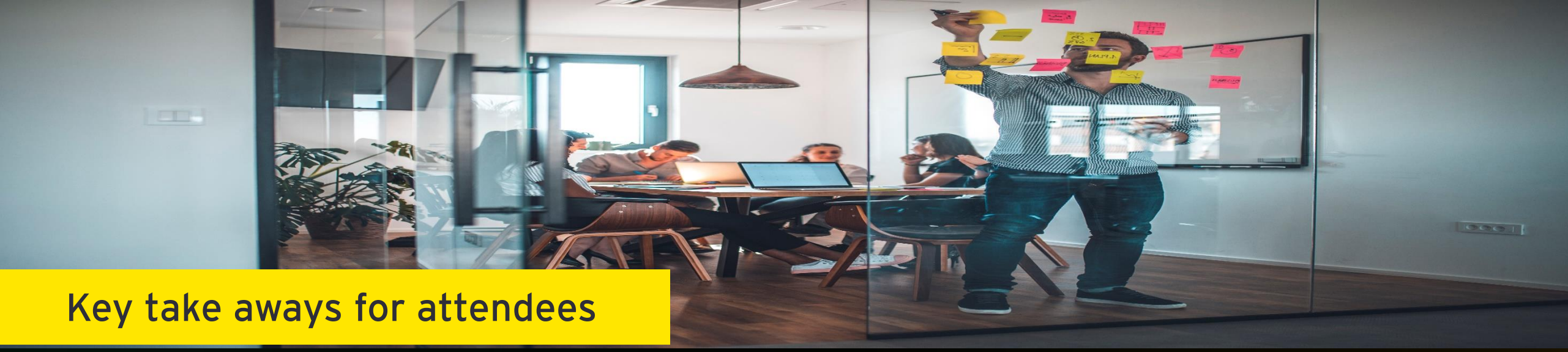
Life Sciences Workshop - 13 November 2025

From Hype to Headache - A case on AI

Plenary	EY Opening - George Fife Ethics Introduction – Nadege Rochelle	10 minutes (9:30- 9.40)
	Introduction to AI, use cases and risks – Bassem Gharbi	10 minutes (9:40- 9.50)
	Case study & workshop presentation - George Fife	10 minutes (9:50- 10.00)
Site break out	Workshop questions – site discussions	40 minutes (10.00- 10.40)
Plenary	Group reconvention to discuss workshop group response - Moderation by George Fife /Paris site	30 minutes (10.40- 11.10)
	Wrap up and Q&A	10 minutes (11.10- 11.20)



Key take aways for attendees

After the educational session the attendees will understand:

- Understand key AI risks and ethical dilemmas in Health & Pharma
- Explore practical approaches for compliance and governance
- Collaborate on case study scenarios to develop actionable insights
- Strengthen cross-functional engagement and leadership influence

Introduction to ETHICS

ethics

INTERNATIONAL SOCIETY OF HEALTHCARE ETHICS AND COMPLIANCE PROFESSIONALS

Who we are, what we stand for.

Join ETHICS Today

Become part of an independent international community of ethics and compliance professionals shaping the future of healthcare.

Your Journey to Professional Excellence

What is Ethics?

Vision

We aim to be recognised as an independent international association of professionals, which sets standards of ethics and compliance and shapes and influences strategies in the changing healthcare environment for the ultimate benefit of patients and society at large.

Mission

7

Why Join ETHICS?

More Than a Network

ETHICS is a resilience booster and a safe professional space where ethics and compliance officers find support when facing challenging situations.

Safe Professional Space

Discuss challenges openly without commercial pressures or competitive barriers in a trusted environment.

Career Advancement

Become a more successful compliance officer through peer learning and professional development.

Global Influence

Shape strategies and set standards in healthcare ethics internationally for patient and society benefit.

What Our Members Say

Career Growth

ETHICS has made me a more successful compliance officer by providing ongoing learning and peer mentorship opportunities.

Emotional Support

A safe space to think and find support when you're struggling with challenging ethical and compliance dilemmas in healthcare.

Your Membership Benefits

Professional Network

Connect with brilliant ethics and compliance professionals across healthcare, industry, academia, and government sectors worldwide.

