Ethos in Action

Decision-Making Framework

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Business Leader Meeting Slides

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The Decision-Making Framework

Guiding Your Decision-Making Flow

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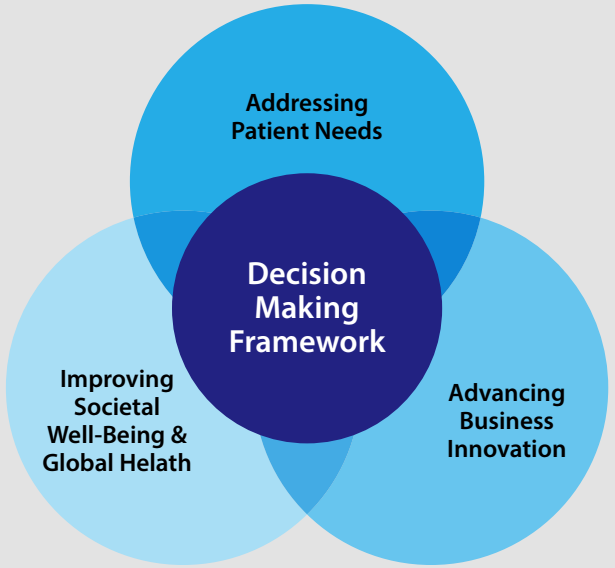
Why Use the IFPMA Decision-Making Framework?

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 is **essential for innovation** and **critical to partnerships** and interactions with patients, HCPs, HCOs, third parties, peer companies, the industry, and society.

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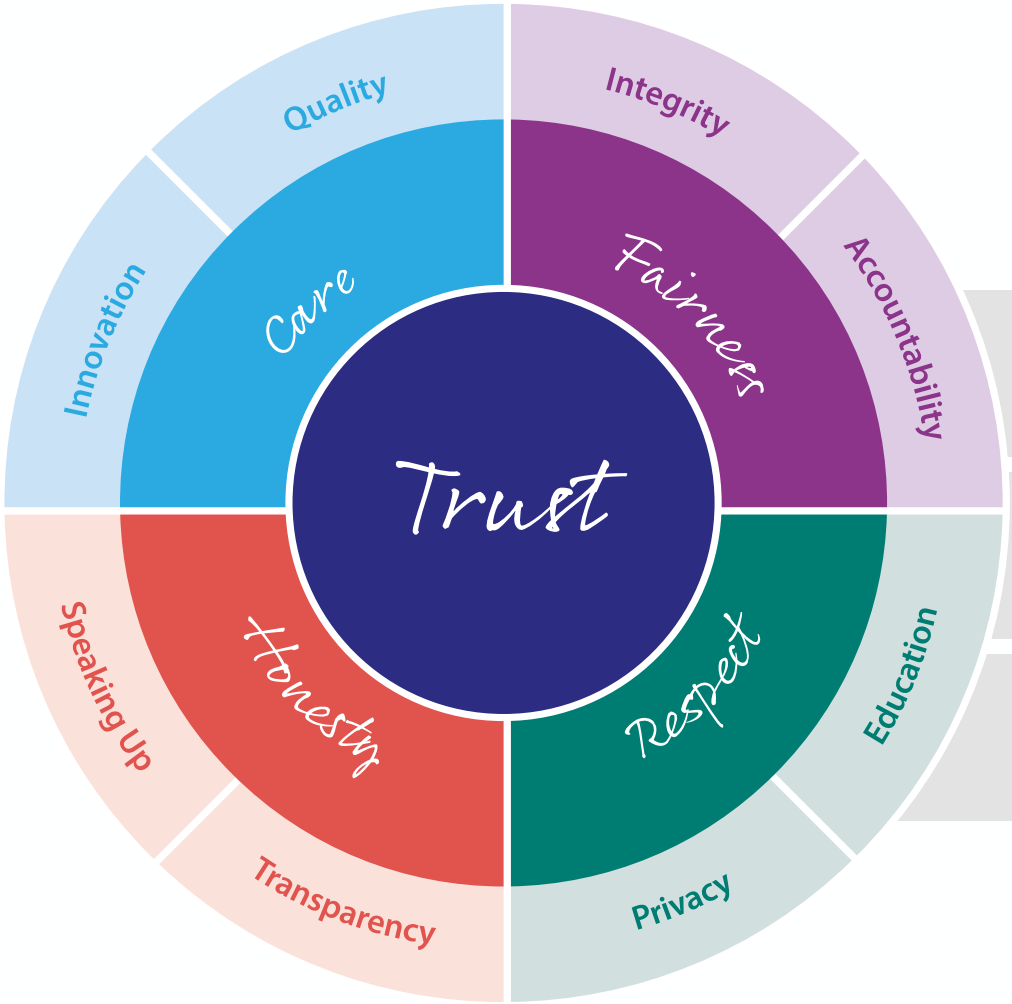
A Framework for Developing Innovative Models



