

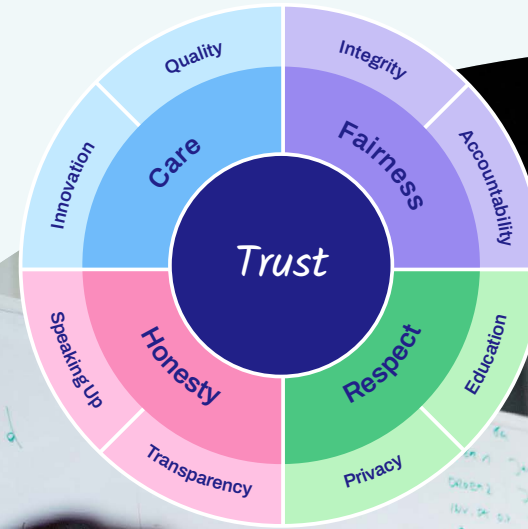


IFPMA

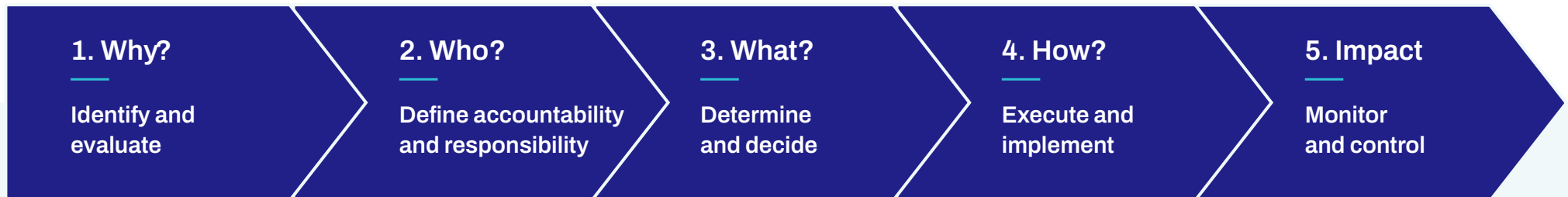
Ethoscope

Decision-Making Framework

Enabling decisions that balance patient needs and expectations of the medical community, society, and regulators with business objectives



The Decision-Making Framework



The IFPMA Decision-Making Framework is a five-phase approach that enables organizations to balance patient needs and expectations of the medical community, society, and regulators with business objectives.

The IFPMA Decision-Making Framework toolkit includes a suite of materials, from a detailed Background deck to Business Leaders Meeting Slides and a complementary Facilitation Guide. These materials are available on [our website](#).



IFPMA Ethos

The Ethos instills a culture of ethics and integrity that guides the way we behave and interact with the rest of the global health community.

It is centered on trust, care, fairness, respect, and honesty and serves as the basis of our five-phase Decision-Making Framework.

Why the Framework is important

This Decision-Making Framework is principles-based and enables leaders to:

Assess new and innovative business models

Ensure decisions are grounded in ethics and integrity to bolster and sustain patient and public trust, which are essential for innovation and critical to partnerships and interactions with patients, healthcare professionals, healthcare organizations, third parties, peer companies, the industry, and society

Ensure we embed the IFPMA [Data](#) and [AI](#) ethics principles and act in alignment with the [IFPMA Ethos](#).



Identify and evaluate

- What is the rationale and purpose for conducting an activity?
- Are patients first in the decision? Will the activity address patients' unmet needs? Have we considered their safety and well-being?
- Will the activity address other stakeholders needs (e.g., healthcare professionals (HCPs))?
- Is the activity proportionate to the identified needs?
- Have we identified the risks?
- Could there be a perception of wrong intent by patients, regulators etc. if we go ahead with the activity?
- Is the timing right for this activity (e.g., use of the data and/or a new technology)?
- What are the issues or challenges to be addressed? Do we have all the information we need?
- Have we assessed potential impact on stakeholders and identified data sources contributing to this assessment?
- Provide data sources and information contributing to assessment.

Remember!