Safe Space

Engage in candid discussions about compliance challenges in an environment free from commercial pressures and competition.

Knowledge Sharing

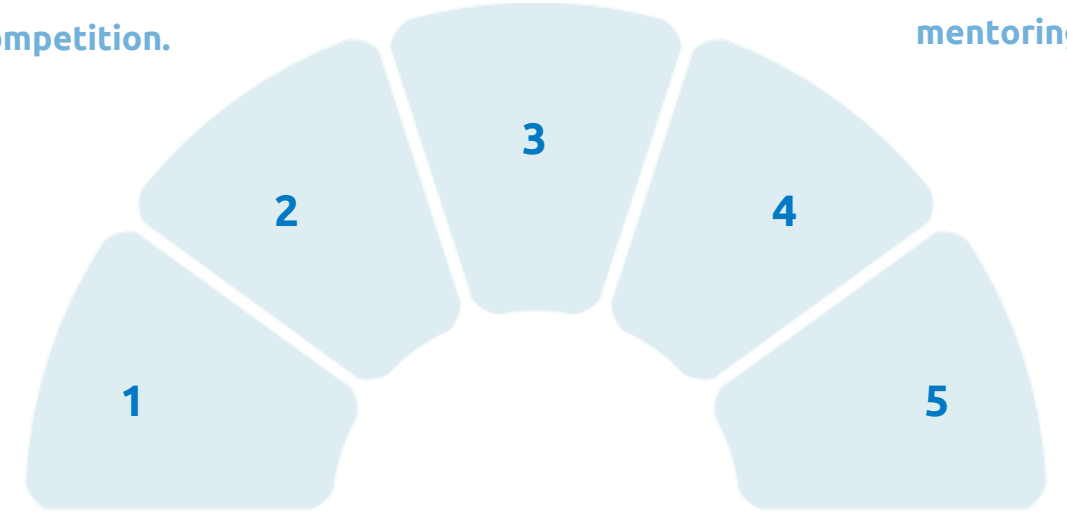
Access best practices, standards, and insights from experienced professionals shaping healthcare ethics globally.

Career Development

Enhance your skills and advance your career through professional development opportunities and peer mentoring.

Global Impact

Participate in shaping and influencing strategies that benefit patients and society in the evolving healthcare environment.



Who Should Join ETHICS?

Industry Professionals

Healthcare compliance officers, ethics managers, and risk professionals seeking peer support and best practices.

- Pharmaceutical and medical device compliance officers
- Healthcare ethics consultants and advisors
- Compliance managers in hospital systems

Academic Leaders

University professors, research ethicists, and training center directors advancing ethics education.

- Healthcare ethics educators and researchers
- University compliance and ethics experts
- Professional training center directors

Government or quasi-government bodies

Public health officials and government bodies shaping healthcare policy and regulations.

- Government health department professionals
- Regulatory compliance specialists
- Policy makers in healthcare sector

ETHICS Membership Tiers Explained

Contributing Members

1,500€

Comprehensive support for the Association through special annual subscription.

- Full member benefits and privileges
- Recognition as sustaining supporter
- Enhanced professional visibility

International Members

250€

Active participation demonstrating commitment to ETHICS' mission and global activities.

- Full network access and resources
- International chapter participation
- Equal member status and benefits

Concession Members

125€

Accessible option for professionals in developing economies (IMF GDP per capita ranking below 50).

- Same benefits as International members
- Affordable access to our community
- Full participation in ETHICS activities

Your Path to Membership

Check Your Eligibility

Healthcare compliance and ethics professionals from industry, academia, government, or related sectors are welcomed. The Board considers all serious candidates.

Submit Your Application

Complete your membership application and select your preferred membership tier based on your circumstances and commitment level.

Join Our Community

Upon approval, gain immediate access to our global network, resources, and the safe professional space that defines ETHICS.

Grow Your Career

Participate in discussions, contribute your expertise, and advance your career while making a positive impact on healthcare ethics globally.

Ready to Join ETHICS?

Start your journey today and become an active part of the international community shaping healthcare ethics and compliance for a better future.

