THE DEBATE

Data and AI in healthcare, welcome to reality!

JULY 3, 2025 - BRUSSELS

Uehp
UNION EUROPÉENNE DE L'HOSPITALISATION PRIVÉE

relyens
EUROPEAN MUTUAL GROUP
INSURANCE AND RISK MANAGEMENT

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Opening remarks

"Hospitals and private clinics in Europe are very optimistic about the potential of new technologies, particularly artificial intelligence. They are calling for this potential to become a reality to benefit the public, the well-being of healthcare professionals and efficiency within the healthcare sector. As you're well aware, the growing prevalence of disease in an aging population, increased costs, staff shortages and inequalities in access to healthcare are making the sector's digital transformation an increasingly urgent issue. In view of this, the adoption of emerging technologies which use artificial intelligence is both inevitable and imperative. That's why we have chosen to make it the subject of today's event."

OSCAR GASPAR
PRESIDENT OF UEHP

"The integration of digital technologies in patient care, particularly Big Data and artificial intelligence, has become a focal point for discussion and experimentation in our daily lives and, increasingly, in medical practice.
The advent of these new technologies inspires hope, but also raises questions. Although they promise to help us improve diagnostics, personalize treatments, improve research and the efficiency of healthcare systems, they also prompt questions: how can health data be protected? How can AI be used ethically? How can the unique nature of the patient-doctor relationship be preserved? How can we ensure that inequalities in access to healthcare do not increase?"

ERWAN TRIVIDIC
HEAD OF EXTERNAL PARTNERSHIPS AT RELYENS

"We are witnessing a major transformation in the healthcare sector. What was merely theory a short time ago is now reality."

"These are just some of the questions we're going to consider today, because we firmly believe that if we can answer those questions, artificial intelligence will play a positive role in improving the performance of private hospitals by enhancing their operational efficiency and their focus on the individual needs of every patient."

OSCAR GASPAR

Opening remarks

ERWAN TRIVIDIC

"Although artificial intelligence has a role to play in healthcare, the risks within the sector are changing, as are the issues of medical liability, decision-making and patient expectations. In this context, at Relyens, our role involves much more than just providing insurance: we are actively working to help manage digital and organizational medical risks. That's why we're going to focus on real-world and ongoing examples in Europe and discuss recent regulations, such as the EU's AI Act and Data Act and their impact on European citizens' safety and innovation."

OSCAR GASPAR

"So I'd like to thank you all for joining us here in Brussels today for this event on the realities of implementing artificial intelligence and Big Data in the healthcare sector. This is the 6th edition of this workshop, organized by UEHP and Relyens, which is always an enjoyable affair and has the same ambitious objective: creating the conditions for stakeholders in the European healthcare sector, including institutions, private hospitals, companies, associations and researchers, to meet and discuss key issues."

ERWAN TRIVIDIC

"Now let's take a deep dive into reality!"

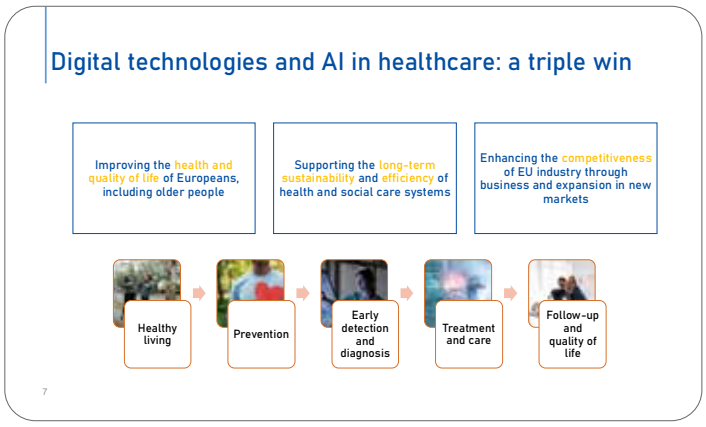
2. AI and health data: what theoretical framework?

New laws have been passed in recent years by the European Union to position the continent at the forefront of digital regulation to benefit its citizens and its strategic autonomy.

From the application of the EU's AI Act to its Data Act, the objective is to ensure that digital health is ethical, sustainable and managed effectively. But are these new regulations sufficient to create the conditions for public trust? Moreover, isn't there a risk that they will hamper innovation?
Read on for insights from institutional and legal experts.

2.1. Public will and public policy: the European Commission wants to support the roll-out of local AI systems.

Saila Rinne began by reiterating the **threefold advantages** of digital technologies and artificial intelligence in healthcare, particularly against the backdrop of an aging population and increased financial pressures on Europe's healthcare systems.



The Head of Unit then presented the **AI Continent Action Plan and its key pillars:** investing in computing infrastructure with AI factories and gigafactories, developing algorithms and skills, investing in data and, lastly, ensuring regulatory simplification.
With regard to this last point, Saila Rinne explained that the European Commission wants to clarify the **interplay between various texts** and hopes to arrive at a simplified, relevant and applicable set of rules for and with the help of various stakeholders.

Time to hear from:

Saila Rinne, Head of Unit on Artificial Intelligence in Health and Life Sciences at the European Commission's Directorate-General for Communications Networks, Content and Technology

The key idea:

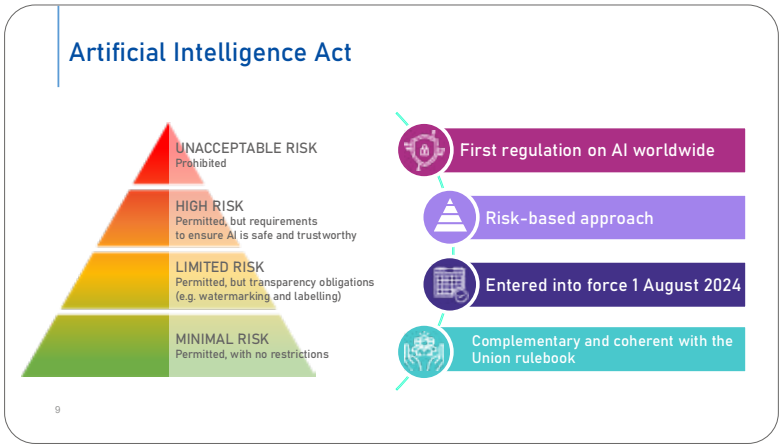
The European Commission is looking to provide the technical and regulatory framework to use AI in healthcare.