A Decision-Making Framework designed to support our evolving industry:

- Advancing innovation using an agile approach
- Fostering patient-centricity
- Ethics based

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The Decision-Making Framework

Five Steps to Navigate Decision-Making Flow

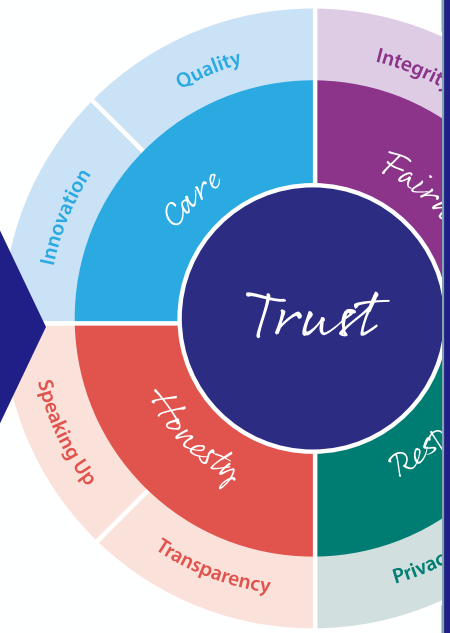
1. Why
Identify and Evaluate

2. Who
Define Accountability and Responsibility

3. What
Determine and Decide

4. How
Execute and Implement

5. Impact & Control
Monitor and Control



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

- **Assess new and innovative business models** and
- **Ensure decisions are grounded in ethics and integrity**

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Ethos in Action Guiding Questions

Integrating Ethos into Decision-Making

C1: How do we play our part in helping solve societal challenges?

C2: How do we ensure patients are first in everything we do (e.g., safety, quality, well-being, innovative solutions)?

C3: In which ways do we adhere to the highest possible scientific and ethical standards from discovery to delivery of our products?

C4: To what extent do we act with integrity in applying scientific medical principles demonstrating the safety and efficacy of our products?

C5: How do we ensure that we move "as fast as we can, but as slow as we must"?