AI in Healthcare

From Generative AI to the Agent System

Chatbot

A chatbot **is an interface that facilitates direct interaction** with a language model (LLM). A simple chatbot has no knowledge outside of the data it has been trained on. It has no long-term memory and only answers questions that are put to it.

Example: ChatGPT, Gemini, etc.

Chatbot RAG

A RAG-augmented chatbot is a conversational assistant that **has access to a private knowledge base**. It is designed to extract confidential information and respond to specific requests by integrating this context. The data used can include information internal to your organization, such as emails, documents, etc.

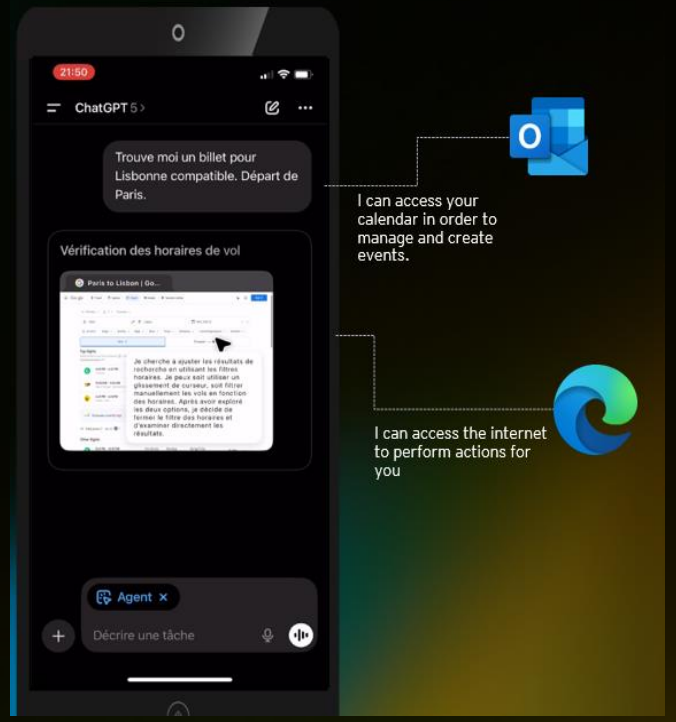
Examples: Microsoft Copilot, specialized internal chatbot, etc.

AI Agent

An AI agent is a chatbot enriched with advanced action features. It is **able to interact with its environment or the computer system** in order to respond to requests, such as managing meetings or forwarding emails, for example.

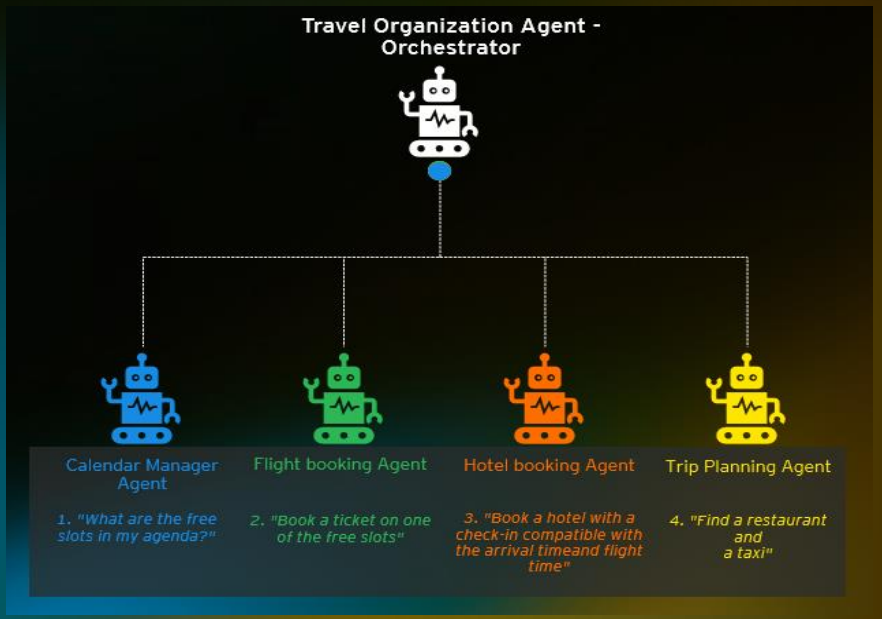
The agent can perform tasks in the background while you're busy.