- ❗ 'Why' is the most important step in the Decision-Making Framework and should happen first.
- ❗ Proactive risk management applies to the whole framework with some steps having explicit reflection questions.
- ❗ Use the IFPMA Data and AI ethics principles to guide decision-making.
- ❗ Support legitimate purpose with a rationale for conducting an activity that addresses patients' unmet medical needs and other stakeholder needs (HCPs).
- ❗ Describe criteria for identifying, qualifying (type: legal, regulatory, compliance etc.; and magnitude), anticipating mitigating measures, communicating, and monitoring.

Ethos in Action guiding questions:

Care

- C1** How do we play our part in helping solve societal challenges?
- C2** How do we ensure patients are first in everything we do (e.g., safety, quality, well-being, innovative solutions)?

Fairness

- F1** How do we act with integrity to earn the trust of patients, healthcare providers, other stakeholders, and the society we serve?
- F5** How do we ensure that we treat our third parties, customers, and stakeholders fairly?

Respect

- R1** What measures do we take to respect human and/or animal rights?
- R2** How do we take our environmental impact into account in our actions?
- R4** In what way are we driving scientific advancements to ensure a more educated industry, communities, and society?

Honesty

- H3** What are the legitimate needs for patients, healthcare providers, ourselves, and society that we intend to meet?

Define accountability and responsibility

- Who is the decision-maker?
- Who is the owner of the activity?
- If cross-functional, what are the other departments involved (in addition to the department of the owner) and what are their roles and responsibilities in the project?
- When using new technology, how do we ensure we maintain human accountability and build in monitoring and feedback loops?
- What are the capabilities required by the individuals/teams who will assess, monitor risks, and implement the solution?

Remember!

- ! Decision must be informed by and based on cross functional insights and context.
- ! The accountable owner of the activity is an individual in the organization, not a committee.
- ! The people accountable and the stakeholders must have the right capabilities (e.g., expertise in tech, law) to advise on risks and challenge the decision-maker.
- ! Describe roles and responsibilities, and interdependencies, if any, of all departments involved in the activity. Decide on the action plan and next steps.

Ethos in Action guiding questions:

Fairness

F3 Through what measures do we hold ourselves and our partners accountable?

Respect

R3 What are we doing to ensure respect for privacy rights?

R5 Through what measures do we ensure and display our appreciation of the value of diversity?

Honesty

H2 How are we ensuring transparency throughout our activities and processes, both internally and externally?

H3 How are we enabling both internal and external stakeholders to speak up and raise potential ethical challenges?

Determine and decide

- Have we considered the option of NO GO (not moving forward with the proposal)?
- What are the potential options and solutions proposed to meet the needs or to resolve the problem? What type of activity will best satisfy the rationale and purpose identified?
- Would we be comfortable to discuss the activity with our family, or the public?
- Are all stakeholders informed and empowered to speak up and raise any potential challenge?
- Did we minimize risk and conclude that potential benefits exceed potential risks?
- Did we value diversity and distribute risk and benefit fairly?
- What are the key elements to take into consideration in conjunction with IFPMA Ethos?
Explain the business decision-making principles that we are going to apply and consider the dilemmas, if any.

Remember!

- ! At this stage, the ethical decision can be to stop the project (NO GO decision).
- ! Define project purpose, clear objectives, and deliverables.
- ! Design and analyze all options (incl. If sequential to meet needs.
- ! Describe necessary steps to take to help ensure appropriate risk mitigation for bold or complex work/projects.
- ! Apply ethical principles (IFPMA Ethos).

Ethos in Action guiding questions:

Care

- C3** In which ways do we adhere to the highest possible scientific and ethical standards from discovery to delivery of our products?
- C4** To what extent do we act with integrity in applying scientific medical principles, demonstrating the safety and efficacy of our products?

Fairness

- F2** How do we ensure that we do what is right, even when no one is watching?
- F4** How do we properly assess and mitigate all the risks associated with our innovative products/services?

Respect

- R1** What measures do we take to respect human and/or animal rights?

Honesty

- H1** What measures are we taking to ensure active, timely, balanced, and truthful communication?
- H5** How are we learning from mistakes as well as best practices and communicating these within the organization?

Execute and implement

- Is the solution compliant with applicable laws and regulations and with the organization's policies?
- Is the action fair, the “right” thing to do? Consider the public perception if made public.
- What are the detailed action plans, timelines, deliverables for each team member at each stage of the project (before, during, and after)?
- What are the available feedback mechanisms to stakeholders and the end-users and how do we propose to handle the feedback?
- What are the total and detailed costs and payment terms based on deliverables?

