



**Ethoscope**

# Ethos in Action

## Decision-Making Framework

LAST UPDATED: FEBRUARY 2024



## Background

This Facilitation Guide is a companion to the Business Leaders Deck and helps guide discussion on the IFPMA Decision-Making Framework and Ethos in Action. It provides talking points and instructions for creating an interactive meeting experience.

These customizable workshop materials were developed to help you introduce IFPMA's Decision-Making Framework ("DMF") to your business. The DMF is a tool that helps identify key business objectives, potential ethical issues, impacted stakeholders, and solutions that effectively balance objectives and ethical considerations. The DMF is particularly valuable for innovative business models that are tackling new issues and new ways of working that sometimes require navigating complex decisions or ethically grey areas (e.g., Tech/AI-related dilemmas).

The DMF provides a Five-Phase approach to seamlessly integrate business objectives and ethical considerations into day-to-day business decisions. The Framework is designed to:

- Enable effective decision-making
- Enhance and support proactive risk management
- Integrate business objectives and ethical, legal, and compliance obligations into the decision-making process
- Encourage ongoing business engagement and accountability
- Foster a culture of integrity.

The workshop materials include an overview of the DMF and four interactive case studies to put learnings into practice. The case studies cover the following topics: 1) Telemedicine, 2) Market Development, 3) Industry Associations (this case study may be best suited for industry associations rather than member companies) and 4) Artificial Intelligence. You may customize your workshop to include 1-4 of the case studies depending on the time allotted for your workshop and your audience's needs. You may also wish to use one or more of the case studies for future sessions. Finally, rather than using the case studies provided here, you may choose to use a real situation that your team is currently trying to remedy, as this may be the most impactful way to bring the DMF to life.

Importantly, the DMF is not mandatory, does not and is not intended to constitute legal advice, and does not replace internal decision-making procedures. The DMF 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 DMF is not a yes-no model. It is rather a supporting tool enabling more effective, ethical decision-making and helps companies do what's right.

To view the complete set of IFPMA DMF materials, [click here](#).

Bolded prompts in blue throughout the Facilitator Guide denote instructions for the facilitator.

## Workshop best practices

- **Limit attendees:** If possible, consider groups of 10 or fewer to facilitate discussion.
- **Set expectations:** Let colleagues know in advance that you encourage full participation and want everyone to speak up and be heard!
- **Encourage video:** If conducting the session virtually, ask all attendees to use video, if they are comfortable, as it creates a more engaging meeting experience.
- **Virtual engagement tools:** If conducting a virtual workshop, leverage video conferencing features such as polling, chat, and whiteboard.
- **Follow up:** Within a day or two of the workshop, thank your attendees, provide a brief recap, ask for candid feedback, and encourage use of the DMF. Consider whether to ask attendees to formalize their commitment to using the DMF (e.g., including use of DMF in their goals and objectives). Also, consider including the DMF as an attachment with your communication to reinforce the key principles. You may also choose to follow up in 3-6 months to evaluate how attendees have put the DMF into practice and if it has had measurable business results.
- **Optional surveys:** Consider using a survey to capture feedback and to refine future sessions. You may also wish to send out a survey prior to the session, with questions addressing how the attendees make decisions, and then send out the same survey 3-6 months post-session and measure the improvement.

### Note to the facilitator

Display the title slide and introduce the session using the below talking points.

## Cover and contents slides

### Talking points

As some of you may be aware, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) developed a Five-Phase Decision-Making Framework, grounded in the IFPMA Ethos or value system. The Framework helps industry organizations make decisions that balance business objectives and ethical considerations to meet patient needs and the expectations of the medical community, society, and regulators.

As many of us have experienced first-hand, particularly as we work day-to-day to innovate and evolve various business models, we are often faced with complexities and competing interests, and sometimes the standards and laws governing our industry don't specifically address the situations we face. In these instances, we must be able to make decisions that effectively meet patient needs, business objectives, societal expectations, and ethical considerations. The IFPMA Decision-Making Framework, or "DMF," is designed to help us do just that.

During today's workshop, we will cover the following:

- Why we can benefit from using the DMF
- How the DMF advances innovative business models
- A review of the Five-Phase Framework
- Ethos in Action Guiding Questions
- One or more interactive case studies, depending on time, to put our learnings into practice.

Throughout today's workshop, I encourage you to speak up, share ideas, and ask questions. If you are not comfortable sharing in this forum, please reach out to me directly and we can set up time.

To get us started, I'd like you to consider a time when you made a good decision and another time when you made a poor decision. What steps did you take, or not take, in each scenario?

### Note to the facilitator

As the conversation progresses, record the responses using a table with two columns ("Good Decision-Making and "Poor Decision-Making"), noting which elements or steps were present when good decision-making occurred, and what elements or steps were present/not present when poor decision-making occurred. You will likely observe that the participants will mention the elements or steps that are mentioned in the DMF, and you can then refer to the points the participants made later in the discussion.

## Slide 3: The Decision-Making Framework

### The Decision-Making Framework

Guiding the decision-making flow



#### Note to the facilitator


Bring up this section divider slide.

## Slide 4: Why use the IFPMA Decision-Making Framework?

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### Why use the IFPMA Decision-Making Framework?


In an increasingly complex and ever-changing environment, the path forward is not always clear.



**The IFPMA Decision-Making Framework:**

- Enables decision-making when faced with complex, ambiguous, or novel circumstances or ethical dilemmas
- Enhances and supports proactive risk management
- Integrates compliance with ethical considerations
- Encourages ongoing business engagement and accountability
- Fosters a culture of integrity and ethical decision-making

Decision-making that integrates **compliance, integrity, and ethical considerations** into day-to-day business activities **bolsters patient and public trust**, which are **essential for innovation** and **critical to partnerships** and interactions with patients, HCPs, HCOs, third parties, peer companies, the industry, and society.



### Note to the facilitator

Before showing this slide, ask the attendees if they recently worked or are currently working on any innovative or complex projects where competing interests were at play, laws or policies don't exist, or if they have otherwise recently struggled with a business activity that lacked clear guidance or presented ethical challenges. Ask them to share what obstacles they had to navigate to determine a path forward and to consider whether they would have benefited from guidance or a structured approach to make decisions in those circumstances. If so, what might that guidance/approach look like?

### Talking points

The innovative pharmaceutical industry bears an enormous responsibility to address patient needs, improve societal well-being and public health, and advance scientific innovation. Our license to operate and our ability to advance as an industry can only be realized when we have the public's trust. The industry earns and sustains that trust by engaging in fair, respectful, honest, and thoughtful business practices.

Of course, we know that we must comply with all relevant laws, regulations, and policies that govern our activities. That's non-negotiable, and it is only the minimum standard we should consider. Given our complex and ever-changing environment, there are times when guidance doesn't exist, or the rules of the road are not clear. Making a business decision under these circumstances is often challenging. In these situations, we must be able to make business decisions responsibly, despite that lack of clear guidance, while ensuring that we balance societal interests and business objectives.