Example: an intelligent assistant dedicated to scheduling meetings.



AI Multi-agent System

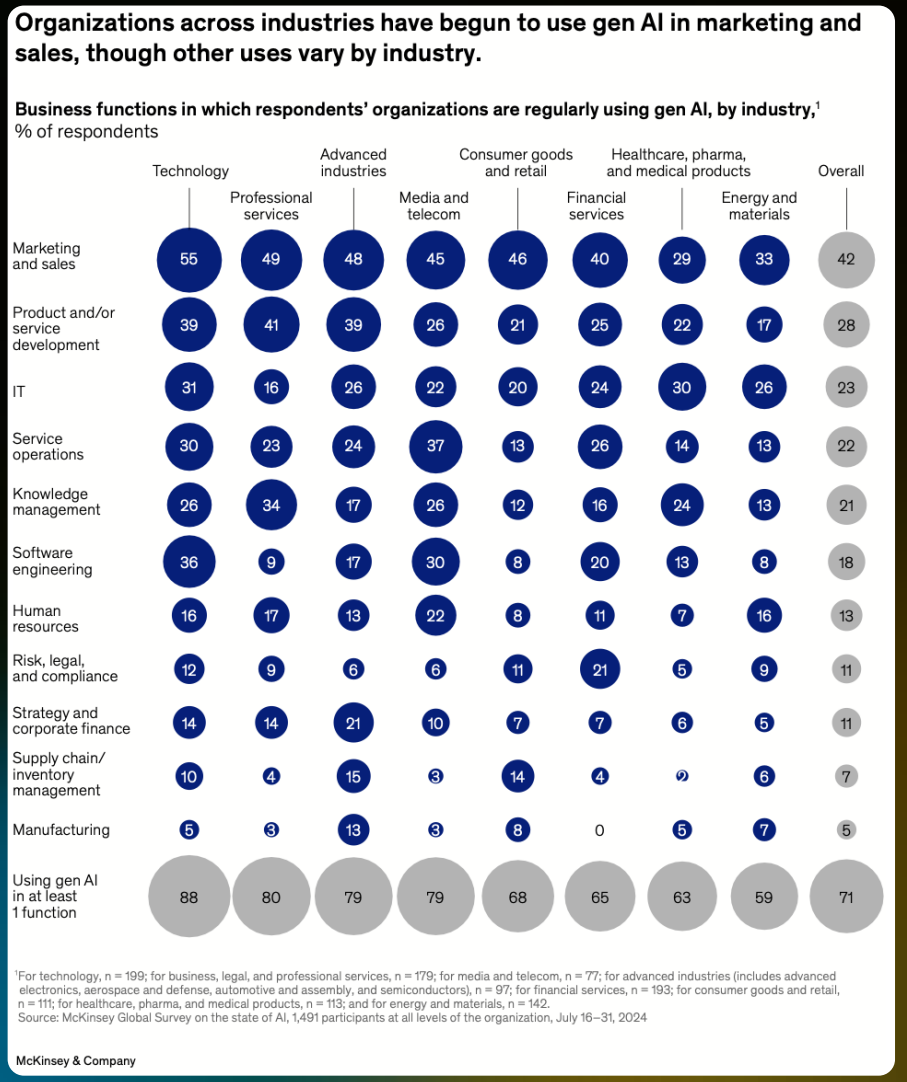
An AI multi-agent system (or agentic) refers to a **set of agents, each with a specific role, who work together in a coordinated manner to achieve a defined overall goal**. Typically, a multi-agent system includes an orchestrator agent that is responsible for distributing tasks, as well as specialized agents that are responsible for performing the corresponding subtasks.



AI - Industry adoption patterns

The adoption of generative AI **is not uniform** ; it reveals the **"strategic signature"** of each sector, which applies AI where it amplifies its core business and its main value lever.

