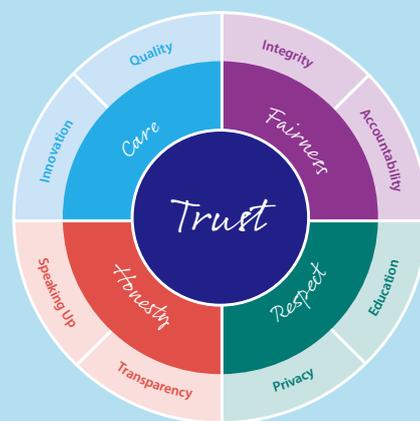**IFPMA**

Decision Making Framework

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

Why is the Decision Making Framework Important?

The pharmaceutical business model is in a vast transition bringing forward many unknown elements, which will be supported by a Decision Making Framework ("DMF").

The Framework will help IFPMA members achieve Business Ethics by Design. Ethical decision making bolsters patient and public trust, which is essential for innovation and critical to partnerships and interactions with patients, HCPs, HCOs, third parties, peer companies, the industry, and society.

1. *Why?* Identify and Evaluate	2. *Who?* Define Accountability and Responsibility	3. *What?* Determine and Decide	4. *How?* Execute and Implement	5. *Impact & Control* Monitor and Follow Up

1. *Why?*

Identify and Evaluate

→ What is the rationale and purpose for conducting an activity?

→ What are the business objectives, stakeholder needs (e.g., HCPs), and patients' unmet medical needs to support legitimate purpose?

→ Describe issues or challenges to be addressed; do you have all the information you need?

→ Identify impact on stakeholders.

→ Provide data sources and information contributing to assessment.

Ethos in Action Guiding Questions:

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 treating third parties, customers & stakeholders fairly?

Respect

- Measures taken to respect human rights and animal rights?
- Environmental impact taken 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?

2. *Who?*

Define Accountability and Responsibility

→ The accountable decision maker is an individual in the organization, not a committee.

→ Explain who is the responsible owner of the project or activity. If cross-functional, which department owns the activity. Explain the various departments involved, if relevant, and their roles and responsibilities.

→ Decision must be informed by and based on cross functional insights and context.

Ethos in Action Guiding Questions:

Fairness

- Measures taken to hold ourselves and our partners accountable?

Respect

- What are we doing to ensure respect for privacy rights?
- Measures taken to ensure and display our appreciation of diversity?

Honesty

- How are we ensuring transparency throughout our activities and processes, both internally and externally?
- How are we enabling internal and external stakeholders to speak up and raise potential ethical challenges?

3. *What?*

Determine and Decide

→ Describe potential options and solutions proposed to meet the needs or to resolve the problem.

→ Define clear objectives and deliverables.

→ If several options could be considered, explain the option you propose or if options will be sequential.

→ What type of activity will best satisfy the rationale and purpose identified?

→ What are the key elements to take into consideration in conjunction with the IFPMA Ethos? Explain the ethical principles that you are going to apply and consider the ethical dilemmas, if any.

Ethos in Action Guiding Questions:

Care

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

Fairness

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

Respect

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

Honesty

- Measures taken to ensure active, timely, balanced, and truthful communication?
- How are we learning from mistakes as well as best practices and communicating these within the organization?

4. *How?*

Execute and Implement

→ Assess the applicable laws, regulations, codes, and internal procedures to help ensure compliance.

→ Trust your judgment – is the action fair, the "right" thing to do, consider the public perception.

→ Describe detailed action plans, timelines, deliverables for each owner at each stage of the project (before, during and after).

→ Explain total and detailed costs and payment terms based on deliverables.

Ethos in Action Guiding Questions:

Care

• How do we ensure that we move "as fast as we can, but as slow as we must"?

Respect

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

Honesty

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

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

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

• How are we learning from mistakes as well as best practices and communicating these?

5. *Impact & Control*

Monitor and Follow up

→ Fully document all decision-making steps and details of the activity in order to keep evidence.

→ Notify appropriate persons (open and transparent communication, disclosure of potential issues).

→ Describe what the key success factors are and align measurements (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.

Ethos in Action Guiding Questions:

Fairness

• How do we ensure treating third parties, customers & stakeholders fairly?

Honesty

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

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

IFPMA