



PATIENT FOCUSED
MEDICINES DEVELOPMENT

PFMD Governance

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Preamble

The **Patient Focused Medicines Development (PFMD)** group, established in October 2015, is an independent multinational coalition, managed in collaboration with The Synergist.

Providing a precompetitive and neutral environment, PFMD seeks to have balanced representation of stakeholders to ensure transparency, inclusiveness, and credibility. Stakeholders include patients and patient organizations across diverse areas of health, healthcare professionals, industry, regulators, payers and other professional organizations are also invited to ensure diversity of perspectives, create synergies and deliver better public health outcomes.

The purpose of this document is to explain PFMD's governance structure today and looking forwards to the future, and how it operates and makes operational and strategic decisions on a day-to-day basis.

Ensuring expertise, commitment and agility are key principles for PFMD, meaning the governance structure should always be interpreted respecting these principles.

What is needed now is a consistent approach to patient engagement, through development and implementation of an efficient, measurable and reliable meta-framework that involves patients as partners. Partnering with patients to design and develop new solutions, means we can co-create methods to help them achieve and maintain their health goals.

Key principles of PFMD

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

Governance for inclusion and agility

We believe that only a partnership across all major stakeholder groups can effectively address this issue. Based on this belief, we have secured the participation of founding partners representing industry and patient advocacy groups, and we are constantly seeking to add members from the regulatory, medical, nonprofit and academic sectors who have an interest and expertise in the different aspects of this issue.

We believe in a balanced combination of inclusion of all stakeholders and agile operations that delivers results.

Commitment and expertise

Before supporting patient engagement best practices in general, membership in this initiative first and foremost represents a commitment to transform one's own organization. PFMD's members, by making this transition and demonstrating patient engagement benefits and act as pilots for other organizations and stakeholders.

When signing up for membership, organizations are committing to adopt and adapt the patient engagement framework co-created by PFMD and help deploy it across all other stakeholders.



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PFMD's purpose

PFMD's goal is to improve global health by codesigning 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 throughout the lifecycle of medicines development, thereby speeding up the creation and implementation of an effective, globally standardized framework as well as the necessary tools and support to allow the adoption of the framework by various stakeholders.

Expected outcomes

PFMD will deliver on the following priorities:

2. Continue to build the PE global network and community
3. Synergize good practices and develop a meta PE framework for the entire lifecycle of medicines development
4. Disseminate good practices and learnings to key stakeholders and PE leads in each organisation
5. Develop all the support material, tools and services that will help adoption and implementation of PE best practices

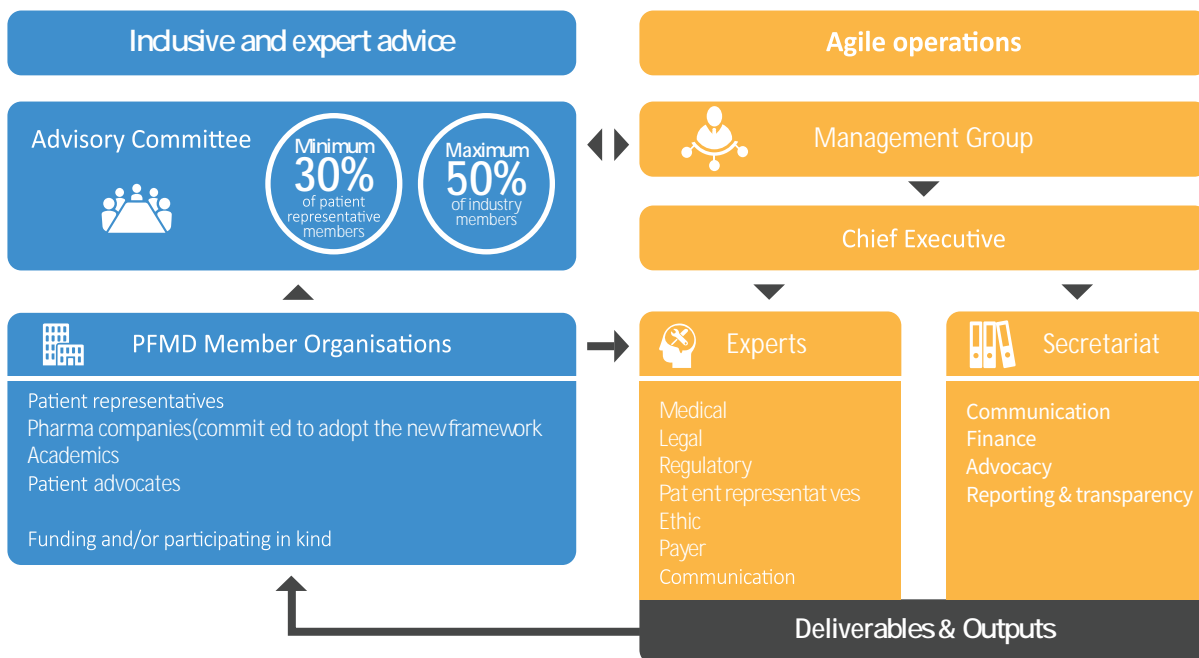
During the lifecycle of the project, the Advisory Committee may decide to modify, add to or cancel expected outcomes if necessary.

Nature of the organisation

The partnership does not constitute nor is deemed to constitute a legal entity between the Members, nor makes 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 partners. All grants shall be unrestricted grants.

Organisation structure

PFMD is governed by an Advisory Committee, which represents members and takes the major strategic decisions for the organization. Day-to-day operational decision making is delegated to the Chief Executive, who, under the supervision of the Management Group, runs the organization. The Chief Executive together with the Secretariat manages the technical, administrative and financial functions, as well as programs to support members in their adoption of the framework.