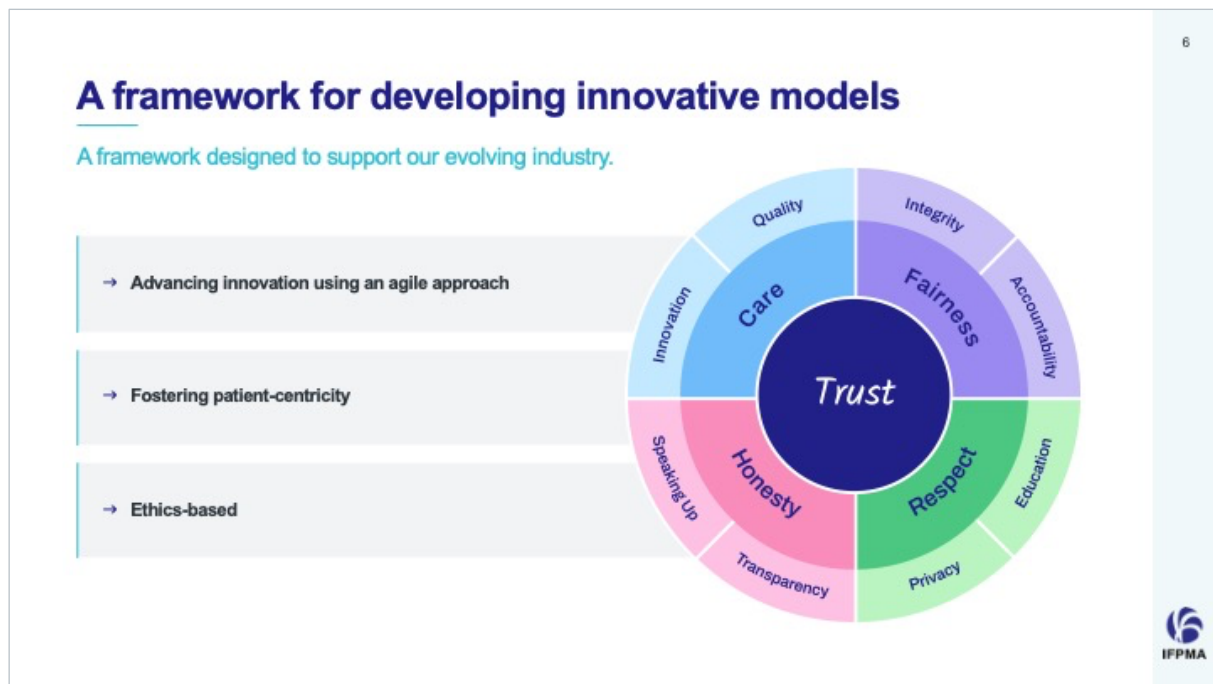


The IFPMA Decision-Making Framework, or “DMF” provides a Five-Phase approach to seamlessly integrate business objectives and ethical consideration into day-to-day business decisions. The Framework:

- Enables effective decision-making, even when we are faced with ambiguous or novel circumstances
- Enhances and supports proactive risk management
- Integrates compliance and ethical considerations
- Encourages ongoing business engagement and accountability
- Fosters a culture of integrity.

Decision-making that integrates business and ethics into day-to-day business activities bolsters patient and public trust, which is essential for innovation and critical interactions with patients, healthcare professionals (HCPs), healthcare organizations (HCOs), third parties, peer companies, the industry, and society.

## Slide 5: A framework for developing innovative models



### Talking points

Our industry is evolving quickly to advance innovation and better serve patient needs. We need to think ahead and prepare for new ways of working and meeting our commitment to society.

We know the risks we face today. For example, Anti-bribery/Anti-corruption, off-label promotion, conflicts of interest, data privacy, money laundering, transparency requirements, trade association interactions, antitrust, and competition. We don't know, however, how these risks will change over time, nor do we know what our future risks will be and how to navigate them.

In addition, our industry will be expected to evolve and make key contributions in areas such as market access and development, digital healthcare solutions, patient assistance and support programs, universal healthcare, and more. We will likely be navigating new territory without a roadmap.

As risks evolve, and as the expectations of our industry advance, we will inevitably be required to make decisions in the absence of clear rules, guidelines, or precedent, where the “right” thing to do may not be easy to determine. Examples include:

- Implementing new business practices and technologies to sell products
- Managing new ways of communicating with HCPs and patients
- Addressing conflicting obligations, including situations where more than one ethical obligation may be at play
- Addressing evolving stakeholder needs and expectations, such as changes to society's expectations of pharmaceutical companies or businesses/corporations in general
- Business activities with elevated or unique risks for life sciences companies, including complex promotional interactions where off-label promotion is a concern, financial relationships with HCPs and other decision-makers, interactions with potential government officials, patient privacy, and more.



No matter the area or activity, we will benefit from a decision-making framework that provides a step-by-step approach to assess new and innovative business models and make decisions that are patient-centric and Ethos-based.

**Note to the facilitator**

Ask the attendees to again consider their recent projects that lacked clear guidance or presented conflicting obligations. You may want to ask them to share their best practices to address these situations. Observe whether they share any best practices that align to the Five-Phase Framework which will be covered on the next few slides.

## Slide 6: Why is the Decision-Making Framework important?

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### Why is the Decision-Making Framework important?

Five steps to navigate decision-making flow to balance patient needs and expectations of the medical community, society, and regulators with business objectives.

**1. Why?**  
Identify and evaluate

**2. Who?**  
Define accountability and responsibility

**3. What?**  
Determine and decide

**4. How?**  
Execute and implement

**5. Impact**  
Monitor and control

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 (HCPs), healthcare organizations (HCOs), 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](#).

**IFPMA Ethos**

### Talking points

To assist us with decision-making, IFPMA developed a Five-Phase process to navigate the decision-making flow. The Framework is rooted in IFPMA's Ethos or value system and integrates ethical considerations into the decision-making process.

## Slide 7: Ethos in Action guiding questions



### Talking points

Before we get to the Framework itself, let's briefly dive a little deeper into the IFPMA Ethos, which is based on four core values:

- **Care:** We protect the safety of those who use our products – from the conduct of clinical trials through the product lifecycle.
- **Fairness:** We support and respect fair trade practices and open competition.
- **Respect:** We respect all people and embrace a culture of diversity and inclusion. We protect the environment and treat animals under our care responsibly.
- **Honesty:** We ensure truthful and balanced communication with governmental authorities, healthcare professionals, patients, and other stakeholders.

Our organization's own value system is aligned to the IFPMA Ethos, and we can therefore leverage and/or adapt the DMF to help us make decisions here.

### Note to the facilitator

To create interaction, ask the participants to share the company's own values. As a follow up question, ask the audience to explain how the company's values align to the IFPMA Ethos – Care, Fairness, Respect, and Honesty.

You'll notice that the Ethos in Action Guiding Questions are designed to help us think about the big picture. We need to consider a) what our moral obligations are to patients and to society, and b) how we can appropriately and responsibly deliver on our business objectives in a way that honors those moral obligations. For example,

- How do we play our part in helping solve societal challenges?
- How do we ensure patients are first in everything we do?
- What are the legitimate needs for patients, healthcare providers, and society that we intend to meet?
- How do we ensure that we move “as fast as we can, but as slow as we must”?
- How do we ensure that we do what is right, even when no one is watching?
- How do we design our processes to make it easier to do what’s right (and harder to do what’s wrong)?
- Through what measures do we hold ourselves and our partners accountable?
- Through what measures do we ensure and display our appreciation of the value of diversity?

Implicit in IFPMA’s Ethos, and connected to all four values, is our ethical responsibility to be aware of and address unconscious bias to reduce its influence on our business decisions and our ability to serve all patients around the world. Biases can create “decision blind spots,” leading to flawed and sometimes unethical decisions without us realizing.

There are many types of unconscious bias that can manifest in the workplace. These can range from stereotyping biases, such as gender or age, to cognitive biases that affect our decision-making, such as status quo bias or groupthink. When it comes to ethical judgement, a particularly prevalent bias to be aware of is moral blindness. This is our ability to conveniently overlook uncomfortable, unethical truths when they contradict our own self-interest.

While it may not be possible to avoid biases altogether, there are techniques we can use to improve our odds of making better, more ethical decisions. An effective strategy to reduce our susceptibility to biased decision-making is to pause and reflect on why and how we’re making a decision, and to follow a decision-making framework, like the IFPMA’s DMF.

For example, for the specific cognitive biases mentioned above, we can systematically ask ourselves:

- Are we only seeing what we want to see? Is there contradictory information that we are ignoring or too easily disregarding? (Moral blindness)
- Are we opting to do something just because “it’s how it’s always been done?” (Status quo bias)
- Are we making a decision just because we want to agree with the group? Are we afraid of disagreeing? (Groupthink)

While we do not intend to explore unconscious bias in detail during this session, it is important to ensure that we know what unconscious bias is and recognize we can all be prone to it affecting our judgement.