Food for thought:

"By applying the new regulation, you are in a better position to serve European patients."
Saila Rinne

“We should not look at the AI Act in isolation; it’s one tool among many to bring legal certainty.”

Saila Rinne



Saila Rinne presenting the risk-based approach of the EU’s AI Act.

Saila Rinne also said that the European Commission is working on an **implementation plan specifically for the healthcare sector** and the pharmaceutical industry: Apply AI Strategy.

She concluded her remarks with a presentation of the various projects related to healthcare data which are supported by the European Commission. These projects included a public-private partnership to develop virtual human twins.

Snippets
OF THE CONVERSATION

Dr Paul Garassus,
Honorary President of UEHP:

“We need a new generation of healthcare professionals with training in these new digital technologies. What steps is the Commission taking to achieve this?”

Saila Rinne :

“The Commission has set up digital skills academies and my department is pushing for a specific healthcare program. We also want more data scientists to join hospitals, because we are firm believers in cross-fertilization.”

David Gruson,
President of Ethik-IA:

“You talked about the need to simplify the regulatory framework around AI: how does the Commission intend to use it to support the implementation of AI in healthcare?”

Saila Rinne :

For example, the European Commission has just published a guide that explains the interplay between the Medical Device Regulation and the AI Act.”.

BENEFITS OF THE ADVANCED VIRTUAL HUMAN TWIN (VHT) PLATFORM

- **collaborative and community-driven**
- **cutting-edge and innovation-enabling**
- **distributed and flexible**
- **secure and privacy-preserving**

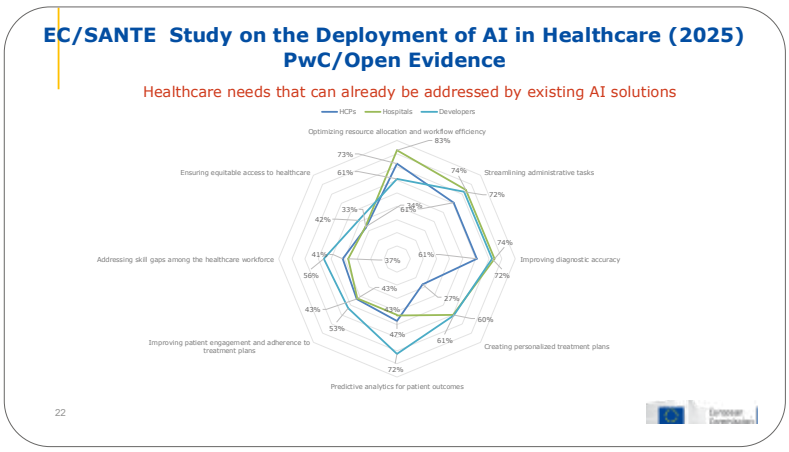
THE DEBATE CONTINUES

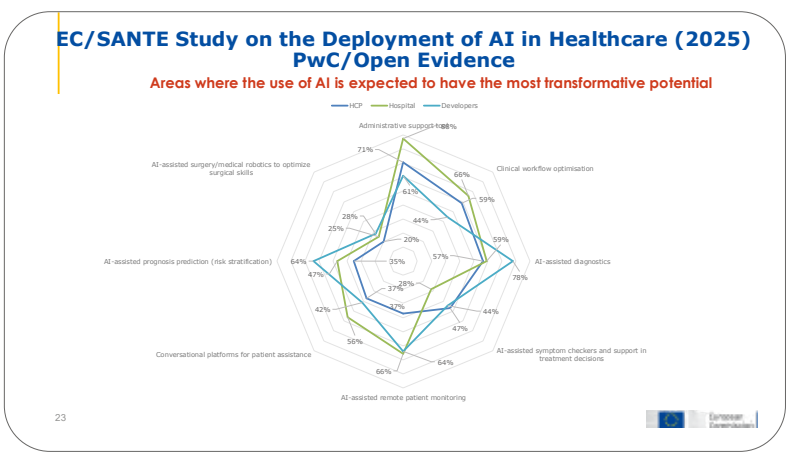
- Read this article on *AI Skills Academies*
- See “European regulations on data and AI: what consequences for the liability of healthcare providers and healthcare facilities?” by Dr Nils Lölfing p. 11

2.2. How things stand: what's the latest with AI in the European healthcare sector?

From the beginning of his presentation, Yiannos Tolias emphasized the urgent need to increase the public's **trust in and acceptance of AI** drawing a parallel with vaccines: if safety is not guaranteed, this technology will not be adopted by patients.
He also presented **the initial results of a study** by PwC and Open Evidence for the European Commission. It aimed to identify barriers to the deployment of AI in clinical settings by healthcare organizations and hospitals.
Looking beyond the differences in perception between healthcare professionals, hospitals and developers, the study shows that **administrative work and diagnostics** are the two areas in which the benefits of existing AI solutions are most evident.

Discussing the transformative potential of AI in healthcare, Yiannos Tolias underlined the issues around remote patient care: if Europe avoids the risk of a new digital divide by ensuring that AI is uniformly available across the entire region, artificial intelligence could help improve the situation in medical deserts.