- **The universal entry point: Marketing and Sales (42% on average).**
- **Industry signatures: AI at the service of the company's DNA.**
- **Risk, legal and compliance are far away... (11% on average, and 6% for Healthcare, pharma and medical products)**



Healthcare AI – Use case examples

Compliance Function

Prevention

Policies and procedures

- Drafting and implementation of policies

Third-Party Risks

- Onboarding & KYS/KYC,
- Due diligence,
- contracting

Detection

Detection and monitoring

- Document fraud detection
- Controls on risky processes: Order to Cash, Procure to Pay, etc.
- Review of contracts
- Market surveillance

Response

Alert lines

- Alert screening
- Trends and KPIs

Investigations

- Analysis of structured and unstructured data
- Support during the closure of reports and remediation actions

Business (Sales & Marketing, R&D, Medical, Market Access)

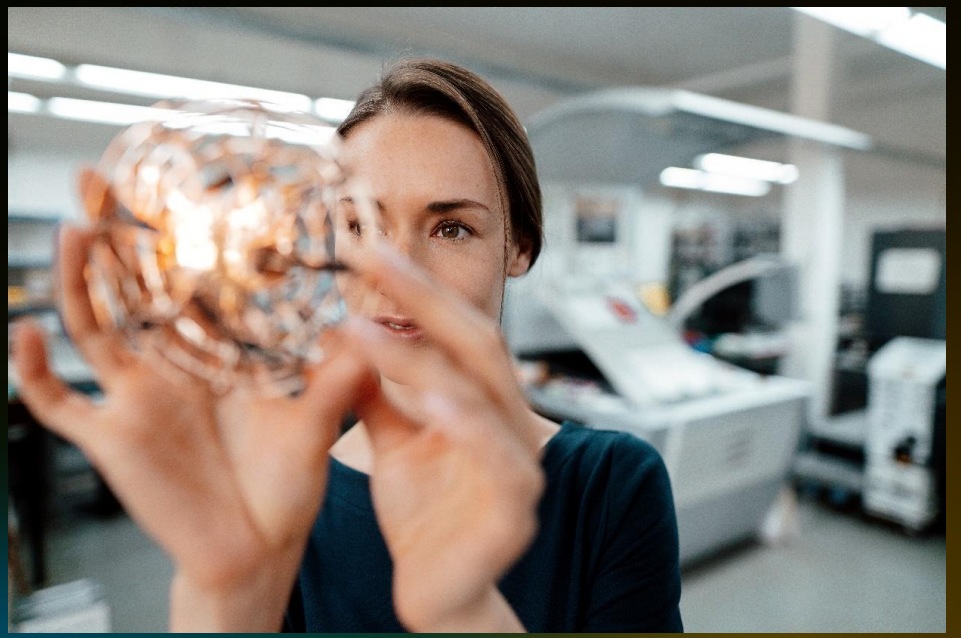
- **Content creation** (promotional materials, training content, etc)
- **Commercial/Sales training**
- **Sales assistant** (Sales Rep enablement & coaching)
- **Translation**
- **Patient education** through chatbots & training avatars / virtual assistants
- **Patient assistance & activation** (reminding patients of next dose, right use of drug, collect data to predict/prevent adverse events)

Risks and limiations of Artificial Intelligence

Whether it's classic AI or generative AI, these technologies can produce errors related to:

- **Decision-making** biases, inherited from biases – conscious or not – introduced during their design and training;
- **The origin and quality of training data**, which may be biased, incomplete or non-representative;
- **The formulation of prompts** (for generative AI), whose accuracy strongly conditions the relevance of the results;
- **Hallucinations** (specific to generative AI), i.e. the production of false but convincingly formulated answers.

This is why **human supervision** is essential today in critical uses.



Case study presentation

Disclaimer

The business case mentioned in the present support is totally hypothetical and entirely fictitious

Any resemblance to actual companies, individuals, or products is coincidental.

Chatam House Rule

*"When a meeting, or part thereof, is held under the Chatham House Rule, **participants are free to use the information received**, but **neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed**."*

Workshop Format

01 **Case Study Presentation:** We will present a case study highlighting AI-related challenges.

02 **Breakout Groups:** Participants will be divided into smaller groups by location for discussion.