When we integrate these guiding questions and considerations into our decision-making process for discrete business activities or initiatives, we ensure that our values and business purpose are aligned. This, in turn, helps us make sound decisions that meet our business objectives, patient needs, and expectations of the medical community, society, and regulators.


**Note to the facilitator**

You may want to refer workshop attendees to your company's internal resources relating to unconscious bias, where appropriate.

## Slide 8: Decision-Making flow summary

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Decision-making flow summary	
Phase	Steps
1. Why Identify and evaluate	<ul style="list-style-type: none"> <li>What is the rationale and purpose for conducting an activity?</li> <li>Are patients first in the decision? Will the activity address patients' unmet needs? Have we considered their safety and well-being?</li> <li>Will the activity address other stakeholders' needs (e.g., healthcare professionals)?</li> <li>Is the activity proportional to the identified needs?</li> <li>Have we identified the risks?</li> <li>Could there be a perception of wrong intent by patients, regulators etc. if we go ahead with the activity?</li> <li>Is the timing right for this activity (e.g., use of the data and/or a new technology)?</li> <li>What are the issues or challenges to be addressed? Do we have all the information we need?</li> <li>Have we assessed potential impact on stakeholders and identified data sources contributing to this assessment?</li> </ul>
2. Who Define accountability and responsibility	<ul style="list-style-type: none"> <li>Who is the decision-maker?</li> <li>Who is the owner of the activity?</li> <li>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?</li> <li>When using new technology, how do we ensure we maintain human accountability and build in monitoring and feedback loops?</li> <li>What are the capabilities required by the individuals/teams who will assess, monitor risks, and implement the solution?</li> </ul>
3. What Determine and decide	<ul style="list-style-type: none"> <li>Have we considered the option of NO GO (not moving forward with the proposal)?</li> <li>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?</li> <li>Would we be comfortable to discuss the activity with our family, or the public?</li> <li>Are all stakeholders informed and empowered to speak up and raise any potential challenge?</li> <li>Did we minimize risk and conclude that potential benefits exceed potential risks?</li> <li>Did we value diversity and distribute risk and benefit fairly?</li> <li>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.</li> </ul>
4. How Execute and implement	<ul style="list-style-type: none"> <li>Is the solution compliant with applicable laws and regulations and with the organization's policies?</li> <li>Is the action fair, the "right" thing to do? Consider the public perception if made public.</li> <li>What are the detailed action plans, timelines, deliverables for each team member at each stage of the project (before, during, and after)?</li> <li>What are the available feedback mechanisms to stakeholders and the end-users and how do we propose to handle the feedback?</li> <li>What are the total and detailed costs and payment terms based on deliverables?</li> </ul>
5. Impact Monitor and control	<ul style="list-style-type: none"> <li>What are the key success factors of the project?</li> <li>Have we planned to notify / report to appropriate persons (open and transparent communication, disclosure of potential issues)?</li> <li>Have we aligned measurements (KPIs) with objectives and deliverables?</li> <li>Ensure an appropriate owner of these factors/KPIs is assigned.</li> <li>Set up reporting and financial controls on costs and monitor the effects of decisions/project, adjust actions to new information as necessary.</li> </ul>



## Talking points

Now, let's talk about the Five-Phase Framework.

IFPMA has come up with a Five-Phase Decision-Making Framework, or DMF. The DMF includes guidance around key process steps and incorporates the Ethos-based questions for consideration at each phase of the decision-making flow.

### Phase 1. Identify and evaluate

The questions in Phase 1 are designed to help us identify issues and evaluate the risks. Here we are trying to determine the following:

- What are the ethical issues, risks, or challenges to address?
- What do laws, regulations, and our policies say that may inform our decision?
- Is this an innovative or evolving area where policies or the law may be grey?

It is critically important in this phase to:

- Assess the business rationale and purpose for conducting an activity
- Evaluate whether the activity will address the stakeholder's needs (e.g., HCPs, patients) and have the desired impact
- Identify challenges and whether additional information is needed to make an informed decision.

As we work through Phase 1, we must examine these issues in the context of our responsibility to a) appropriately care for patients and prioritize legitimate patient needs, b) operate fairly and honestly to earn societal trust, and c) understand the potential impact of our decisions (whether



on people, animals, the environment, society at large) and address that impact responsibly and respectfully.

### Phase 2. Define accountability and responsibility

The goal in Phase 2 is to define accountabilities and responsibilities so that decisions can be made by the appropriate parties with the appropriate inputs. The nature of the accountable party should match the objective. In this phase, it's important to consider cross-functional inputs and interdependencies. By defining roles and responsibilities, decision-making will likely be faster, as it will be clear from the onset who is doing what.

### Phase 3. Determine and decide

In Phase 3, we begin to evaluate potential solutions and make decisions around which solution meets the need or resolves the issue while honouring our Ethos.

### Phase 4. Execute and implement

In Phase 4, we focus on executing and implementing our activities in an appropriate manner. We must adhere to all laws, regulations, codes, and procedures – that's a given. How we get things done is as important as what we get one. Throughout the execution and implementation phase, we must continue to assess whether our activities are the right thing to do, whether they will be perceived as the right thing to do by our stakeholders, and whether changing circumstances require us to modify our plans.

### Phase 5. Monitor and control

Finally, Phase 5 requires us to monitor our approach and evaluate whether our business goals are achieved and whether they adequately and appropriately address the ethical issues and obligations we've identified. If not, we must consider what else can be done to ensure that our actions meet the business objectives while meeting our ethical obligations to our stakeholders. By measuring impact, we can more quickly decide whether an initiative is working or not.

As you can see, the DMF provides step-by-step guidance, enabling us to make business decisions, advance innovative business models, and behave with integrity no matter how challenging or ambiguous the circumstances.

Let's pause here for some questions. Please know that if you are not comfortable sharing in this forum, you can reach out to me directly after this session and we can set up time to talk.

#### Note to the facilitator

Allow the audience to time to collect their thoughts and speak up. If there are no questions or comments, proceed to the case studies.

## Slide 9: Case study exercises

### Case studies

Putting decision-making to work



#### Note to the facilitator

Bring up this section divider slide.

## Slide 10: Case studies intro

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### Putting decision-making to work

#### Case study exercise

The purpose of the case studies is to use IFPMA Decision-Making Framework to identify and discuss complex, innovative, or "grey areas" and develop proposals that balance competing needs and obligations and ensure our decisions are consistent with the IFPMA Ethos.

 **Use slides 14 – 18 of the Background deck to guide the approach**

#### How to use the case studies?

The case studies are intended to facilitate cross-functional discussion. You do not need to solve the case. Use the Decision-Making Framework to discuss the impact of the different scenarios.

#### Adaptation and localization

The case studies provided are general fictitious examples for the purpose of discussion only. Local adaptation of the facts of each case study scenario might be needed to suit local market conditions and to ensure adherence to local laws, regulations, and industry codes.

Disclaimer: These case studies are purely fictitious examples for the purposes of discussion. IFPMA does not endorse any of the views or scenarios in these case studies. All related compliance guidance should always be subject to applicable local laws, regulations, and industry codes.



### Talking points

Now we're going to use case studies to put our DMF to work. Our goal is to use the DMF to navigate situations that are new, lack clear guidance, and where it may be difficult to figure out the "right" path forward. I expect that you will find these case studies relevant, given current industry trends. We may only have time for one or two case studies. We want these discussions to be interactive and as inclusive as possible. Please feel free to ask questions, share thoughts, and propose ideas along the way.

Note that the case studies are purely fictitious examples for purposes of discussion. IFPMA does not endorse any of the views or scenarios in these case studies. As we work through these case studies, **let's remember that any decisions we make at our organization should and will be subject to applicable local laws, regulations, and industry codes.**

**Note to the facilitator**

This workshop can be customized to include 1-4 case studies, depending on the time you have available and the audience's needs. Please review the available options and select the case studies of greatest relevance for your team. Bring up this slide and advise the attendees that the first case study will explore telemedicine (or whichever case study you select).

