

Interoperability in practice - What are the MedTech Industry's costs for not becoming interoperable?

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Agenda



1. AI and interoperability in Healthcare
2. EU Legal Context
3. An example from Italy
4. Interoperability as an enabler
5. Conclusion: Towards a Future of Interoperable MedTech

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AI and interoperability in Healthcare - Implications



- Using AI-based solutions in healthcare brings several major implications for both citizens and Governments
- Major implications coming from usage of AI fall into 4 key areas:



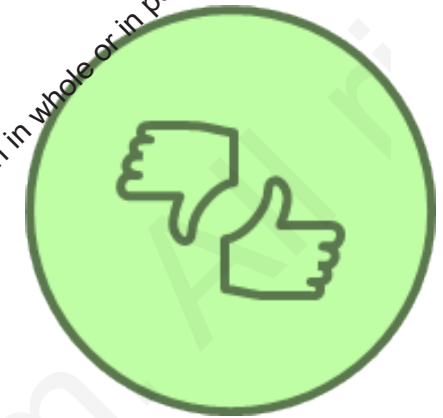
Social
Implications



Economic
Implications



Operational
Implications



Ethical
Implications

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EU Legal Context

• Data Regulations

- Open Data Directive
- Data Governance Act
- Data Act proposal
- European Health Data Space

• Privacy and Data Protection

- Council of Europe and Convention 108+
- European Treaties
- GDPR and its implementation guidance
- National laws implementing specific provisions