03 **Group Discussion:** Each group will analyse the various case scenarios, identify the risks, and address the questions raised

04 **Debrief Session:** We will reconvene to share insights and recommendations from each site. Each site can nominate one reporter to facilitate the discussion

Case Study Context (1/3)
Introduction

Background

Your company, a multinational in the life sciences sector, is exploring a partnership with a **startup AI company**. The startup has developed an algorithm that promises to **identify patients with a rare disease faster**, reducing time-to-market for clinical trials and improving patient outcomes.

The initiative looks promising, but several **ethical and governance challenges** quickly emerge.

Key Elements of the Case

1. **The Startup Partner**
   - Innovative but immature: limited financial history, weak governance, no ethics & compliance framework.
   - Documentation and transparency are scarce. Proper due diligence would take time.
2. **The AI Tool**
   - Early testing shows strong potential and would bring a lot of benefit for the patients and your organization, allowing to increase by 25% patient identification.
   - But the model is biased: it underrepresents certain minority groups, which could mean unequal access to trials.
   - Fixing this issue would delay rollout.

Case Study Context (2/3)
Introduction

3. Leadership Pressure

- The Chief Scientific Officer (CSO) is a powerful champion of the project.
- He insists on launching within 4 months for something completely new to your organization (it usually takes much more time internally for new project!)
- The Chief Scientific Officer got full back up from Senior Leadership Team and AI has been put recently in all Goals & Objectives of the employees.
- He dismisses compliance, privacy, and IT concerns as “blockers” and suggests that the functions should stop over-worrying and that issues can be “fixed later.” Competition is already leveraging AI to enhance and accelerate patient enrollments in clinical trials.
- Your colleagues from Legal, IT, and privacy are not willing to openly challenge him.

4. Terminology & Communication

- Teams use different technical language: “predictive algorithm,” “AI tool,” “machine learning model.” It is hard to understand and ensure we are all on the same page.
- Misunderstandings fuel silos and risk misalignment.

ethics EY

Case Study Context (3/3)
Introduction

5. Governance & Process

- No clear AI governance framework exists internally.
- Departments disagree on ownership and on when Compliance, Privacy, Legal, and IT should be involved.

6. Reputation & Patients

- Potential benefit: faster diagnoses, quicker clinical trials, improved access for patients.
- Potential risk: reputational damage if bias is exposed, patient harm if errors occur, regulatory or media backlash if shortcuts are revealed.

You are invited to the upcoming **steering committee** to give your recommendation as Ethics & Compliance.

Worskhop questions

1 Third Party Risks

1. How should you assess an **immature AI startup** for ethics, compliance, and governance?
    - What minimum due diligence would you require before signing? Is there anything you can leverage from your existing DD process?
    - Is it ethical to proceed without all the information if patient benefits are high?

2 Governance and Ownership

1. Who should own AI ethics internally: Compliance, Legal, IT, R&D, or a cross-functional team ?
2. How do you balance innovation speed with risk mitigation?
3. Transparency & Terminology: How do you ensure teams share a common language on AI?

5 Ethical considerations

1. If AI improves diagnoses overall but disadvantages certain groups, should it be deployed?
2. What kind of risk mitigations would you suggest are put in place, if any at all?
3. Beyond regulation, what ethical principles should guide AI use in healthcare?

3 Compliance Role

1. At what stage should Compliance engage in an AI project?
2. What is the depth of review necessary for the CO ? Is it primarily the intended use, and intended audience, facilitate building of a governance process, but no active «daily» role? Is it a mix of the all of the above or anything else?

