules—including any alternatives to the proposed transaction or arrangement, and a record of any votes taken in connection therewith.

Procedures for Addressing a Conflict of Interest

A Board, Executive Committee or SAB member who has declared or has been found to have a conflict of interest shall abstain ~~refrain~~ from participating in the Board or Executive Committee or SAB meeting unless 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.

Transactions with parties with whom a conflicting interest exists may be undertaken only if all of the following are observed:

1. The conflicting interest is fully disclosed;



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2. The person with the conflict of interest is excluded from the discussion and approval of such transaction (except to the extent otherwise permitted herein);
3. A competitive bid or comparable valuation exists;
4. The Board with the Executive Committee (or a duly constituted committee thereof) has determined that the transaction is fair and reasonable and in the best interest of the organization.

Violations of the Conflicts of Interest Policy

If the Board has reasonable cause to believe that an Executive Committee, Board or SAB Member has failed to disclose actual or possible conflicts of interest, it shall inform the interested person of the basis for such belief and afford such person an opportunity to explain the alleged failure to disclose.

If, after hearing the interested person's response and after making further investigation as warranted by the circumstances, the Board determines the interested person has failed to disclose an actual or possible conflict of interest, it shall take appropriate disciplinary and corrective action.

Administration

All declarations required under this policy and amendments thereto, shall be directed in writing to the Executive Director. The Executive Director shall be responsible for the implementation of this policy. Issues under this policy shall be reported initially to the Executive Director to initiate the appropriate actions and evaluation in coordination with the Executive Committee. Information disclosed under this policy shall be held in confidence by the persons authorized to receive and act upon it except where, in the judgement of any of such persons, the best interest of the organization requires further disclosure. This review process shall be reported annually to the Board by the Executive Director.



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 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 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".



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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: _____



Annex 4 - 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 recognized 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 authorized 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 Tax 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



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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.