Initial results of a study by PwC and Open Evidence for the European Commission

Time to hear from:

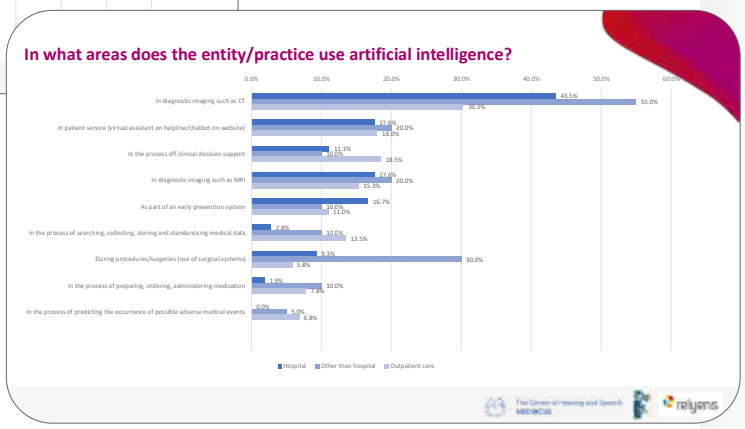
Yiannos Tolias, Legal Lead on AI and AI liability in healthcare for the European Commission's Directorate-General for Health & Food Safety.

The key idea:

Trust in and acceptance of AI are at the heart of this implementation phase.

Food for thought:

3 out of 4 hospitals say that existing AI solutions can help them streamline administrative tasks.



IN POLAND

The figures for Poland, presented by Łukasz Bruski, echo those of the European Commission's study: widespread adoption of AI solutions by imaging departments and plans for a growing number of applications to benefit patients.

Snippets
OF THE CONVERSATION

Dr Nils Lölfing :

"Can you talk a little more about the withdrawal of the AI Liability Directive?"

Yiannos Tolias :

"The directive had moved away from the original idea of automatic liability and there was no consensus about the way in which to address the issue of liability at this level. The Commission felt that the directive wasn't ready for implementation."

THE DEBATE CONTINUES

- Read this article on the withdrawal of the AI Liability Directive
- See "A US perspective: the DECODE project uses generative AI to create digital twins" by Maryaline Catillon, p. 17

2.3. The WHO is working to shape an ethical future for digital technology and AI in European healthcare.

Keyrellous Adib began his presentation with **statistics** which showed a keen interest **among European countries** in artificial intelligence in healthcare and the widespread adoption of national electronic health record solutions.

He also emphasized significant disparities in the implementation (or lack thereof) of policies for digital health management.

Keyrellous Adib describing the WHO's mandate in Europe and the key areas of focus of the regional digital health action plan for the WHO European Region 2023–2030.

Time to hear from:

Keyrellous Adib, Technical Officer for Data Science and Digital Health at the World Health Organization's Regional Office for Europe

The key idea:

The WHO in Europe works to support Member States in applying the regulatory framework for AI to ensure the technology's ethical implementation.

Food for thought:

48% of surveyed countries see legal uncertainties as a major challenge to the adoption of AI.

Snippets
OF THE CONVERSATION

Dr Paul Garassus :

"How do you work with the European Union on these issues?"

Keyrellous Adib :

"When we're drafting a new guide, for example, we make sure that it's proofread in advance by relevant contacts who work at European institutions to ensure the closest possible alignment. This year, we've prepared a module on the AI Act which we delivered to Member States during our annual training session. This is also useful for non-Member States: when the GDPR came into effect, many of them used it to develop their own regulations. That's how we make ourselves useful not only to the EU's 27 Member States, but also to our 53 Member States in the region."

Olena Chernenko, Founder and CEO of MedCapitalGroup:

"What formats do you recommend for the implementation of disruptive technologies, while ensuring interoperability?"

Keyrellous Adib :

"Interoperability involves various factors. In addition to standards and infrastructure, sometimes policies, regulatory frameworks and bodies need to be made interoperable. We have observed a common difficulty, which is the lack of interoperability between the public and private sectors, whatever the size of the country."

"There is no AI governance without data governance."

Keyrellous Adib

The WHO official explained that the agency provides **hospital IT system assessment services** in Europe and **supports the secondary use** of health data, in addition to its initiatives regarding Big Data and artificial intelligence (including providing training, publishing guides and creating toolboxes).

With just 14 of 50 countries reporting that they have policies in place to manage the ethical implications of AI, Keyrellous Adib listed the six core principles of ethics and governance for artificial intelligence in healthcare, as announced by the WHO back in 2021:

1. **Protecting autonomy,**
2. **Promoting human well-being, human safety and the public interest,**
3. **Ensuring transparency, explainability and intelligibility,**
4. **Fostering reproducibility and accountability,**
5. **Ensuring inclusivity and equity,**
6. **Promoting ai which is responsive and sustainable.**

The presentation concluded with a review of the associated risks and challenges of AI in healthcare, particularly the technology's **environmental impact.**

THE DEBATE CONTINUES

- Read the regional digital health action plan for the WHO European Region 2023–2030
- See "Hôpital Foch manages its AI governance" by Alexandre Drezet, Hélène Marin and David Gruson, p. 14

2.4. European regulations: what consequences for the liability of healthcare providers and healthcare facilities?

"Who is liable when AI has a negative impact on patient care?" The aim of the presentation by Dr. Nils Lölfing and Lucie Curtit was to help healthcare professionals **better appreciate the issues** and understand both the inherent risks of this new liability and existing mitigation strategies. The lawyer stressed that, beyond the legal and regulatory risks, healthcare organizations must be mindful of the **reputational risks** caused by AI system failure.

The AI Act and the new Product Liability Directive have introduced numerous legal obligations to protect patients. Consequently, even if these legal obligations are met, healthcare facilities and doctors may still be **held liable.**


Time to hear from:

Dr Nils Lölfing, Counsel in the Technology & Communications Sector Group, Bird & Bird Germany
Lucie Curtit, Digital Legal Director at Relyens

The key idea:

AI and data provide an opportunity that should be regulated for the healthcare organizations that use them.

Food for thought:

"The potential damage has not yet occurred, so we are very early with this conversation."