4 Leadership pressure

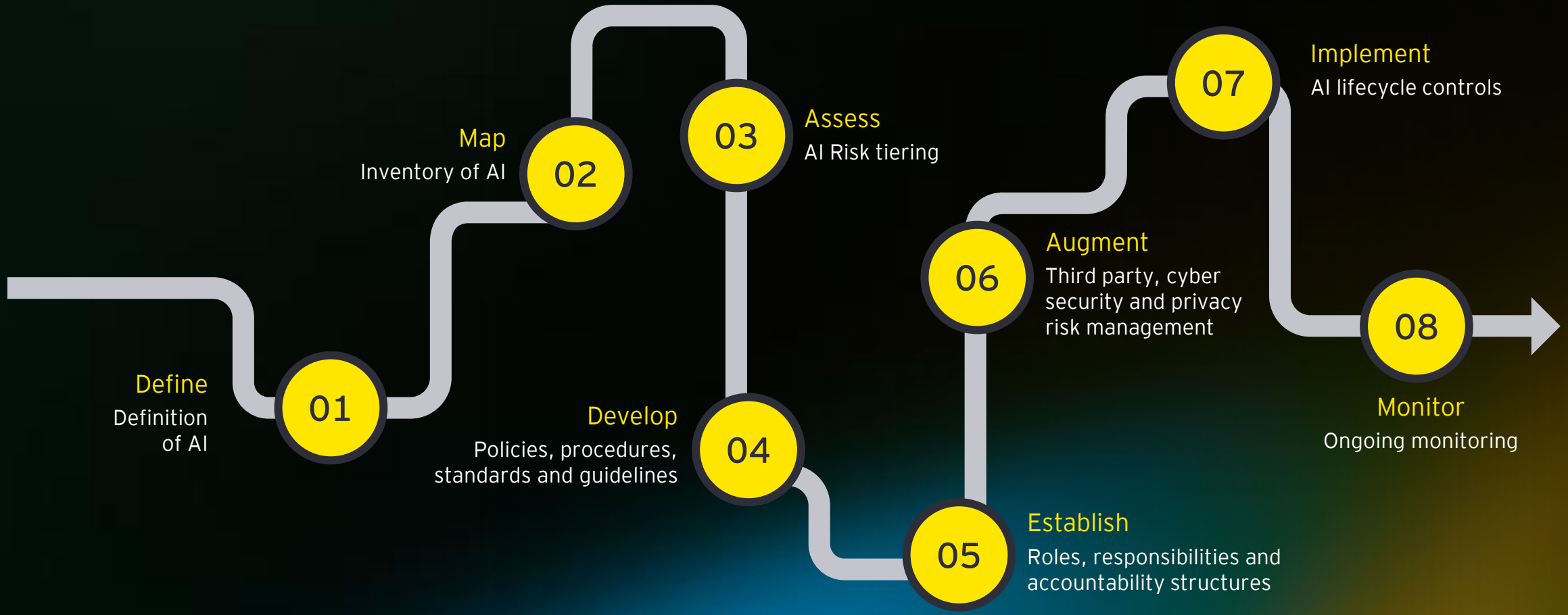
1. How do you influence a difficult leader who dismisses compliance concerns?

Site break out

Moderators	Paris	Zurich	Munich	Barcelona	Milan	Brussels
EY	Assia Baba-Ali	Matthias Grossenbacher	Markus Jüttner	Stefano Di Miceli	Piero Di michele	Frederik Verhasselt
Ethics	Laetitia Ducroquet	Thomas K Hauser	Elena Starinskaya	Anne Munoz	Nadège Rochel	Frédéric POELS

Group Discussion

AI governance



Discussion points – Third party risks

Partner Third Party Risk

- Enhance Third-Party Risk-Tiering Frameworks to account for AI applications/ use cases
- Involve relevant internal stakeholders such as legal, data privacy, IT, IT security etc.
- Supplement existing due diligence questionnaires with increased AI-focused inquiries during assessments,
    - Compliance: Assess how the startup ensures current and future regulatory compliance
    - Fairness, Transparency, and Accountability: Inquire about AI model design, data sources, and monitoring processes.
    - Data Privacy and Security: Gather information on data protection measures and breach protocols

Deployment Ethical considerations

- Delay partnership until controls are built
- Assess extent to which your organization can support them in maturing quickly (Templates, shared policies, training)
- Incorporate ethics, compliance and governance requirements in contractual agreement
- Pilot program under strict controls are in place

Discussion points – Governance & Ownership

Accountability and Leadership
Cross functional governance

- Cross functional team involved from Legal/Data Privacy, Compliance, Business, IT, IT Security for comprehensive risk considerations
- Dedicated AI committee
- Clearly defined roles and responsibilities