Importantly, these case studies are general fictitious examples for the purpose of discussion only. Local adaptation of the facts of each case study scenario might be needed to suit local market conditions and to ensure adherence to local laws, regulations, and industry codes.

You may also wish to consider using a real situation that you are currently trying to remedy at your company, as this may be the most impactful way to bring the DMF to life.

## Slide 11: Case studies summaries

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### Case study summaries

 <p><b>Case study 1</b> <b>Telemedicine</b> Innovative opportunities</p> <p>New, innovative business models and technologies such as telemedicine can present significant opportunities as well as new dilemmas related to appropriate HCP interactions.</p>	 <p><b>Case study 2</b> <b>Market development</b> Innovative opportunities</p> <p>Entering a new therapy for a chronic disease and expanding an existing one presents a lot of new business opportunities but also gives rise to new challenges related to interactions with HCP, HCOs, and patients.</p>	 <p><b>Case study 3</b> <b>Industry associations</b> Hiring with integrity</p> <p>Some association activities, such as hiring for policy-related positions, can pose significant risks that need to be mitigated, including potential conflicts of interest and reputational harm.</p>	 <p><b>Case study 4</b> <b>Artificial intelligence</b> Innovating ethically</p> <p>Entering the realm of artificial intelligence (AI) entails navigating the landscape of AI-related risks and harms. To mitigate them, it is crucial to adopt a decision-making framework that embeds ethics and integrity.</p>
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### Note to the facilitator

Bring up this overview slide and let the audience read the different case study scenarios that will be covered. Note this slide is optional if only one or two case studies will be covered in the session.


## Slide 12: Telemedicine: Innovative opportunities

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### Telemedicine Innovative opportunities

Case study 1



### Note to the facilitator

Bring up this introductory case study slide.



## Slide 13: Telemedicine: Background

Case study 1

Telemedicine Innovative opportunities

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### 1. Background

To pursue growth opportunities outside of the traditional pharmaceuticals space, **your company is looking into a potential role in telemedicine**. Telemedicine is a rapidly growing opportunity driven by changes in technology and patient and provider preferences.

In assessing this opportunity, your team is **investigating potential business model options**. One option currently being discussed involves the following:

**Your company would provide selected HCPs with hardware (iPads) and software** (free licenses to telemedicine video conferencing software) in exchange for collecting blinded patient diagnosis and prescription data through the platform.

**Your company would also provide these HCPs with company-developed software that assists HCPs with diagnosis and treatment decision-making.** The software uses AI to analyze the video, audio, and HCP notes from the telemedicine visit and recommends potential diagnoses and treatment options. While the software is designed to provide unbiased recommendations, its AI was trained in part with proprietary company data.



### Note to the facilitator

Allow the attendees to read the information on this slide or ask someone to read the case study aloud.

## Slide 14: Telemedicine: Considerations

Case study 1

Telemedicine Innovative opportunities


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### 2. Considerations

There are few guidelines or regulations in this space, and competitors have not yet adopted similar approaches. Your team should assess and balance the commercial and ethical considerations prior to making a formal recommendation to leadership.

Consider how your answers and reflections would change in the following circumstances:

- What if different stakeholders are potentially provided hardware/software to support the telemedicine, for example, patients, HCPs, hospitals, medical practices, and other providers? Does this impact the decisions or risk management?
- Local legal/regulatory considerations may impact the decision or local industry guidance exists on telemedicine that may impact the preferred approach (including potential near-term changes or regulations). What legal changes or advocacy may be needed for the group's approach to be viable (e.g., industry, company, digital, stakeholder engagement)?
- Are there different implications due to the country medical insurance/reimbursement system (e.g., public, private)?



### Note to the facilitator

Allow the attendees to read the information on this slide or ask someone to read the case study aloud.

## Slide 15: Telemedicine: Applying the Decision-Making Framework

Case study 1


Telemedicine Innovative opportunities

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### 3. Applying the Decision-Making Framework

A non-exhaustive list of questions to support decision-making:

<b>1. Why</b> Identify and evaluate	<ul style="list-style-type: none"> <li>What are the legitimate business needs and the business objectives you are trying to achieve?</li> <li>Are we respecting patients and protecting their privacy rights?</li> <li>Was the IA algorithm designed ethically, avoiding biases and without creating any potential discrimination?</li> <li>Was patient safety top of mind?</li> <li>How would the society perceive these initiatives?</li> <li>Do these initiatives help to build trust with the society?</li> </ul>
<b>2. Who</b> Define accountability and responsibility	<ul style="list-style-type: none"> <li>Discuss various roles and responsibilities.</li> <li>If cross-functional, which department owns which activity?</li> </ul>
<b>3. What</b> Determine and decide	<ul style="list-style-type: none"> <li>What are the key ethical and risk management areas for consideration and related mitigation actions?</li> <li>If several options could be considered, what decision will best satisfy the rationale and purpose identified and reflect business decision-making?</li> <li>Are there other external developments on the horizon that may impact the decision and should be considered?</li> </ul>
<b>4. How</b> Execute and implement	<ul style="list-style-type: none"> <li>What are the existing laws and codes to be considered?</li> <li>In light of applicable laws, codes, and industry guidelines, is the initiative permitted?</li> <li>Is it appropriate to provide these benefits to individual HCPs?</li> <li>Is the execution and implementation strategy sustainable?</li> </ul>
<b>5. Impact</b> Monitor and control	<ul style="list-style-type: none"> <li>Describe what the key success factors would look like.</li> <li>Are measurements (KPIs) aligned with objectives and deliverables?</li> <li>How would these success factors be viewed by stakeholders?</li> <li>Are there significant financial controls required and what are the costs to support effective controls (e.g., monitor the effects of decisions/project)?</li> </ul>


  
IFPMA

### Talking points

Let's apply our DMF to this situation.

#### 1. Why: Identify and evaluate

Let's begin with Phase 1, Why: Identify and evaluate. What are the issues here? Who wants to start?

#### Note to the facilitator

Allow the audience time to think and share their thoughts. Depending on their responses, you may want to supplement their responses with the following:

The following is a non-exhaustive list of questions to consider when using the DMF to support decision-making:

- What are the legitimate business needs and the business objectives we are trying to achieve?
- Are we respecting patients and protecting their privacy rights?
- Was the AI algorithm designed ethically, avoiding biases, and without creating any potential discrimination?
- Was patient safety top of mind?
- How would society perceive these initiatives?
- Do these initiatives help to build trust with society?

Potential issues include:

- Providing items of value to HCPs
- Determining how to select HCPs who receive free items – could our selection criteria be perceived as a reward or inducement?
- Issues related to collecting patient data, such as HIPAA considerations, GDPR, and other data protection rules
- Whether company-created software interferes with the doctor/patient relationship
- Whether company-created software could make incorrect diagnoses
- Whether company-created software biases treatment toward company-created medicines
- Perception risk – potential that patients may not trust medical decisions due to HCPs' arrangement with the pharmaceutical industry
- Whether competing stakeholder motivations could lead to moral blindness.

I think we have identified the key issues.

Let's take a moment to identify the impact on stakeholders. Does anyone have any thoughts on who the stakeholders are here and what the impact to them could be?

#### **Note to the facilitator**

Allow the audience time to think and share their thoughts. Depending on their responses, you may want to supplement their responses with the following:

Potential impact to stakeholders includes:

- Patients who are treated using this new telemedicine approach and those patients who are less digitally able or have limited digital access
- HCPs who may change their clinical behavior/prescribing activity due to the arrangement
- Hospitals, medical practices, and other HCP employers who need to determine how to respond/operationalize this telemedicine model
- Company shareholders who may financially benefit or suffer based on the outcome of this approach.

#### **Note to the facilitator**

Allow the audience time to think and share their thoughts, then proceed to a discussion of Phase 2.