Theoretical framework

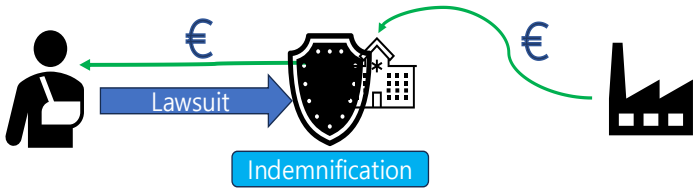
Dr Nils Lölfing outlined **three theoretical liability scenarios** in light of these new European and local regulations, before making a few recommendations for best practices to mitigate the risks for healthcare facilities and doctors.

"The administrative director of hospitals in me can't shake the feeling of my blanket being too short."

Paolo Silvano
UEHP Auditor and moderator of the workshop

Example 1: PLD – Defective AI Software

Scenario: An AI diagnostic tool used by hospital staff provides a faulty diagnosis due to a latent software defect. A patient suffers harm and files a claim.



- **Manufacturer**
  - Strict product liability under PLD implementation
  - Liable without negligence if defect and causation are proven
- **Hospital**
  - Not strictly liable but may face initial lawsuits
  - Liability possible under medical negligence for improper AI monitoring
- **Key Takeaways**
  - Negotiate indemnification with and confirm insurance of manufacturer
  - Validate, test, and document AI tools
  - Train staff on AI limitations

Dr. Nils Lölfing rounded off this presentation by emphasizing that AI liability must be subject to clear protocols, robust contracts and strict oversight.

Dr. Nils Lölfing presenting a specific scenario involving the liability of a healthcare facility.

Risk Mitigation & Best Practices (1) Liability

- **Choosing AI Systems Wisely**
  - Conduct thorough risk assessment before procurement
  - Scrutinise vendor compliance and history of product performance
- **Training & Awareness**
  - Provide "AI literacy" for clinicians to minimise user errors
  - Encourage clinicians to review and question AI outputs
- **Patient Consent & Documentation**
  - Update consent forms to reflect AI use and associated risks
  - Keep detailed records of system inputs, outputs, and any overrides

Insight from
LUCIE CURTIT

Digital Legal Director at Relyens

"The Product Liability Directive still needs to be transposed into the national law of EU Member States, which may result in local differences, unlike the AI Act, which is immediately and universally applicable."

Snippets
OF THE CONVERSATION

David Gruson :

"Are you seeing an increase in claims related to these issues? Should we expect a tsunami?"

Lucie Curtit :

"It's too early to say whether the adoption of AI will lead to an increase in claims and insurance premiums. For several years now, we've tried to prepare for this new reality to be able to take proactive measures and help our customers prevent and limit claims."

Omar Tujjar, President of the International Society of Medical AI:

"Do you see the potential usefulness of a tool that can assess internal processes and certify that a hospital is ready to implement AI solutions? Could that be beneficial in terms of liability and the cost of insurance?"

Dr Nils Lölfing :

"I would say that it all depends on how precise the tool is: if it's too generic, it won't be sufficient to mitigate the risk of legal liability. But if it can incorporate specific policies in addition to standard criteria, then yes, it would clearly be beneficial for the hospital, the insurer and, ultimately, the patient."

THE DEBATE CONTINUES:

- Find out more about the International Society of Medical AI
- See "Data as fuel" by Maryaline Catillon, p. 20

3. How are healthcare stakeholders incorporating AI and data into their approach to patient care?

Artificial intelligence is already part of everyday life for some healthcare organizations in Europe.

Using three specific examples, we were able to gauge the real-world impact of these technologies on medical practice, patient care and treatment quality and safety, going beyond the hype and what are often unrealistic expectations.

3.1. Hôpital Foch manages its AI governance.

After a brief reminder of the changes in the concept of "human oversight" since 2017, David Gruson welcomed the **acceleration of the roll-out** of tools to implement AI systems, from methodologies to platforms like those of Ethik-IA. Hélène Marin explained that at Hôpital Foch, the first stage involved setting up an **AI Committee**, including doctors, within the organization to determine its strategy for this technology.
A **Human Oversight Committee** was also created to address more operational issues related to AI, such as the obligation to inform the patient. The hospital's DPO and CISO are involved in this, along with a representative of patients.

Hôpital Foch has also used the Ethik-IA platform to **map all its AI systems in use** "This mapping has been particularly valuable and must be updated to ensure its continued relevance," Hélène Marin stressed.

"We also need doctors to be a part of the AI Governance Committee to limit the effects of 'shadow AI'."
Hélène Marin



Time to hear from:

Alexandre DREZET, Head of Innovation at Hôpital Foch near Paris,
Hélène Marin, Executive Director of Ethik-IA,
David Gruson, President and Founder of Ethik-IA

The key idea:

The roll-out of AI is about more than just technology: hospitals must adapt their organization and engage all stakeholders.

Hôpital Foch in figures:

600 beds

A budget of €350 million

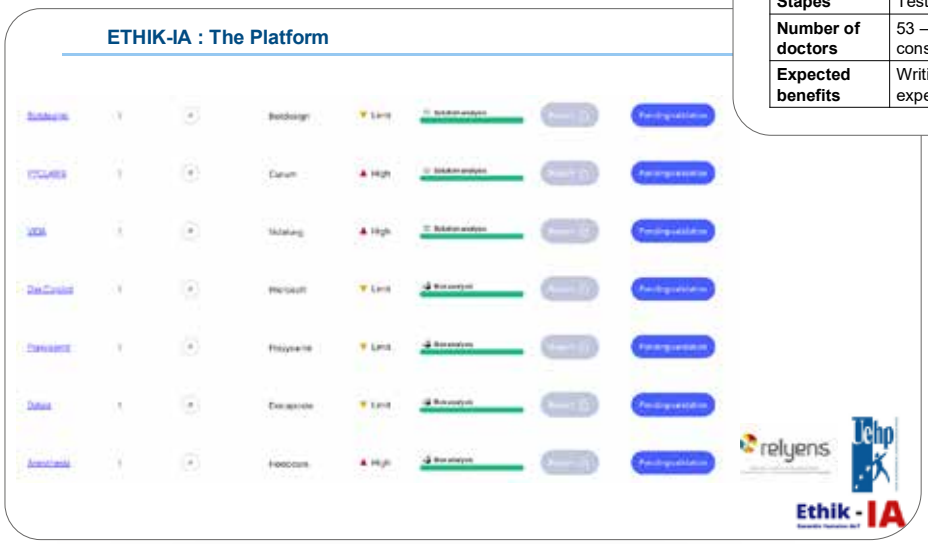
Food for thought:

"AI is a tool and but the decision must continue to be made by the doctor."
David Gruson

Alexandre Drezet explaining the testing of two generative artificial intelligence tools at Hôpital Foch.

GenAI tools tested for several weeks.

	Dragon Copilot	Dalvia
Provider	Microsoft	Docaposte (filiale LPSA)
Use	Automatic recording of medical reports through doctors–patients dialogues	Generative synthesis from multiple documents to write a care transition letter
Stapes	Testing phase	Testing phase
Number of doctors	53 – 1042 medical consultations	3
Expected benefits	Writing time and patient experience	Writing time



The Ethik-IA platform listing AI solutions and compliance-related tasks linked to their use.

Snippets
OF THE CONVERSATION

Omar Tujjar, President of the International Society of Medical AI

"I'm wondering how you go about assessing suppliers of AI systems. With a tool like Microsoft's DAX Copilot, for example, what data are you basing your assessment on?"

Hélène Marin, Executive Director of Ethik-IA:

"We contacted Microsoft to ask them to provide us with as much information as possible. Our audit is then able to determine whether or not it is compatible with the AI Act."

David Gruson, President and Founder of Ethik-IA:

"Hôpital Foch's support was instrumental in Microsoft's decision to agree to our request: that really shows how much stronger our ecosystem is when we work together."

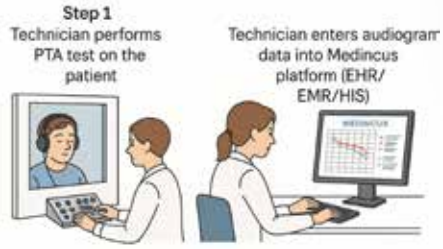
THE DEBATE CONTINUES

- Find out more about AI governance at the European Commission
- See "How things stand: what's the latest with AI in the European healthcare sector?" by Yiannos Tolias, p. 8

3.2. Medincus automates and standardizes hearing tests.

Łukasz Bruski explained the issue which led his Center to develop an audiology AI solution: a **lack of experts with sufficient training** in detection tests and the considerable subjectivity involved in the diagnosis and treatment of detected pathologies.
Medincus then compared this AI system's performance with the results of experienced audiologists, using a separate and independent data set to ensure accuracy and reliability.

Our AI solution for PTA



Just a few weeks after the launch of this solution, Łukasz Bruski already saw several benefits for the organization, starting with **data standardization,** followed by less reliance on its sole in-house expert, who is now consulted only in particularly complex cases. Moreover, this solution provides the same level of patient care in the other countries in which Medincus operates, including Kyrgyzstan and Senegal.

Snippets
OF THE CONVERSATION

Dr Francesco Petracca :

"You've said that the algorithm provides advice; what is the impact of this advice on the decision-making process?"

Łukasz Bruski :

"We don't currently have enough information to answer that question, but overall, the specialists are delighted to be able to rely on this new tool, as these tests are very difficult to interpret. I hope to be able to come back next year to provide you with more specific data."

Time to hear from:

Łukasz Bruski, President of the Board of the Medincus Center of Hearing and Speech and member of the Board of the Polish Association of Private Hospitals

The key idea:

When applied to a specific field, AI makes it possible for all patients to benefit from the same level of expertise.

Food for thought:

€100,000. That was the asking price for Medincus' access to the database to train its AI solution. The price was later reduced to €10,000, given the project's scientific importance.

THE DEBATE CONTINUES

- Read the definition of "automation bias" in Article 14.4.b of the AI Act
- See "Culture and skills: what AI is changing for healthcare professions" by Dr. Francesco Petracca, p. 18

3.3. A US perspective: the DECODE project uses generative AI to create digital twins.

Maryaline Catillon presented the DECODE project (Dynamic Evaluation of Cardiometabolic Obesity DiseasE), developed by a specialist AI team led by Jimmy Royer, Principal and Data Science Director at Analysis Group. This project uses data from more than **13 million patients**, treated in more than 60 hospitals. This data covers the entire care pathway (including hospital and outpatient treatment and administrative procedures) and is made up of structured data (diagnostics, prescriptions, laboratory results) and unstructured data (clinical notes, medical imaging). This comprehensive and reliable data about the health outcomes of a large patient population makes it possible to **create an accurate simulation of the progression of a complex condition** such as obesity and its cardiometabolic comorbidities.

After presenting the project's methodology, Maryaline Catillon presented its results, which showed and quantified the significant benefits of weight loss, taking into account real-world complexities. Work is underway to further expand the data sources used and verify the results with cohorts in the long term.
This example proves that interoperable, comprehensive and high-quality health data is the vital foundation of modern AI-based medicine. This foundation ensures that digital tools can work effectively in real-world situations, enabling all healthcare stakeholders, including health professionals, researchers and public authorities, to make informed decisions, based on a comprehensive and reliable understanding of the care pathways of the relevant patients and/or populations.

Time to hear from:

Maryaline Catillon,
Manager, Analysis Group

The key idea:

AI models can only make an effective contribution to improvements in patient care, advances in health research and the development of public policy if they draw on comprehensive and high-quality interoperable data which reflects the care pathway in its entirety.