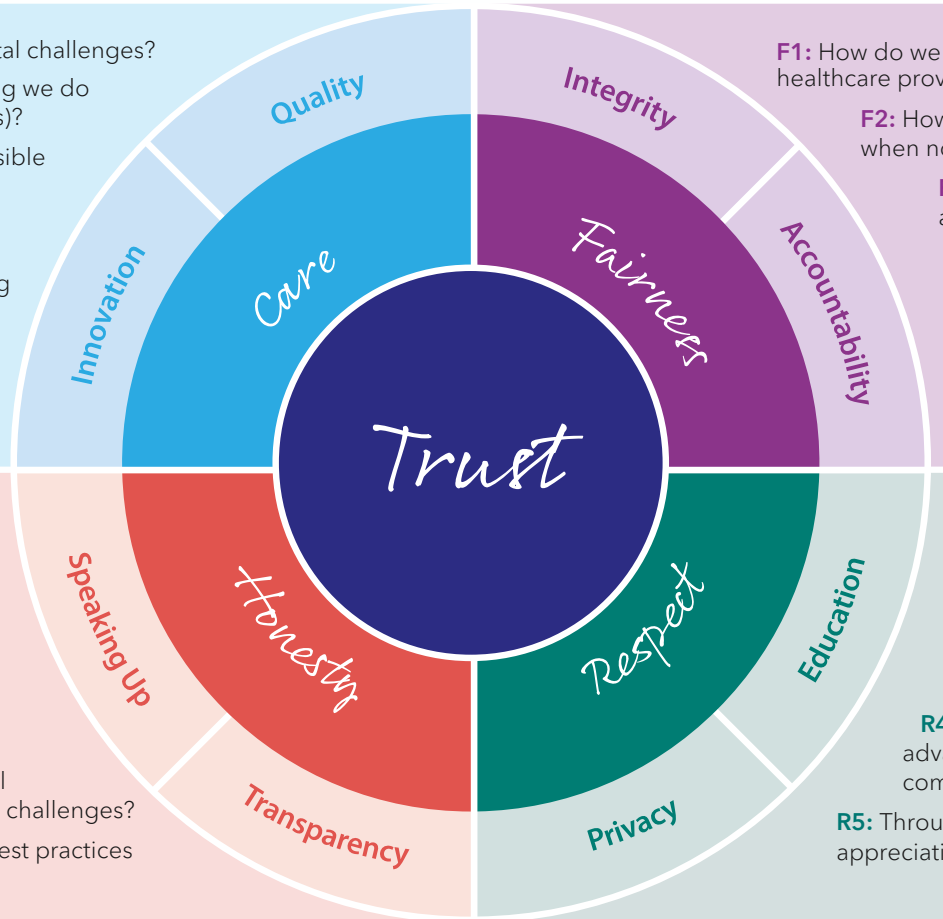
F1: How do we act with integrity to earn the trust of patients, healthcare providers, other stakeholders and the society we serve?

F2: How do we ensure that we do what is right, even when no-one is watching?

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

F4: How do we properly assess and mitigate all the risks associated with our innovative products/services?

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



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

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

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

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

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

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

R2: How do we take our environmental impact into account in our actions?

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

R4: In what way are we driving scientific advancements to ensure a more educated industry, communities and society?

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

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Decision-Making Flow Summary

Ethos in Action Guiding Questions for Each Phase of the Decision-Making Framework

Phase	Steps
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.
2. Who Define Accountability and responsibility	• The accountable decision maker is an individual in the organization, not a committee. • Explain who is the owner of the project or activity. If cross-functional, which department owns the activity. Explain the various company departments involved, if relevant and their roles and responsibilities. • Decision must be informed by and based on cross functional insights and context.
3. What Determine and Decide	• Describe potential options and solutions proposed to meet the needs or to resolve the problem. • If several options could be considered, explain the option you propose or if options will be sequential. • Define clear objectives and deliverables. • What type of activity will best satisfy the rationale and purpose identified? • What are the key elements to take into consideration in conjunction with IFPMA Ethos? Explain the ethical principles that you are going to apply and consider for ethical dilemmas, if any.
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 if made public. • 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.
5. Impact and Control Monitor and Control	• Document all decision-making steps and details of the activity in order to maintain a record of all activities. • 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.

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Case Studies

Putting Decision-Making to Work

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Case Study Exercise

Putting Decision-Making to Work

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 6 through 8 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 fictious 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 fictious 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.

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Case Study Summaries

Case Study 1

Innovative Opportunities:

Telemedicine

New, innovative business models and technologies such as telemedicine can present significant opportunities as well as new dilemmas related to appropriate HCP interactions.

Case Study 2

Innovative Opportunities:

Market Development

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.

Case Study 3

Hiring with Integrity:

Industry Associations

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.