Membership

New members apply to join as PFMD members to the Chief Executive, who submits a recommendation together with the Management Group to the Advisory Committee for a vote. The vote can happen digitally.

Members:

1. follow the principle of partnership, the key commitments and the governance principles of PFMD;
2. have the right to participate in working groups and expert committees;
3. have the right to access and use PFMD data & assets;
4. have the right to be beneficiaries from services provided by the Secretary and have the possibility to access certain licenses from PFMD (e.g. "labels", collective or certification marks);
5. act as PFMD Ambassadors.

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

Member eligibility to the Advisory Committee

Members can qualify to become eligible to the Advisory Committee upon fulfillment of the following criteria:

1. having proven commitment and value provided to PFMD, based on the participation in PFMD activities;
2. formal validation by the Advisory Committee based on a recommendation of the Management Group;
3. have a commitment to PFMD membership for at least 3 years from the time of joining the Advisory Committee;

Advisory committee

Starting from 2017, the Advisory Committee has 12 members elected for a 1-year mandate plus a seat for each member of the Management Group. Members of the Advisory Committee shall be individuals from member organisations. As a principle, the members of the Advisory Committee are elected to act as trustees ahead of their role as representatives of their respective organisations.

The Advisory Committee's role is:

1. to lead PFMD, and therefore to define the long and medium term goals of the project, respecting internal rules;
2. to give a clear mandate to the Management Group and/or to the Secretariat to act on a day-to-day basis;
3. to represent the interests of members;
4. to oversee the Management Group and the Secretariat's actions, granting them discharge based on the approval of the annual report and budget.

Members are represented on the Advisory Committee according to the following principles:

1. minimum 30% of patient representative members;
2. maximum 50% of industry members;

Elect on and rotation

Members apply to the Advisory Committee through the Chief Executive and the Management Group who assess eligibility to the Advisory Committee based on criteria above. The Management Group organizes and monitors the election process.

As of January first of 2017, third year of PFMD, there will be at least 3 new members to the Advisory Committee every year, on a volunteer basis or based on recommendation from the Management Group if there are no volunteers.



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A simple rotation and staging system will be put in place with the possibility for the Management Group to extend the mandate of existing members of the Advisory Committee based on specific added value and expertise criteria.

Decision making process

The Advisory Committee reviews PFMD's achievements, work in process and reporting on a regular 6-month basis and monitors compliance with the project's objectives.

Upon receiving the Management Group's proposal, the Advisory Committee validate the project's scope and/or organization and rules.

The Advisory Committee makes decisions through a voting process with a quorum of 7 members, by a simple majority. In case there is no simple majority (50/50), the Management Group will take the final decision.

Meetings and milestones

The Advisory Committee meets at least twice a year, with a minimum of one face to face meeting per year.

Management Group

The Advisory Committee meets at least twice a year, with a minimum of one face to face meeting per year.

Role/ mandate

The Management Group is responsible for the supervision of the Chief Executive and the day to day management of the project.

Meetings and milestones

The Management Group meet as often as needed to keep PFMD agile and efficient.

Decision making process

Decisions are made by a simple majority of the Management Group's members.

If any situations arise that have not been foreseen in this document, the management team will take the most appropriate decision and not the Advisory Committee.

Elect on

The Advisory Committee will appoint the Management Group members for a 3-year renewable mandate.

Renewal is based-on a recommendation from the Management Group to the Advisory Committee.

As of January first of 2018, fourth year of PFMD, there will be at least 1 new member to the Management Group every year, on a volunteer basis or based on recommendation from the Management Group if there are no volunteers.

External/Observing Advisory Group

An External Observing Advisory Group may be created. The goal will include, but will not be limited to, offering a collaborative environment to organizations that cannot join PFMD official membership for structural and/or governance reasons.



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The Synergist

The Synergist has been appointed to take care of the operations of PFMD.

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

The Synergist hosts PFMD. PFMD will not be incorporated at any stage, therefore The Synergist will host the project and will act as a proxy holder on behalf of PFMD upon the Management Group's control.

Project Management

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

Funding

PFMD funding shall come from several complementary sources described hereafter.

Core funding

Core funding of the project shall be provided for by Industry and For-Profit members.

Funding raised from Industry and For-Profit members shall be unrestricted grants.

An annual membership fee shall be charged as follows for industry:

- 3-year commitment
- EUR 100 000 commitment per year – which may be adjusted as per the Advisory Committee's voted strategy and related budget

Project-specific funding

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

Alternate funding

PFMD might raise alternate funding 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 Management Group and the Advisory Committee needs to be informed.

Deadlocks

The governance has been designed to avoid deadlocks. However would a deadlock still happen, the Management Group will take the appropriate decision and inform the Advisory Committee.



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Liability of members

PFMD not being incorporated, the project 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's project.

Intellectual property

A significant part of PFMD's expected outcome will be IP. Members agree that such IP will belong to the Synergist as proxy and host for PFMD. In compliance with the philosophy of the project and the rights of all members defined by the Term Sheet, the Synergist will make the IP available to all eligible members as the Advisory Committee and the Management Group requests.

As described below, should the Management Group decide to put an end to PFMD, the Synergist would receive full ownership of the project's IP.

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.

The PFMD program and strategy approved by the Advisory Committee may provide for a full completion of each member's commitment prior to any withdrawal.

The Management Group may decide to exclude members for serious breaches to PFMD's philosophy or to the governance. The Advisory Committee will validate any member exclusion.

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The Management Group may decide to exclude members for serious breaches to PFMD's philosophy or to the governance. The Advisory Committee will validate any member exclusion.

Closure – end of PFMD

The Advisory Committee may decide to put an end to PFMD either because all expected outcomes of the project 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 project is made by the Advisory Committee, the project IP and assets can be used by The Synergist to pursue a similar or related mission.

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