## 2. Who: Define accountability and responsibility

Let's move on to Phase 2, Who: Define accountability and responsibility. Who would the accountable decision-maker be? Who would be the project owner? What functions/departments would need to be involved, why, and what activities would they own?

### Note to the facilitator

Allow the audience time to think and share their thoughts. You may want to supplement their responses with the following:

Remember, Phase 2 of the DMF is designed to drive efficient decision-making by clearly defining roles and responsibilities and ensuring that we include cross-functional insights and manage cross-functional interdependencies.

Of course, this phase, like every phase in the DMF, requires us to consider our Ethos in Action Guiding Questions.

- **Care:** What are our obligations related to patient health? What are our obligations to support the integrity of the doctor / patient relationship?
- **Fairness:** What measures are we using to hold ourselves and our partners accountable? How does this impact our competition?
- **Respect:** What are we doing to help ensure respect for privacy rights, given that new patient data would be collected? Through what measures do we ensure and display our appreciation of the value of diversity?
- **Honesty:** 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?

As we think through our Ethos in Action Guiding questions, we will likely want to evaluate the need for additional cross functional inputs and incorporate interdependencies into our planning.

## 3. What: Determine and decide

Let's now move to Phase 3: What: Determine and decide. Some key questions here include:

- What are the key ethical and risk management areas for consideration and related mitigation actions?
- If several options could be considered, what decision will best satisfy the rationale and purpose identified, and reflect ethical decision-making?
- Are there other external developments on the horizon that may impact the decision and should be considered?
- Finally, why does it matter that we get this right and what happens if we get it wrong?

### Note to the facilitator

Allow the audience to share their thoughts on how the organization's values might influence the business decision and customize the below talking points accordingly.

When deciding on options and solutions, it's important to bear in mind the following:

- Patient health may be impacted if our software produces incorrect diagnoses or treatment recommendations.
- Our company's reputation can be harmed if we don't protect patient safety and patient information appropriately.
- The reputation of our industry can be harmed if we are perceived as influencing treatment or prescribing decisions.
- "Getting it right" aligns with our values, industry standards, and our commitment to patients.
- "Getting it right" may position us well to comply with upcoming regulations in this area.

### 4. How: Execute and implement

Let's now think a bit about Phase 4, How: Execute and implement. A few questions to be considered in Phase 4 are:

- What are the existing laws and codes to be considered?
- In light of applicable laws, codes, and industry guidelines, is the initiative permitted?
- Is it appropriate to provide these benefits to individual HCPs?
- Is the execution and implementation strategy sustainable?

As the project progresses and you hit potential roadblocks, consider what changes would need to be made to make the approach viable (e.g., industry support, leadership support, digital solutions, increased/different stakeholder engagement)?

- Are there any opportunities to innovate, appropriately collaborate and partner, or advocate?
- How can potential risks be managed?
- List project activities and milestones, including detailed descriptions, timelines, and deliverables
- Implement training and communications as needed
- Explain total and detailed costs and payment terms based on deliverables.

### 5. Impact: Monitor and control

Finally, Phase 5: Monitor and control.

- Document all decision-making steps and details of the activity to maintain a record.
- Ensure open and transparent communication, disclose potential issues to the appropriate people.




- Describe the key success factors and align measurements (Key Performance Indicators or “KPIs”) with objectives and deliverables. We must make sure we assign ownership of the KPIs.
- Set up reporting and financial controls on costs and monitor the effects of decisions/project, adjust actions to new information as necessary.
- A few Ethos in Action Guiding Questions for consideration during the monitor and control phase include:
  - **Honesty:** How are we ensuring transparency throughout our activities and processes, both internally and externally?
  - **Honesty:** How are we learning from mistakes as well as best practices and communicating these within the organization?
  - **Fairness:** How do we ensure that we treat our third parties, customers, and stakeholders fairly?

Let's pause here for some questions. If you are not comfortable sharing in this forum, please reach out to me directly and we can set up time to talk.

#### Note to the facilitator

Allow the audience time to collect their thoughts and speak up. If there are no questions or comments, proceed to the next case study.

## Slide 16: Market development: Innovative opportunities



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### Market development Innovative opportunities

Case study 2



### Talking points

Let's move on to our second case study.

## Slide 17: Market development: Background

Case study 2

Market development innovative opportunities

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### 1. Background


Your company is entering a **new therapy for a chronic disease where there have previously been no treatment options available**. This means that the market will need to be developed to increase patient awareness of the disease and to train healthcare professionals in providing quality of care with the new treatment option your company has developed that is currently in phase 3 of clinical trials.

**Your team is investigating potential development strategy and tactics for this area.** The options currently being discussed include:

**Your company would run company driven medical education events for the top disease specialists.** Attendees would be invited to discuss the phase 3 results of your company's clinical trials. The new treatment option is not yet approved but there are no competitors in this therapy area and the results are so good, your team is sure it will be approved soon so why wait!

**Your local affiliates will work with local patient associations to run a social media campaign for patients on disease awareness.** As part of this campaign, you will highlight that a new treatment option is on the way, and that patients should ask their doctor about it.

**As part of the social media disease awareness campaign, patients will be asked to share their personal experiences of living with the disease in a Facebook group.** Your team will use these testimonials as part of the brand campaign to make sure they take into account the patient experience.



### Note to the facilitator

Allow the audience time to collect their thoughts and speak up. If there are no questions or comments, proceed to the next case study.

## Slide 18: Market development: Considerations

Case study 2

Market development innovative opportunities


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### 2. Considerations

You should assess and balance the commercial and ethical considerations prior to making a formal recommendation to leadership about the suggested development strategy and tactics.

**Consider how your answers and reflections would change in the following circumstances:**

- What if a competitor entered the therapy area with a new but unapproved product?
- What if a competitor product was already approved and available?
- What difference would it make (if any) if other treatment options existed?
- What if the company decides to run the disease awareness campaign by itself - are there other things you will need to take into account?
- What if your company's new treatment option (which is the only one available) is approved but not available via the public healthcare systems or public reimbursement lists? What additional elements do you need to think about?
- Would you use social media as a tool in disease awareness in the same way if the chronic disease only affected adolescents? Or children?



### Note to the facilitator

Allow the attendees to read the information on this slide or ask someone to read the case study aloud.

## Slide 19: Market development: Applying the Decision-Making Framework

Case study 2


Market development innovative opportunities

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### 3. Applying the Decision-Making Framework

A non-exhaustive list of questions to support decision-making:

<b>1. Why</b> Identify and evaluate	<ul style="list-style-type: none"> <li>What are the legitimate business needs and the business objectives we are trying to achieve?</li> <li>Could these initiatives be or be perceived as pre-approval promotion/promotion to the public?</li> <li>Are you respecting patients and their disease?</li> <li>Is it ethical to make patients aware of a treatment option knowing that it might only be available on the private market?</li> <li>Is it responsible to use social media to conduct disease awareness activities towards children and adolescents?</li> <li>What are the implications of using patient testimonials in brand campaigns? Does the answer change if the patients are children?</li> <li>How do you approach issues of affordability and patient access in these circumstances?</li> <li>How would the society perceive these initiatives?</li> </ul>
<b>2. Who</b> Define accountability and responsibility	<ul style="list-style-type: none"> <li>Discuss various roles and responsibilities.</li> <li>If cross-functional, which department owns which activity?</li> <li>What is the appropriate function to run these activities based on roles and responsibilities (medical versus commercial)?</li> </ul>
<b>3. What</b> Determine and decide	<ul style="list-style-type: none"> <li>What are the key ethical and risk management areas for consideration and related mitigation actions?</li> <li>If several options could be considered, what decision will best satisfy the rationale and purpose identified and reflect business decision-making?</li> <li>Are there other external developments on the horizon that may impact the decision and should be considered?</li> </ul>
<b>4. How</b> Execute and implement	<ul style="list-style-type: none"> <li>What are the existing laws and codes to be considered?</li> <li>In light of applicable laws, codes, and industry guidelines, is the initiative permitted?</li> <li>Is it appropriate to provide these benefits to individual HCPs?</li> <li>Is the execution and implementation strategy sustainable?</li> <li>How do we ensure that we move "as fast as we can, but as slow as we must?"</li> </ul>
<b>5. Impact</b> Monitor and control	<ul style="list-style-type: none"> <li>Describe what the key success factors would look like.</li> <li>Are measurements (KPIs) aligned with objectives and deliverables?</li> <li>How would these success factors be viewed by stakeholders?</li> <li>Are there significant financial controls required and what are the costs to support effective controls (e.g., monitor the effects of decisions/project)?</li> </ul>



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### Note to the facilitator

Read the questions on this slide aloud. You may wish to focus on a subset of these questions, depending on the audience's needs and time available.