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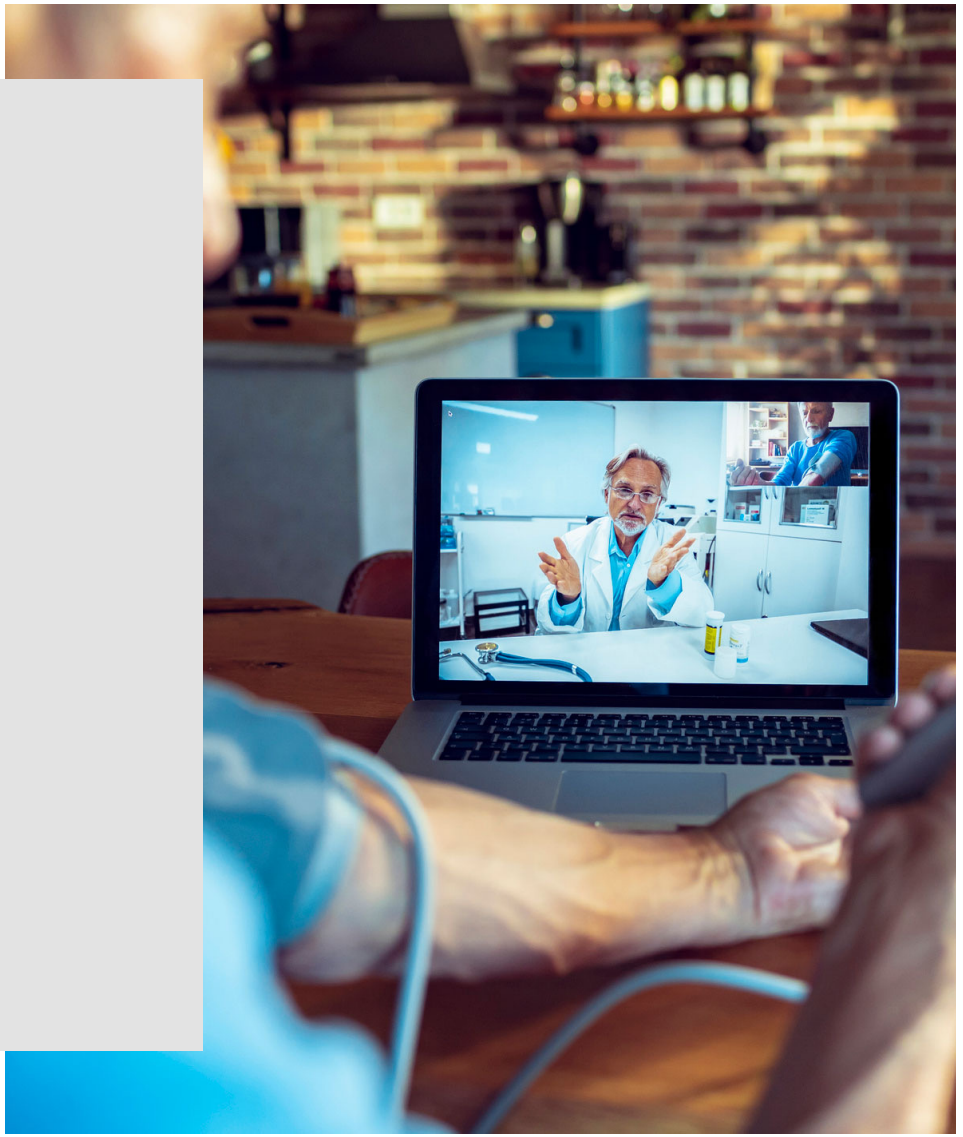
Case Study 1

Innovative Opportunities:

Telemedicine



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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.

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2. Considerations

There are few guidelines or regulations in this space, and competitors have not yet adopted similar approaches. Therefore, **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)?

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3. Applying the Decision-Making Framework

A non-exhaustive list of questions to consider when using the DMF to support decision-making:

1. Why Identify and Evaluate	• 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 IA algorithm designed ethically, avoiding biases and without creating any potential discrimination? • Was patient safety top of mind? • How would the society perceive these initiatives? • Do these initiatives help to build trust with the society?
2. Who Define Accountability and responsibility	• Discuss various roles and responsibilities. • If cross-functional, which department owns which activity?
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 business decision-making? • Are there other external developments on the horizon that may impact the decision and should be considered?
4. How Execute and Implement	• 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?
5. Impact and Control Monitor and Control	• Describe what the key success factors would look like. • Are measurements (KPIs) aligned with objectives and deliverables? • How would these success factors be viewed by stakeholders? • Are there significant financial controls required and what are the costs to support effective controls (e.g., monitor the effects of decisions/project)?