Food for thought:

When applied to health research, generative AI is revolutionizing our understanding of diseases and the impact of treatments, particularly through the use of digital twins.

Snippets
OF THE CONVERSATION

Georges Romero :

"Could this specific situation have occurred in Europe? What would have been different?"

Maryaline Catillon :

"It absolutely could have occurred in Europe, but there would have been specific challenges, linked to the fragmentation of healthcare systems and continued limited access to interoperable databases covering all healthcare settings. Unlike the United States, where standards such as HL7 FHIR and open APIs (SMART on FHIR and SMART/HL7 Bulk FHIR Access) have been made mandatory by federal regulations since 2022, Europe is still working towards a standard infrastructure. However, this situation is evolving rapidly: the entry into force of the European Health Data Space (EHDS) in 2025 is a decisive step towards transcontinental interoperability."

THE DEBATE CONTINUES

- Read the relevant US federal regulations
- See "Public will and public policy: the European Commission wants to support the roll-out of local AI systems" by Saila Rinne, p. 6

4. What challenges need to be overcome to ensure that data and AI deliver tangible benefits?

When it comes to artificial intelligence and health data, the transition from technological innovation to real-world improvements in patient care involves much more than the adoption of tools.

It entails a fundamental transformation of professional practices, technical and ethical expertise in health data and careful adaptation to the organizational and operational constraints of the healthcare system. Rather than being purely technical, these challenges lie at the heart of what healthcare professionals do and raise questions about skills development, data governance and how these solutions can be embedded in healthcare facilities' day-to-day realities.

4.1. Culture and skills: what AI is changing for healthcare professions

Dr. Francesco Petracca described a **revolution operating at several different speeds:** the first wave, which is already well established, is "silently" transforming administrative processes.

The second wave is focused on clinical activity; here, implementation is sparking more discussion, both in the media and among professionals, because it's akin to a medical decision-making. The researcher also emphasized that the issues raised by responsive AI tools are bound to become more pressing with agentic AI. Agentic AI, or AI agents, is a term for AI systems which require very little human intervention and complete tasks by establishing the intermediate steps themselves, which they then follow independently.

Early insights on the impact of ambient scribe adoption

Impact Area	Example Metrics	What We Know Today
Clinician	Attrition	■ Too early to draw a conclusion
	Burnout	✚ Emerging evidence suggests a positive impact
	Clinician experience	● Mixed feedback on the impact
	Clinician time saved	● Mixed feedback on the impact
	Cognitive load	✚ Emerging evidence suggests a positive impact
	Pajama time	● Mixed feedback on the impact
	Quality of clinical note summary	✚ Data/anecdotal feedback support a positive impact, with a human in the loop

Initial insights into the impact of using ambient scribes, solutions which use AI to automatically transcribe doctor-patient conversations during a consultation.

Time to hear from:

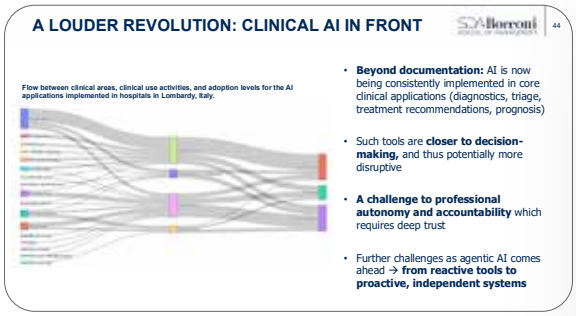
Dr Francesco Petracca, SDA Bocconi

The key idea:

The roll-out of artificial intelligence is, first and foremost, a human endeavor.

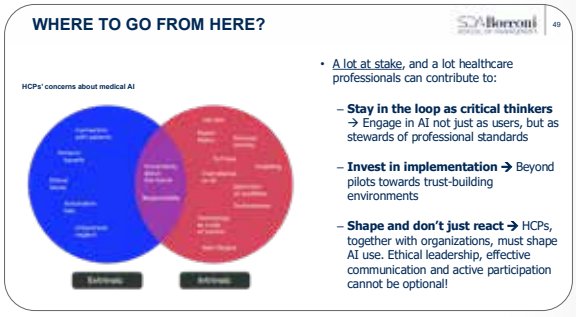
Food for thought:

"Teaming up with peers is challenging, but teaming up with AI brings other challenges, because it learns much faster and better than you do."



Dr. Francesco Petracca presenting a study conducted in Lombardy which shows that a significant proportion of the 60 identified applications of AI is already used in routine clinical tasks.

That's why Dr. Francesco Petracca spoke about **professional identities coming "under pressure"** in healthcare professions, mentioning the existing tension between delegation and deskilling. After presenting some of the lessons learned from analysis of various implementation strategies for AI tools, he concluded his presentation by underlining the active role which healthcare professionals must play in this revolution.



Dr. Francesco Petracca urging healthcare professionals to address the issue of AI proactively to shape its use, rather than passively.

THE DEBATE CONTINUES

- Read the study cited by Dr. Francesco Petracca
- See "Recognizing the reality on the ground" by Sarada Das, p. 22

AI, A WHOLE NEW WORLD FOR CYBERCHONDRIACS?

Valérie Vocanson, Deputy CEO European Development at Relyens, asked about the acceptance and use of [generative] AI by patients. She wondered whether people are increasingly turning to these technologies for self-diagnosis. Dr. Francesco Petracca's response: "For the moment, the phenomenon is limited to individuals who are enthusiastic about technology or innovation, but given the speed at which AI is being adopted, we are likely to see a trend along these lines within the next two years."

Snippets
OF THE CONVERSATION

Valérie Vocanson :

"With regards to what you said about professional identity, do you see a correlation with healthcare professionals' age?"

