Ethoscope

Decision-Making Framework

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

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The IFPMA Ethos

The IFPMA Ethos instils 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.

The IFPMA 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.
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.
Ethos in Action guiding questions:

1. Why?

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 rational for conducting an activity that addresses patients’ unmet medical needs and other stakeholder needs (HCPs).

**Care**

- How do we play our part in helping solve societal challenges?

- How do we ensure patients are first in everything we do (e.g., safety, quality, well-being, innovative solutions)?

**Fairness**

- How do we act with integrity to earn the trust of patients, healthcare providers, other stakeholders, and the society we serve?

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

**Respect**

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

- How do we take our environmental impact into account in our actions?

- In what way are we driving scientific advancements to ensure a more educated industry, communities, and society?

**Honesty**

- 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?

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?

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.
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.

Ethos in Action guiding questions:

<table>
<thead>
<tr>
<th>Care</th>
<th>Fairness</th>
<th>Respect</th>
<th>Honesty</th>
</tr>
</thead>
<tbody>
<tr>
<td>C3</td>
<td>F2</td>
<td>R1</td>
<td>H1</td>
</tr>
<tr>
<td>In which ways do we adhere to the highest possible scientific and ethical standards from discovery to delivery of our products?</td>
<td>How do we ensure that we do what is right, even when no one is watching?</td>
<td>What measures do we take to respect human and/or animal rights?</td>
<td>What measures are we taking to ensure active, timely, balanced, and truthful communication?</td>
</tr>
<tr>
<td>C4</td>
<td>F4</td>
<td></td>
<td>H5</td>
</tr>
<tr>
<td>To what extent do we act with integrity in applying scientific medical principles, demonstrating the safety and efficacy of our products?</td>
<td>How do we properly assess and mitigate all the risks associated with our innovative products/services?</td>
<td></td>
<td>How are we learning from mistakes as well as best practices and communicating these within the organization?</td>
</tr>
</tbody>
</table>

Remember!

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

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!
1. Define monitoring and controls KPIs.
2. Control the budget versus actual spend.
3. Check completeness of project implementation.
4. Measure impact in line with initial objectives.
5. 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?

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

**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?

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

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