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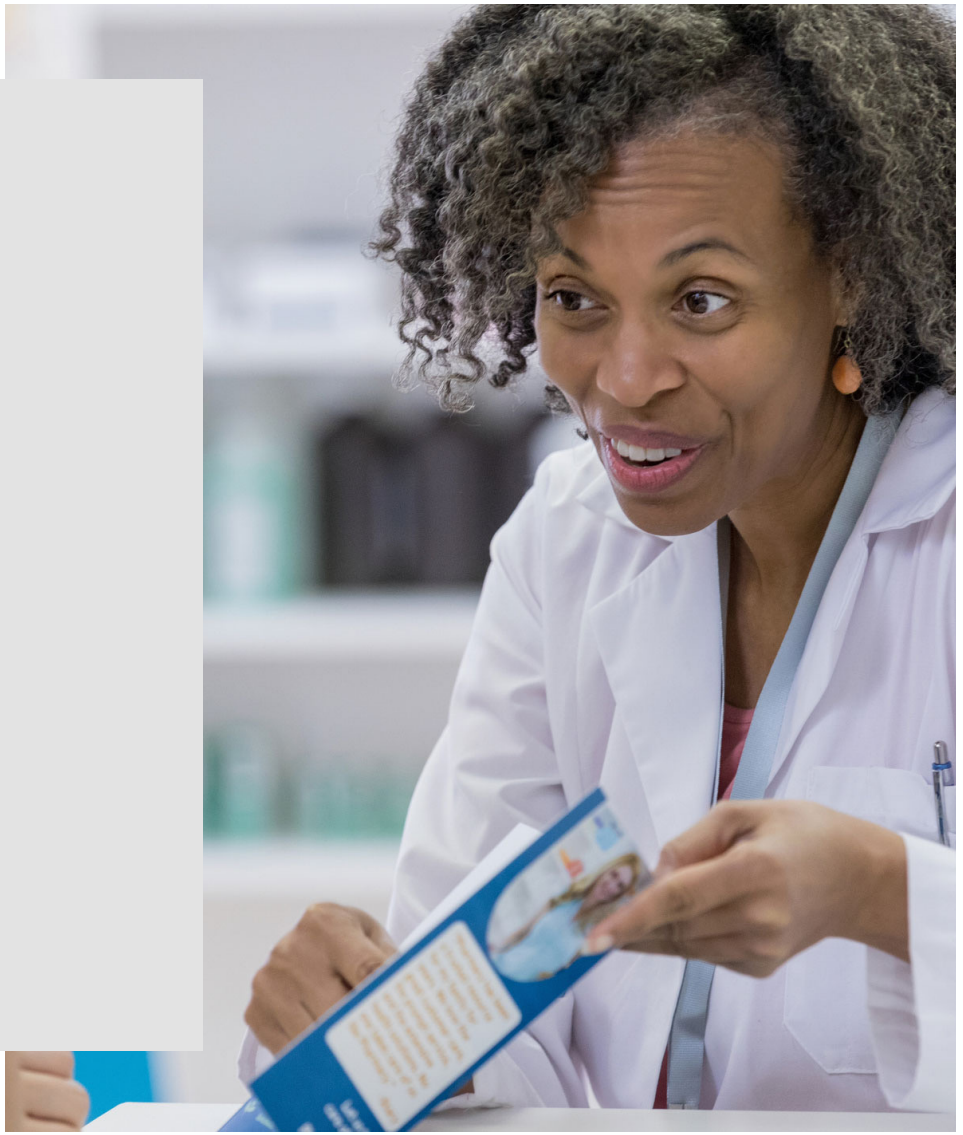
Case Study 2

Innovative Opportunities:

Market Development



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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 also, 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 clinics 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.

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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?

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3. Applying the Decision-Making Framework

A non-exhaustive list of questions to consider when using the DMF to support decision-making:

1. Why Identify and Evaluate	• 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 you 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 you approach issues of affordability and patient access in these circumstances? • How would the society perceive these initiatives?
2. Who Define Accountability and responsibility	• Discuss various roles and responsibilities. • If cross-functional, which department owns which activity? • What is the appropriate function to run these activities based on roles and responsibilities (medical versus commercial)?"
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 business decision-making? • Are there other external developments on the horizon that may impact the decision and should be considered?
4. How Execute and Implement	• 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? • How do we ensure that we move "as fast as we can, but as slow as we must"?
5. Impact and Control Monitor and Control	• Describe what the key success factors would look like. • Are measurements (KPIs) aligned with objectives and deliverables? • How would these success factors be viewed by stakeholders? • Are there significant financial controls required and what are the costs to support effective controls (e.g., monitor the effects of decisions/project)?