### Talking points

Let's apply our DMF to this situation.

#### 1. Why: Identify and evaluate

Let's begin with Phase 1, Why: Identify and evaluate. What are the issues here? Who wants to start?

### Note to the facilitator

Allow the audience time to think and share their thoughts. Depending on their responses, you may want to supplement their responses with the following:

Here are some questions to get us started:

- What are the legitimate business needs and the business objectives we are trying to achieve?

- Could these initiatives be or be perceived as pre-approval promotion/promotion to the public?
- Are we respecting patients and their disease?
- Is it ethical to make patients aware of a treatment option knowing that it might only be available on the private market?
- Is it responsible to use social media to conduct disease awareness activities towards children and adolescents?
- What are the implications of using patient testimonials in brand campaigns? Does the answer change if the patients are children?
- How do we approach issues of affordability and patient access in these circumstances?
- How would the society perceive these initiatives?

Additional questions may be:

- Are there competing motivations for the stakeholders involved? How could these lead to moral blindness?
- How do we make sure that any scientific information presented on our new company product is fair and balanced if there are no alternative treatment options?

## 2. Who: Define accountability and responsibility

Let's move on to Phase 2, Who: Define accountability and responsibility. Who would the accountable decision-maker be? Who would be the project owner? What functions/departments would need to be involved, why, and what activities would they own?

### Note to the facilitator

Allow the audience time to think and share their thoughts. You may want to supplement their responses with the following:

Remember, Phase 2 of the DMF is designed to drive efficient decision-making by clearly defining roles and responsibilities and ensuring that we include cross-functional insights and manage cross-functional interdependencies.

## 3. What: Determine and decide

Let's now move to Phase 3: What: Determine and decide.

- What are the key ethical and risk management areas for consideration and related mitigation actions?
- If several options could be considered, what decision will best satisfy the rationale and purpose identified and reflect ethical decision-making?
- Are there other external developments on the horizon that may impact the decision and should be considered?
- Finally, why does it matter that we get this right and what happens if we get it wrong?

### Note to the facilitator

Allow the audience to share their thoughts on how the organization's values and mission might influence the business decision and customize your talking points accordingly.

When deciding on options and solutions, let's consider the following:

- What if phase 4 trial results raise safety concerns?
- What if our new therapy is not approved?

### 4. How: Execute and implement

Let's now think a bit about Phase 4, How: Execute and implement. A few questions to be considered in Phase 4 are:

- What are the existing laws and codes to be considered?
- In light of applicable laws, codes, and industry guidelines, is the initiative permitted?
- Is the execution and implementation strategy sustainable?

As the project progresses and we hit potential roadblocks, consider what changes would need to be made to make the approach viable (e.g. industry support, leadership support, digital solutions, increased/different stakeholder engagement)?

- Are there any opportunities to innovate, appropriately collaborate, or advocate?
- How can potential risks be managed?
- In this phase, we would list project activities and milestones, including detailed descriptions, timelines, and deliverables.
- We must remember to implement training and communications as needed.
- We will need to be sure to explain total and detailed costs and payment terms based on deliverables.

### 5. Impact: Monitor and control

Finally, Phase 5: Monitor and control. In this phase, we...

- Document all decision-making steps and details of the activity to maintain a record.
- Ensure open and transparent communication, disclose potential issues to the appropriate people.
- Describe the key success factors and align measurements (Key Performance Indicators or "KPIs") with objectives and deliverables. We must make sure we assign ownership of the KPIs.
- Set up reporting and financial controls on costs and monitor the effects of decisions/project, adjust actions to new information as necessary.

A few Ethos in Action Guiding Questions for consideration during the monitor and control phase include:



- **Honesty:** How are we ensuring transparency throughout our activities and processes, both internally and externally?
- **Honesty:** How are we learning from mistakes as well as best practices and communicating these within the organization?
- **Fairness:** How do we ensure that we treat our third parties, customers, and stakeholders fairly?

## Slide 20: Industry associations: Hiring with integrity



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### Industry associations Hiring with integrity

Case study 3



### Talking points

Let's move on to our next case study.

## Slide 21: Industry associations: Background

Case study 3

Industry associations Hiring with integrity

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### 1. Background

Your Pharmaceutical Industry Association ("Association") is currently **undergoing a hiring process**, as there is an open full-time position for the Director of Public Affairs role. As the Executive Director of the Regulatory & Science Committee within the Association, you are part of the election panel.


Multiple applicants were screened, and the **hiring process is close to final stage**, with the three top candidates going through the defining election panel interviews with the Board Members in about a month.

The **Regulatory & Science Committee raises a last-minute recommendation** to hire a well-recognized consultant, whose vast professional experience would perfectly fit the needs for the role and who would be ready to start immediately. The candidate currently advises the government on public procurement decisions related to inclusion of new technologies. The **Association is invited to an important upcoming public Working Group meeting** regarding the dialogue on procurement policies with government authorities and other industry stakeholders. The meeting is critical in advancing the Association's priorities, and the new Director of Public Affairs would play a pivotal role at the meeting, representing the Association.

A **recommendation** needs to be made to the Board Members in terms of:

Hiring the candidate recommended by the internal Committee, who would be ready to start immediately.

Continuing with the current selection process and likely not having the position filled until after the meeting.



### Note to the facilitator

Allow the attendees to read the information on this slide or ask someone to read the case study aloud.

## Slide 22: Industry associations: Considerations

Case study 3

Industry associations Hiring with integrity


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### 2. Considerations

You should assess and balance the commercial and ethical considerations prior to making a formal recommendation to the Board.

**Consider how your answers and reflections would change in the following circumstances:**

- There is no upcoming meeting requiring the role to be filled immediately.
- The recommendation did not come from an internal Committee but instead from a headhunter that is aware of the Association's ongoing hiring process.
- A job offer was about to be released to a final candidate.
- Are there different implications if the candidate's governmental advisory role is official (i.e., is formally appointed) or unofficial (i.e., not formally appointed but consulted due to publicly known key expertise)?
- Are there different implications if the candidate's governmental advisory role is not related at all to the upcoming meeting topic and objectives?



### Note to the facilitator

Allow the attendees to read the information on this slide or ask someone to read the case study aloud.