Dr Francesco Petracca :

"We haven't identified any correlation with age. Nevertheless, given that professional identity among young people is less well established and doctors approaching retirement don't feel particularly concerned by professional identity, we might assume that experienced healthcare professionals, who are in the middle of their careers and are accustomed to a certain status, feel the most threatened by this revolution. But that's merely an assumption, I don't have any data on that."

Olena Chernenko :

"We've talked a lot about continuing professional development for healthcare professionals, but what about initial training? Today's medical school curriculum is outdated; shouldn't we reconsider our approach entirely?"

Dr Francesco Petracca :

"The situation varies from country to country: France has introduced a module on the use of digital tools, but I agree with you, it's a considerable challenge. Especially given that artificial intelligence is also having a huge impact on how we pass down knowledge and skills from one generation to the next."

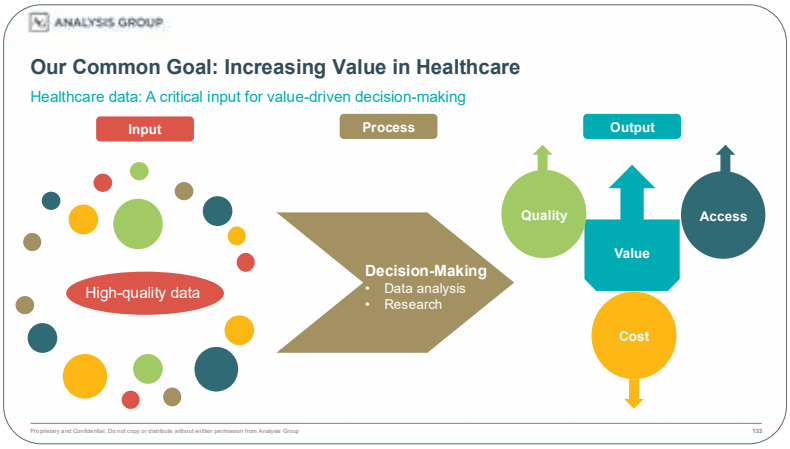
4.2. Data as fuel.

Maryaline Catillon began by defining value creation in healthcare as the combination of three major objectives: **the quality of patient care, access to healthcare and cost control.** She then underlined the decisive role of the quality, availability and interoperability of health data in this process: data is the source of information needed to analyze patient care, optimize access to healthcare and understand (and control) costs.

Picking up on the day's discussions on the regulatory framework which explored the risks of sharing health data and using AI, the researcher and consultant warned of the **risks of not sharing** health data and not using AI. These risks are very significant and can result in a loss of chance for patients because of avoidable diagnostic errors and/or suboptimal treatment choices, for instance. They can also affect the health of entire populations – for example, by delaying the assessment and adoption of innovations and/or the detection of public health risks.

These considerations prompted Maryaline Catillon to mention the differences in interoperability between the United States and the European Union.

She explained that the interoperability of health data has seen major progress in the United States, through a combination of regulations, innovations and collaborative efforts.



Maryaline Catillon presenting a diagram of the value creation process in the healthcare sector.

Time to hear from:

Maryaline Catillon,
Manager, Analysis Group

The key idea:

Comprehensive, reliable and interoperable health data is a prerequisite to reap the benefits of AI in healthcare.

Food for thought:

"Right now, hospitals are investing in obsolete solutions. Others are investing in AI without having first invested in preparatory work to ensure the quality of the necessary data. Decision-makers don't always have all the necessary information to make informed decisions in this area. Despite their highly strategic implications, necessitating the involvement of hospital leaders, the technical aspects of data are too often considered to be a nerdy subject, which is left to technical teams."

Health Data Interoperability – US vs EU Regulatory Landscape

	US	EU
Regulatory Framework	21st Century Cures Act (2016), CMS Interoperability Rule, ONC Final Rule (2020)	European Health Data Space (EHDS) Regulation (EU 2025/327)
Key Goals	- Promote data exchange across systems - Empower patients with access rights	- Enable cross-border health data access - Foster secondary use for research & innovation
Patient Access Rights	Mandatory access via APIs; "without special effort" clause (information blocking rule)	Citizens must have full access, control, and portability across EU; no equivalent blocking rule
Governance	HHS/ONC/State Agencies	EU-wide & national Health Data Access Bodies (HDABs)
Timeline	Key provisions in effect since 2021	Phased rollout: 2025 (adopted) → 2027 (HDABs) → 2029–2031 (mandatory exchanges)

Abbreviations: CMS: Centers for Medicare and Medicaid Services; EHDS: European Health Data Space; HDAB: Health Data Access Bodies; HSS: U.S. Department of Health and Human Services; ONC: Office of the National Coordinator for Health Information Technology

**"In the United States, progress in interoperability has been driven by regulations that have mandated the adoption of standards and the use of the open-source framework known as SMART*.
This framework has made it possible to develop a common language around health data, benefiting patients, doctors, hospitals and researchers, along with innovative companies, from start-ups to pharmaceutical groups."**

Lastly, at a time of regulatory change and budgetary constraints, Maryaline Catillon encouraged European hospitals to be part of the AI revolution in the healthcare sector by joining research programs and international corporate partnerships. These initiatives are an opportunity for healthcare facilities to keep up with changes in research (real-life data, AI), continuously train their teams, leverage their data to access new funding and contribute to international scientific output, all while enhancing their ability to innovate and improving Europe's competitiveness in AI.

THE COMPLEXITY OF INTEROPERABILITY

When presenting his case study, Łukasz Bruski explained that Medincus had approached two major manufacturers of hearing aids: each one used a different export format and one manufacturer requested payment for this data. But that's not all: each version of the chosen manufacturer's devices produced different data too. Proof that data sharing is no simple matter!