Remember!

- ❗ Use good judgement.
- ❗ Identify the applicable laws, regulations, codes, and internal procedures to help ensure compliance.
- ❗ List project activities and milestones, (detailed descriptions, timelines, and deliverables), including trainings and communication.
- ❗ Describe criteria for communicating and monitoring risks and outline how issues will be resolved (e.g., governance and escalation pathways).
- ❗ Show discipline in execution.
- ❗ And document all steps of the activity, including how to respond to feedback.

Ethos in Action guiding questions:

Care

C5 How do we ensure that we move “as fast as we can, but as slow as we must?”

Respect

R1 What are we doing to ensure respect for privacy rights?

Honesty

H1 What measures are we taking to ensure active, timely, balanced, and truthful communication?

H2 How are we ensuring transparency throughout our activities and processes, both internally and externally?

H4 How are we enabling both internal and external stakeholders to speak up and raise potential ethical challenges?

H5 How are we learning from mistakes as well as best practices and communicating these within the organization?

Monitor and control

- What are the key success factors of the project?
- Have we planned to notify / report to appropriate persons (open and transparent communication, disclosure of potential issues)?
- Have we aligned key performance indicators (KPIs) with objectives and deliverables?
- Ensure an appropriate owner of these factors/KPIs is assigned.
- Set up reporting and financial controls on costs and monitor the effects of decisions/project; adjust actions to new information as necessary.

Remember!

- ! Define monitoring and controls KPIs.
- ! Control the budget versus actual spend.
- ! Check completeness of project implementation.
- ! Measure impact in line with initial objectives.
- ! Monitor and modify outcome, as needed.

Ethos in Action guiding questions:

Fairness

F5 How do we ensure that we treat our third parties, customers, and stakeholders fairly?

Honesty

H2 How are we ensuring transparency throughout our activities and processes, both internally and externally?

H5 How are we learning from mistakes as well as best practices and communicating these within the organization?

Appendix: Ethos in Action guiding questions

- C1:** How do we play our part in helping solve societal challenges?
- C2:** How do we ensure patients are first in everything we do (e.g., safety, quality, well-being, innovative solutions)?
- C3:** In which ways do we adhere to the highest possible scientific and ethical standards from discovery to delivery of our products?
- C4:** To what extent do we act with integrity in applying scientific medical principles demonstrating the safety and efficacy of our products?
- C5:** How do we ensure that we move “as fast as we can, but as slow as we must?”



- F1:** How do we act with integrity to earn the trust of patients, healthcare providers, other stakeholders, and the society we serve?
- F2:** How do we ensure that we do what is right, even when no one is watching?
- F3:** Through what measures do we hold ourselves and our partners accountable?
- F4:** How do we properly assess and mitigate all the risks associated with our innovative products/services?
- F5:** How do we ensure that we treat our third parties, customers and stakeholders fairly?

- H1:** What measures are we taking to ensure active, timely, balanced, and truthful communication?
- H2:** How are we ensuring transparency throughout our activities and processes, both internally and externally?
- H3:** What are the legitimate needs for patients, healthcare providers, ourselves, and society that we intend to meet?
- H4:** How are we enabling both internal and external stakeholders to speak up and raise potential ethical challenges?
- H5:** How are we learning from mistakes as well as best practices and communicating these within the organization?

- R1:** What measures do we take to respect human rights and/or animal rights?
- R2:** How do we take our environmental impact into account in our actions?
- R3:** What are we doing to ensure respect for privacy rights?
- R4:** In what way are we driving scientific advancements to ensure a more educated industry, community, and society?
- R5:** Through what measures do we ensure and display our appreciation of the value of diversity?



Learn more about the
Ethoscope at ifpma.org



The Decision-Making Framework is not mandatory, does not and is not intended to constitute legal advice, and does not replace internal decision-making procedures. Present Framework should not be used by any company to further any anti-competitive or collusive conduct, or to engage in other activities that could violate any antitrust or competition law, regulation, rule, or directives of any country or otherwise impair full and fair competition. The Framework is not a yes-no model, it is rather a supporting tool enabling ethical decision-making.