## Slide 23: Industry associations: Applying the Decision-Making Framework

Case study 3


Industry associations Hiring with integrity

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### 3. Applying the Decision-Making Framework

A non-exhaustive list of questions to support decision-making:

<b>1. Why</b> Identify and evaluate	<ul style="list-style-type: none"> <li>What are the legitimate business needs and the business objectives you are trying to achieve?</li> <li>Do you have all the information you need to make a decision?</li> <li>How might hiring the consultant recommended by the Regulatory and Science Committee benefit the Association?</li> <li>How might hiring the consultant recommended by the Regulatory and Science Committee harm the Association?</li> <li>Are you being fair to the 3 top candidates?</li> <li>How does the upcoming public Working Group meeting impact your hiring decision? Should it have an impact?</li> </ul>
<b>2. Who</b> Define accountability and responsibility	<ul style="list-style-type: none"> <li>Discuss various roles and responsibilities.</li> <li>How is transparency throughout the activities and processes being ensured, both internally and externally?</li> <li>How are we enabling both internal and external stakeholders to speak up and raise potential ethical challenges?</li> <li>Through what measures throughout the hiring process do we ensure and display our appreciation of the value of diversity?</li> </ul>
<b>3. What</b> Determine and decide	<ul style="list-style-type: none"> <li>What are the key ethical and risk management areas for consideration and related mitigation actions?</li> <li>How does the IFPMA Ethos and Decision-Making Framework apply?</li> <li>If several options could be considered, what decision will best satisfy the rationale and purpose identified and reflect business decision-making?</li> <li>Are there external developments on the horizon that may impact the decision and should be considered?</li> <li>Why does it matter that we get this right and what happens if there are significant issues?</li> <li>How are we assessing reputational impact?</li> </ul>
<b>4. How</b> Execute and implement	<ul style="list-style-type: none"> <li>What are the existing applicable laws, regulations, codes, and internal procedures to be considered?</li> <li>How are we assessing the applicable laws, regulations, codes and internal procedures to help ensure compliance?</li> <li>In light of applicable laws, regulations codes, and internal procedures, is it appropriate to move forward?</li> <li>How do we ensure that we move "as fast as we can, but as slow as we must"?</li> </ul>
<b>5. Impact</b> Monitor and control	<ul style="list-style-type: none"> <li>Describe what the key success factors would look like.</li> <li>Are measurements (KPIs) aligned with objectives and deliverables?</li> <li>How would these success factors be viewed by stakeholders?</li> <li>How do we ensure that we treat our third parties, customers and stakeholders fairly?</li> </ul>


  
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### Note to the facilitator

Read the questions on this slide aloud. You may wish to focus on a subset of these questions, depending on the audience's needs and time available.

### Talking points

Let's apply our DMF to this situation.

#### 1. Why: Identify and evaluate

Let's begin with Phase 1, Why: Identify and evaluate. What are the issues here? Who wants to start?

### Note to the facilitator

Allow the audience time to think and share their thoughts. Depending on their responses, you may want to supplement their responses with the following:

Here are some questions to get us started:

- What are the legitimate business needs and the business objectives we are trying to achieve?
- Do we have all the information we need to make a decision?

- How might hiring the consultant recommended by the Regulatory and Science Committee benefit the Association?
- How might hiring the consultant recommended by the Regulatory and Science Committee harm the Association?
- Are we being fair to the three top candidates?
- How does the upcoming public Working Group meeting impact our hiring decision? Should it have an impact?

## 2. Who: Define accountability and responsibility

Let's move on to Phase 2, Who: Define accountability and responsibility. Remember, Phase 2 of the DMF is designed to drive efficiency decision-making by clearly defining roles and responsibilities and ensuring that we include cross-functional insights and incorporate cross-functional interdependencies into our planning.

A few questions we may want to consider here are as follows:

- How is transparency throughout the activities and processes being ensured, both internally and externally? Who is accountable for managing this?
- How are we enabling both internal and external stakeholders to speak up and raise potential ethical challenges? What role does each person involved play in encouraging stakeholders to speak up?
- Through what measures throughout the hiring process do we ensure and display our appreciation of the value of diversity? Who are the decision-makers?

## 3. What: Determine and decide

Let's now move to Phase 3: What: Determine and decide.

- What are the key ethical and risk management areas for consideration and related mitigation actions?
- If several options could be considered, what decision will best satisfy the rationale and purpose identified and reflect ethical decision-making?
- Are there other external developments on the horizon that may impact the decision and should be considered?
- Finally, why does it matter that we get this right and what happens if we get it wrong?

### Note to the facilitator

Allow the audience to share their thoughts on how the organization's values and mission might influence the business decision and customize your talking points accordingly.

## 4. How: Execute and implement

Let's now think a bit about Phase 4, How: Execute and implement. A few questions to be considered in Phase 4 are:

- What are the existing applicable laws, regulations, codes, and internal procedures to be considered?

- How are we assessing the applicable laws, regulations, codes, and internal procedures to help ensure compliance?
- In light of applicable laws, regulations codes, and internal procedures, is it appropriate to move forward?
- How do we ensure that we move “as fast as we can, but as slow as we must?”

## 5. Impact: Monitor and control

Finally, Phase 5: Monitor and control. In this phase, we...

- Document all decision-making steps and details of the activity to maintain a record.
- Ensure open and transparent communication, disclose potential issues to the appropriate people.
- Describe the key success factors and align measurements (Key Performance Indicators or “KPIs”) with objectives and deliverables. We must make sure we assign ownership of the KPIs.

A few Ethos in Action Guiding Questions for consideration during the monitor and control phase include:

- **Honesty:** How are we ensuring transparency throughout our activities and processes, both internally and externally?
- **Fairness:** How do we ensure that we treat our third parties, customers, and stakeholders fairly?
- **Fairness:** What are the legitimate needs for patients, healthcare providers, and society that we intend to meet?



## Slide 24: Artificial intelligence: Innovating ethically



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### Artificial intelligence Innovating ethically

Case study 4



### Talking points

Let's move on to our fourth case study.

## Slide 25: Artificial intelligence: Background

Case study 4

Artificial intelligence *Innovating ethically*

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### 1. Background


Imagine you are an Ethics & Compliance professional for a pharmaceutical company deeply committed to safeguarding patient data and upholding fundamental human rights. A major tech company has approached your organization with a proposal to extract personal healthcare data of patients for the development of an AI-based technology aimed at centralized medical record storage, real-time medical information, rapid and accurate diagnosis, and expanding access to healthcare.

The tech company assures that personal data of all patients shall remain anonymized and used solely for research and medical purposes. As a member of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), your company follows the IFPMA's Code of Practice and is aware of the recently launched Decision-Making Framework, which helps organizations put IFPMA ethical foundation into action.

Utilizing both the [Decision-Making Framework](#) and the [IFPMA Artificial Intelligence Principles](#), respond to the following question:

How would you respond to this proposition, keeping in mind the many instances of AI-enabled data breaches that occurred in the past, especially in the [pharmaceutical and biotechnology industry](#)?

What steps would you take to ensure ethical and responsible use of patient data while fostering innovation in healthcare technology?



### Note to the facilitator

Allow the audience time to collect their thoughts and speak up. If there are no questions or comments, proceed to the next case study.

## Slide 26: Artificial intelligence: Considerations

Case study 4 Artificial intelligence *Innovating ethically*

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### 2. Considerations

As is widely acknowledged, the AI space currently lacks globally agreed upon and comprehensive guidelines or regulations around its ethical use. With the increasing recognition of adopting a risk-based approach, as advocated by the [EU AI Act](#), your team should assess and balance the commercial and ethical considerations prior to making a formal recommendation to leadership.

**Consider the following AI-focused questions while applying the Decision-Making Framework:**

- Is the AI-based technology primarily focused on addressing societal needs, or does it lean toward a purely profit-centric motive?
- Who is the owner of the activity, and has this individual or entity been associated with any controversies or incidents involving malicious activities in the past?
- Does the technology comply with existing human rights standards and international guidelines to safeguard patient rights in the context of data sharing?
- How can we establish a risk-based system for the use of such technologies, aligned with the ethics and integrity principles, while fostering a culture of innovation?
- Would any of the proposed uses fall under software as a medical device (SaMD) regulations?



### Note to the facilitator

Allow the attendees to read the information on this slide or ask someone to read the case study aloud.