THE DEBATE CONTINUES

- Find out more about SMART*
- See "Medincus automates and standardizes hearing tests" by Łukasz Bruski, p. 16

Substitutable Medical Applications and Reusable Technologies

4.3. Recognizing the reality on the ground.

Sarada Das spoke **on behalf of doctors**. Their views must be considered to ensure the successful implementation of AI. To this end, they must be involved in the process as early as possible and included in dynamic feedback loops. It should also be noted that previous digital projects haven't always lived up to the hype, despite promising to save time and reduce stress. With AI, doctors expect an **evidence-based approach** and an objective way to quantify the related workload.

Sarada Das continued by emphasizing that trust is particularly important to healthcare professionals, which is why it is important to be able to answer their questions, whether they're about data storage or the development of AI solutions. According to the CPME, doctors are calling for the **right not to use AI**, particularly given that the liability regime has not yet been clearly defined. There are also questions about solutions' certification and the inclusion of these new skills in medical training.

In view of these concerns, the CPME has published ten key recommendations, including the development of AI systems which meet the actual demands of the healthcare sector and the evaluation of AI's efficiency and efficacy. In her conclusion, Sarada Das advocated for a **clear liability regime** and mandatory insurance coverage for AI systems.

CPME: 10 RECOMMENDATIONS

- Design AI on actual healthcare demands and in dynamic loop
- Evaluate AI efficiency and efficacy
- Compliance of AI systems with medical ethics, data protection and privacy required
- Certify AI systems to increase trust among healthcare professionals
- Demystify AI by improving literacy and foster competence development
- Mitigate deskilling risks and ensure critical thinking
- Promote adequate tools and methods to interpret and explain AI output and provide detailed and clear instructions for use for deployers
- Ensure adequate monitoring and oversight with a clear liability regime
- Encourage AI and cyber insurance coverage
- Coordinate knowledge environment at EU and national level

"Implementation isn't a matter of doing, it's a matter of thinking before doing."

Paolo Silvano

Time to hear from:

Sarada Das, Secretary General of the Standing Committee of European Doctors (or CPME, in French), an international organization which represents the EU's 27 national medical associations

The key idea:

Doctors are not reluctant to use AI, but they advocate for an evidence-based approach.

Food for thought:

"When deploying AI, do not cut funding from other areas of healthcare systems."

Snippets
OF THE CONVERSATION

Ilaria Giannico,
Secretary General of UEHP

"At a European level, it seems to me that we're focused on skills development, but I'm not sure we're addressing the risk of deskilling you mentioned."

Sarada Das :

"Yes, that's a key issue and I'd also add that there are some misconceptions about digital skills, especially among younger generations. But they have a limited time for training and diagnostic training can't be replaced with digital training!"

Olena Chernenko :

"On the ground, there's little demand for digital transformation, particularly in high-pressure environments such as Ukraine right now: they don't have the resources to listen to us or to change. Should we perhaps rethink our approach to the roll-out to be more directive?"

Sarada Das :

"The situation in Ukraine is sadly extreme, but that's not necessarily the whole picture, because lots of doctors are taking advantage of the opportunities of digital technologies and AI. We've seen radiology departments making use of these technologies, along with administrative departments, with a reduction in errors and data duplication. On the other hand, Canadian doctors recently told me that one of their AI tools enables them to organize... faxes."

THE DEBATE CONTINUES

- Read all the suggestions from the CPME
- See "The WHO is working to shape an ethical future for digital technology and AI in European healthcare" by Keyrellous Adib, p. 10

Closing discussion

"What makes our workshops unique is the space they provide for open discussion and the sharing of real-world experiences. Thanks to the continued partnership between UEHP and Relyens, once again, this 6th edition has been an invaluable event, providing the opportunity to learn from one another, strengthen connections and look ahead together."

DR PAUL GARASSUS
HONORARY PRESIDENT
OF UEHP

"Yes, in light of today's discussions, it seems important to me to highlight the distinction between AI which aims to optimize hospital operations and AI as a medical device. Because they don't have the same impact on the patient, the liability of these two kinds of AI is not the same."

GEORGES ROMERO
DIRECTOR OF MEDICAL RISK
MANAGEMENT AT RELYENS

VALÉRIE VOCANSON
DEPUTY CEO
EUROPEAN DEVELOPMENT

"Absolutely, Georges! Today's agenda was tantalizing and we've been treated to a cornucopia of an event, with plenty of food for thought, proving that the AI revolution is already well underway. I feel very privileged to have been here today."

PAOLO SILVANO
UEHP AUDITOR
AND EVENT MODERATOR

"I would add that we are very proud to have been able to explore such a topical subject this year. In doing so, we have presented a wide range of views, something that I believe to be vital when addressing such a pressing issue."

GEORGES ROMERO

"I agree, Paolo. I'm conscious that the roll-out of AI is a complex subject which entails data standardization, along with social and cultural challenges, including demystification. Nevertheless, it seems that healthcare professionals' lack of trust in this technology isn't really related to the issue of liability, but to fears about losing autonomy when making medical decisions."

VALÉRIE VOCANSON

"There's real appetite for AI and I've got three main takeaways when it comes to the implementation of these technologies: **collaboration**, reinforced by all the progress made by the European Commission in its efforts over the last year to create the conditions for acceleration, ownership, which relates to professional identity and, lastly, trust and acceptance. These last two are key issues for Relyens, given that the challenge is to ensure a safe system and clear liability. As an insurer, it's our role to alleviate concerns and make sure that coverage is sufficient. In any case, this conversation isn't over yet."

Georges Romero drew a parallel with preventable adverse events in the operating room, such as wrong-site surgery. This problem has long since been addressed by means of a checklist. However, today in France, this checklist is completed in fewer than 50% of cases. This example serves as a reminder of the importance of humility when faced with the challenges of the implementation phases of any project.

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Uehp

UNION EUROPÉENNE DE L'HOSPITALISATION PRIVÉE

The European Union of Private Hospitals (UEHP) is the European association representing and defending the interests of private hospitals in Europe. Based in Brussels, at the heart of the EU, UEHP represents about 5,000 clinics in 16 European countries.

OUR DEBATE SERIES

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