Governance & Ownership

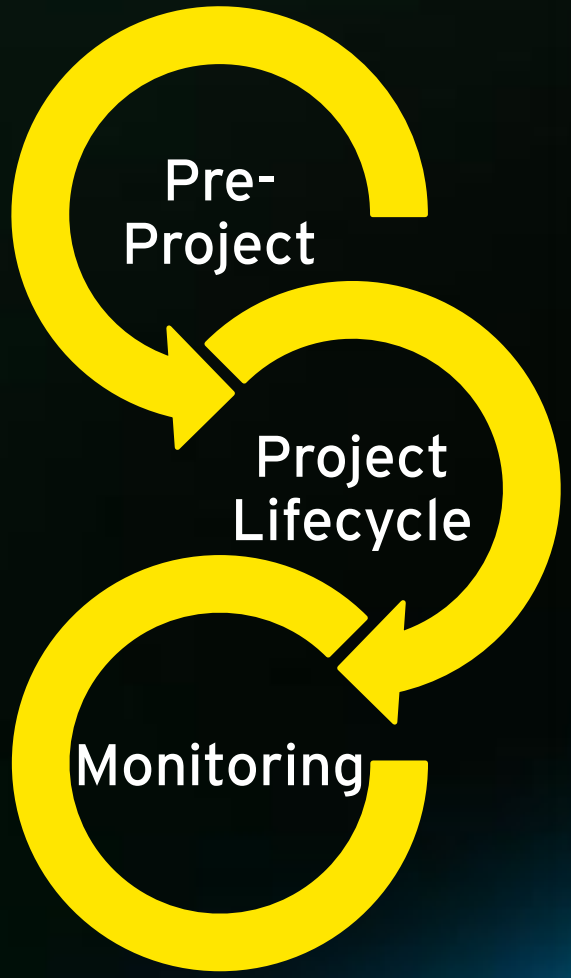
Transparency & Terminology

- Policies and procedures
- Standardized templates
- Training of employees

Innovation vs speed

- Risk based streamlined approval process (use case risk classification, new vs existing vendor, internal vs external AI tools)
- Clearly defined processes: (clear functions, timing, scope of review and approval tools/ templates)

Discussion points – Compliance role



- AI use case risk classification
- Development of policies and procedures
- Vendor due diligence
- Contracting with third parties

- Risk based approval process
- Ongoing adhoc involvement throughout the project lifecycle

- Conduct periodic monitoring
- Update frameworks with new regulations and updates

Discussion points – Compliance role

Influence and escalation

Data-Driven Arguments:

- Present consequences of non-compliance, such as regulatory fines, legal issues, or reputational damage.
- Use real-world examples

Align with Business Goals:

- Emphasize potential impact on reputation, trust, and business success.

Propose Solutions:

- Propose practical solutions that address compliance concerns while still allowing for innovation and speed.

Engage Other Stakeholders:

- Obtain support from other influential stakeholders

Discussion points – Ethical considerations

Considerations

- Ethical Principle of Fairness: AI that systematically disadvantages certain groups (e.g., based on race, gender, age) risks perpetuating or worsening health inequities
- Regulatory Compliance: Many guidelines (like the EU AI Act, FDA) emphasize the need to identify, mitigate, and monitor bias in high-risk AI systems.
- Risk vs Benefit Analysis: While AI may improve outcomes overall, the harm to disadvantaged groups could be significant and ethically unacceptable.

Mitigation Strategies

- Phased or pilot deployments: Limited use cases with close monitoring to detect issues early.
- Identify potential biases, measure them and implement controls (e.g., human-in-the-loop, fail-safes).
- Transparency: Clearly communicate AI limitations to stakeholders and patients.
- Governance and compliance: Frameworks to oversee AI use, ethical concerns, and regulatory adherence.
- Continuous monitoring and improvement cycles: Use real-world data to iteratively improve AI performance and reduce flaws.
- Development of an ethical decision-making framework to tackle ethical considerations overall (which could be used to take decision on AI)


THANK YOU FOR YOUR
ACTIVE PARTICIPATION!