## Slide 27: Artificial intelligence: Applying the Decision-Making Framework

Case study 4 Artificial intelligence innovating ethically 27

### 3. Applying the Decision-Making Framework

A non-exhaustive list of questions to support AI-focused ethical decision-making:

<b>1. Why</b> Identify and evaluate	<ul style="list-style-type: none"> <li>What is the rationale and purpose of using AI technology here?</li> <li>Which specific category of risk (unacceptable risk, high risk, limited risk, and minimal or no risk) as defined by the <a href="#">EU AI Act</a>, does the AI application fall into?</li> <li>How are we mitigating and managing these risks, especially those related to patient safety and well-being?</li> <li>Is the activity proportionate to the identified needs?</li> <li>Explore the key performance indicators (KPIs) that could potentially help to assess the ethical performance of the AI technology.</li> </ul>
<b>2. Who</b> Define accountability and responsibility	<ul style="list-style-type: none"> <li>Who is the decision-maker?</li> <li>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?</li> <li>Who should be responsible and accountable to take steps against data breaches, ensure full consensus of patients through the AI-lifecycle, and set a proper framework for cybersecurity?</li> </ul>
<b>3. What</b> Determine and decide	<ul style="list-style-type: none"> <li>What strategies and safeguards will be implemented to ensure patient data is shared responsibly, minimizing the risk of misuse?</li> <li>Have we considered the option of NO GO (not moving forward with the proposal)?</li> <li>Are all stakeholders informed and empowered to speak up and raise any potential challenge?</li> <li>Did we minimize risk and conclude that potential benefits exceed potential risks?</li> <li>Did we value diversity and distribute risk and benefit fairly?</li> </ul>
<b>4. How</b> Execute and implement	<ul style="list-style-type: none"> <li>How would we ensure taking a multidisciplinary approach toward ethics in AI (such as sciences, psychology, social sciences, ethnography)?</li> <li>Is the action fair, the "right" thing to do? Consider the public perception.</li> <li>How can we ensure the ongoing relevance of our AI Ethics programs and effectively accommodate the rapid advancements in technology?</li> <li>How to set an open and transparent culture considering the "black box" nature of AI?</li> </ul>
<b>5. Impact</b> Monitor and control	<ul style="list-style-type: none"> <li>Have we planned to notify/report to appropriate persons (open and transparent communication, disclosure of potential issues)?</li> <li>Set up reporting and financial controls on costs and monitor the effects of decisions/project; adjust actions to new information as necessary.</li> <li>How can we establish a robust system for the continuous monitoring of ethical deployment of AI throughout its lifecycle?</li> <li>Is there a platform/mechanism for the patients to raise concerns and for them to get it addressed quickly if something goes wrong?</li> </ul>



### Note to the facilitator

Read the questions on this slide aloud. You may wish to focus on a subset of these questions, depending on the audience's needs and time available.

### Talking points

Let's apply our DMF to this situation.

#### 1. Why: Identify and evaluate

Let's begin with Phase 1, Why: Identify and evaluate. What are the issues here? Who wants to start?

### Note to the facilitator

Allow the audience time to think and share their thoughts. Depending on their responses, you may want to supplement their responses with the following:

Here are some questions to get us started:

- What is the rationale and purpose of using AI technology here?
- Which specific category of risk (unacceptable risk, high risk, limited risk, and minimal or no risk), as defined by the [EU AI Act](#), does the AI application fall into?

- How are we mitigating and managing these risks, especially those related to patient safety and well-being?
- Is the activity proportionate to the identified needs?
- Explore the key performance indicators (KPIs) that could potentially help to assess the ethical performance of the AI technology.

## 2. Who: Define accountability and responsibility

Let's move on to Phase 2, Who: Define accountability and responsibility. Remember, Phase 2 of the DMF is designed to drive efficiency decision-making by clearly defining roles and responsibilities and ensuring that we include cross-functional insights and incorporate cross-functional interdependencies into our planning.

A few questions we may want to consider here are as follows:

- Who is the decision-maker?
- If cross-functional, which other departments are involved (in addition to the department of the owner) and what are their roles and responsibilities in the project?
- Who should be responsible and accountable to take steps against data breaches, ensure full consensus of patients through the AI-lifecycle, and set a proper framework for cybersecurity?

## 3. What: Determine and decide

Let's now move to Phase 3: What: Determine and decide.

- What strategies and safeguards will be implemented to ensure patient data is shared responsibly, minimizing the risk of misuse?
- Have we considered the option of NO GO (not moving forward with the proposal)?
- 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?

### Note to the facilitator

Allow the audience to share their thoughts on how the organization's values and mission might influence the business decision and customize your talking points accordingly.

## 4. How: Execute and implement

Let's now think a bit about Phase 4, How: Execute and implement. A few questions to be considered in Phase 4 are:

- How would we ensure taking a multidisciplinary approach toward ethics in AI (such as sciences, psychology, social sciences, ethnography)?
- Is the action fair, the "right" thing to do? Consider the public perception.

- How can we ensure the ongoing relevance of our AI Ethics programs and effectively accommodate the rapid advancements in technology?
- How can we set an open and transparent culture considering the [“black box”](#) nature of AI?

## 5. Impact: Monitor and control

Finally, Phase 5: Monitor and control. In this phase, we...

- Have we planned to notify/report to the appropriate persons (open and transparent communication, disclosure of potential issues)?
- What measures can we take to set up reporting and financial controls on costs, monitor the effects of decisions/project, and adjust actions to new information as necessary?
- How can we establish a robust system for the continuous monitoring of ethical deployment of AI throughout its lifecycle?
- Is there a platform/mechanism for the patients to raise concerns and for them to get it addressed quickly if something goes wrong?

A few Ethos in Action Guiding Questions for consideration during the monitor and control phase include:

- **Care:** How do we ensure patients are first in everything we do (e.g., safety, quality, well-being, innovative solutions)?
- **Honesty:** How are we learning from mistakes as well as best practices and communicating these within the organization?
- **Respect:** In what way are we driving scientific advancements to ensure a more educated industry, community, and society?
- **Fairness:** How do we ensure that we treat our third parties, customers, and stakeholders fairly?

## Slide 28: Key takeaways


### Key takeaways

Business objectives must be **balanced** against other key considerations, including:


- Laws, regulations, policies, guidance
- The needs of patients, clinical trial participants, medical community, and healthcare systems
- Broader societal needs and obligations related to healthcare
- Key risk areas and related mitigations
- Ethical considerations and social expectations

The Decision-Making Framework:

- Helps to identify key business objectives, potential ethical issues, impacted stakeholders, and solutions that **better meet our purpose and duty in bringing innovation to patients.**
- **Advances business objectives while putting the IFPMA Ethos in Action** to navigate ethical grey areas inherent to our industry and complex operating environment.



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### Talking points

As you can see, the DMF helps us identify key business objectives, potential ethical issues, impacted stakeholders, and solutions that effectively balance our business objectives and ethical obligations. It advances business objectives while putting the IFPMA Ethos in Action to help us navigate gray areas inherent to our business and complex operating environment.

#### Note to the facilitator

Consider whether you wish to ask a team member(s) to use the DMF on an existing project and share their experience using it at a follow-up team meeting. You may wish to customize the close of your presentation by adding a slide on the resources and channels for raising concerns available at your organization. If you don't include a slide on the resources and speak up channels, you may speak to them.




Does anyone have any questions? Please reach out to me directly after this session if you prefer to speak about anything we've discussed here, or any other matter, on a one-on-one basis.

Remember, we have many resources available, in addition to the DMF, that will help guide our business decisions. (Customize this section to provide specific information about how employees can find policy information and related resources at the company.)

It's particularly important for you to know and understand how to raise concerns about any inappropriate or unethical conduct at this organization. (Customize this section to provide specific information about how employees can raise concerns at the company.)



## Slide 29: Thank you

 <h1>Thank you</h1> <p>Thank you for your time and your interest to learn more about the IFPMA Code!</p> <p>Your involvement will be essential to ensure that the new provisions, as well as our Ethos are reflected in business practices.</p> <p><b>Enabling innovation and business decisions with Ethos in Action!</b></p>	<h2>Contact us</h2> <p><a href="https://ifpma.org">ifpma.org</a></p> <p> /company/ifpma</p> <p> @ifpma</p>
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### Note to the facilitator

Bring up the presentation closing slide.

### Talking points

Thank you so much for your attention today and for your commitment to making business decisions with integrity.