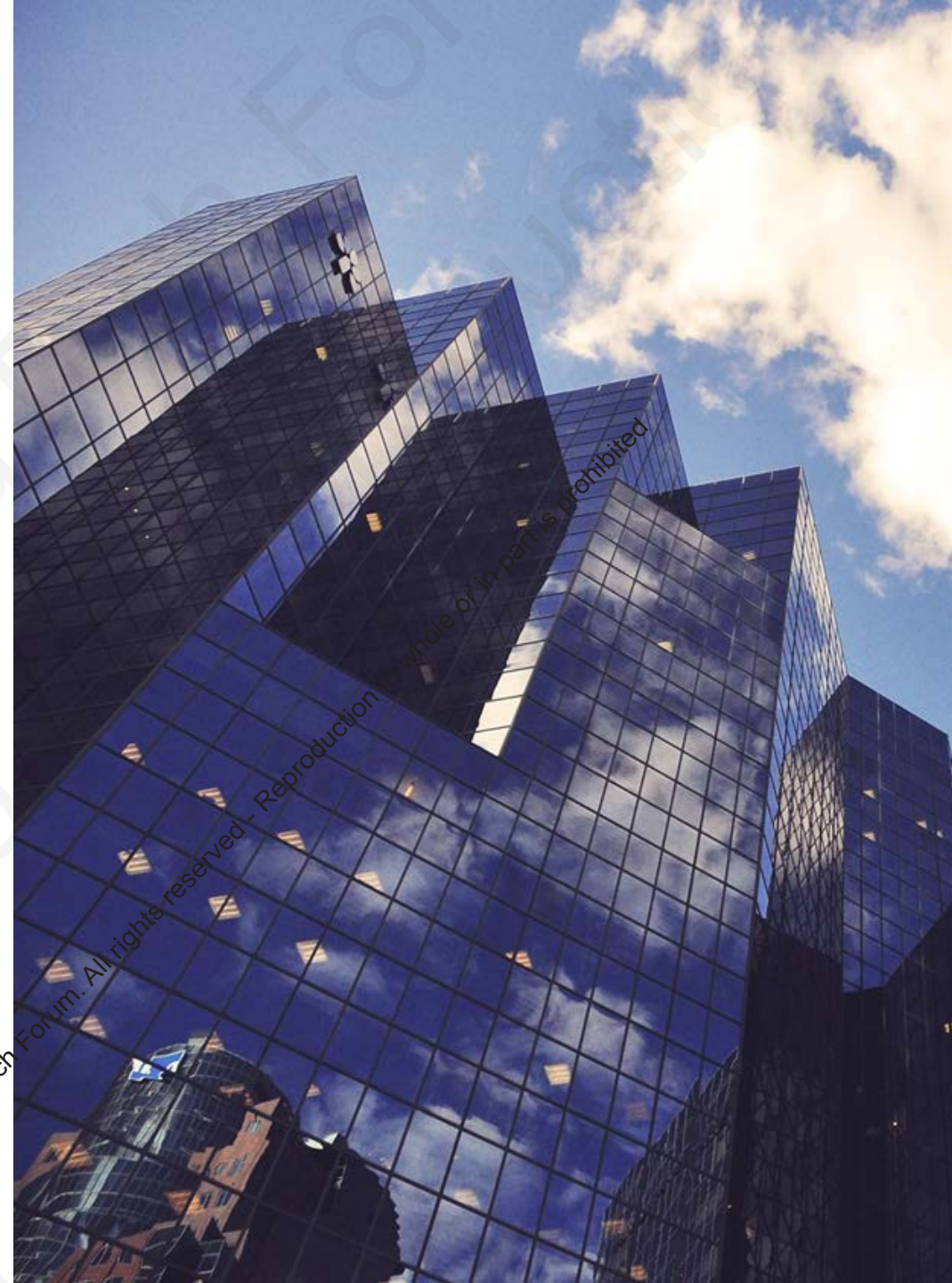
• Cybersecurity

- NIS 2 Directive
- Cyber Resilience Act proposal
- Cybersecurity Act
- Guidance provided by ENISA and national bodies



EU Legal Framework

- Conventions and International Resources
- Liability Frameworks
- Sector specific regulations
- National laws and implementations
- Ethics
 - Biomedical ethics principles (Autonomy, Justice, Beneficence, Non-maleficence)
 - HLEG Guidelines on Trustworthy AI



An example from Italy: National AI Platform for Public Healthcare



The Italian **National Healthcare Service** is adopting AI with the main objective of supporting and facilitating the diagnosis and treatment through support services to doctors.

In territorial care processes, **AI can act as an enabling factor** to improve continuity, access and personalization of care, ensuring greater effectiveness and efficiency of the health system.

AI, with the ability to learn during normal operation and **overcoming the codified rules typical of expert systems**, can support the doctor by optimising and enhancing the anamnestic, diagnostic and monitoring processes

An example from Italy: National AI Platform for Public Healthcare



The Platform:

1. guarantees a **centralised governance** of technologies and processes;
2. defines a **certification and validation of the algorithms** according to forthcoming EU regulations;
3. creates **support services** for health professionals, from prevention to chronicity management;
4. creates support services for doctors in **daily clinical practice** through **non-binding suggestions** from the AI system.

Interoperability as an enabler



- **Interoperability in MedTech Industry:**

- Interoperability allows diverse healthcare systems and software applications to communicate, exchange data, and use the exchanged information.

- **Costs of Lack of Interoperability:**

- **Potential Roadblocks:** Non-interoperable systems can hinder AI's full potential in medical processes.
- **Financial Impact:** Non-interoperability can lead to increased costs due to inefficient data exchange, duplicated tests, delayed procedures, and possibly compromised patient care.

Conclusion: Towards a Future of Interoperable MedTech



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1. The Power of AI:

1. AI's potential in the Italian National Healthcare Service and beyond is undeniable, significantly improving care continuity, accessibility, and personalization.

2. The Necessity of Interoperability:

1. Interoperability in the MedTech industry is no longer a luxury but a necessity. It enables efficient data exchange, reduces duplicated procedures, and ensures optimal patient care.

3. The Costs of Non-Interoperability:

1. The financial implications of non-interoperability are substantial, causing increased healthcare costs and potential patient safety issues due to fragmented data and delayed procedures.

4. Moving Forward:

1. The MedTech industry needs to prioritize interoperability to fully leverage the potential of AI in healthcare. Seamless data exchange, improved efficiencies, and enhanced patient care are achievable with interoperable systems.

Thank you

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