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Case Study 3

Hiring with Integrity:

Industry Associations

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Case Study 3 Hiring with Integrity: **Industry Associations**

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.

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2. Considerations

You should assess and balance the business 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?

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3. Applying the Decision-Making Framework

A non-exhaustive list of questions to consider when using the DMF to support decision-making:

1. Why Identify and Evaluate	• 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 3 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	• Discuss various roles and responsibilities. • How is transparency throughout the activities and processes being ensured, both internally and externally? • How are we enabling both internal and external stakeholders to speak up and raise potential ethical challenges? • Through what measures throughout the hiring process do we ensure and display our appreciation of the value of diversity?
3. What Determine and Decide	• What are the key ethical and risk management areas for consideration and related mitigation actions? • How does the IFPMA Ethos and principles of EDM apply? • If several options could be considered, what decision will best satisfy the rationale and purpose identified and reflect business decision-making? • Are there external developments on the horizon that may impact the decision and should be considered? • Why does it matter that we get this right and what happens if there are significant issues? • How are we assessing reputational impact?
4. How Execute and Implement	• 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 and Control Monitor and Control	• Describe what the key success factors would look like. • Are measurements (KPIs) aligned with objectives and deliverables? • How would these success factors be viewed by stakeholders? • How do we ensure that we treat our third parties, customers and stakeholders fairly?

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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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Thank You

Thank you for your time and your interest to learn more about the IFPMA Code!

Your involvement will be essential to ensure that the new provisions, as well as our Ethos are reflected in business practices.

Enabling innovation and business decisions with Ethos in Action!

Learn more and stay connected:
ifpma.org

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Guidance Notes

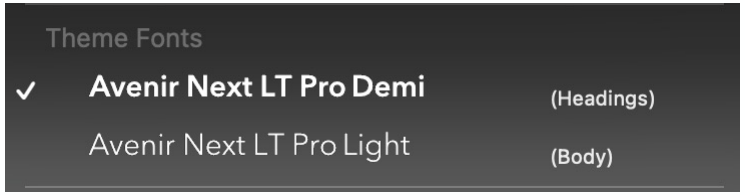
Fonts

The document templates use the typeface: **Avenir Next**
The two fonts that are used throughout are:

- Headings: **Avenir Next LT Pro Demi**
- Body copy: Avenir Next LT Pro Light

The fonts are freely available with your Microsoft package but you must download them from the font's menu. Scroll down the font's menu to the **Avenir Next** fonts and click on the download button to the right of each one.

If you do not download the font the presentation will default to the typeface **Calibiri** and some layouts may not display perfectly.



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Guidance Notes

Type Styles

The main text placeholder on a slide includes predefined type levels that help you format your text.

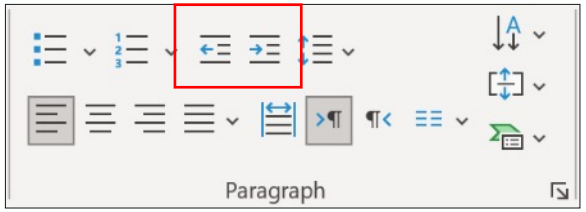
Level one is the standard text

Level two is for subheadings

- Level three is the first bullet level
  - Level four is the second bullet level
    - Level five is the third bullet level

You can move up or down the levels using the increase and decrease level buttons in the paragraph section of the Home ribbon.

We recommend tat you do not use the bullet button, as this does not apply the correct formatting.
A text box or shape does not include these levels.



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Guidance Notes

Pre-set Colour Theme

The template, and any documents you create with it, already has a default colour theme applied. This is used throughout and is automatically used by charts, diagrams and any new shapes you add.

The top row of the colour theme are the main Ethos brand colours which relate to the colours on the Ethos wheel.

Office automatically generates a set of tint values from the main colours, which can be used to manually assign to shapes and slide assets.

The standard colours row is supplied by Office and should not be used.

It is recommended avoiding manually apply colours using RGB values.

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