Digital Health and AI: Benefits and Costs of Data Sharing in the EU
FEAM European Biomedical Policy Forum | Annual Lecture - 26 October 2022

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Background

Data science and digital technology is rapidly evolving, holding great promise in improving healthcare systems as well as paving the way for scientific breakthroughs and innovation. The new technologies have a huge positive impact in all areas, but also lead to consequences and challenges on regulatory and policy frameworks. Whilst the world has faced the pandemic, digital technology such as telemedicine, storage of electronic medical records, virtual education and, sharing of data on emerging viruses have contributed positively towards resilience of healthcare systems. These tools build upon advances in Big Data and Artificial Intelligence (AI), provide major opportunities to push the boundaries of science and improve healthcare innovation.

In its communication on the European strategy for data, the Commission emphasizes the importance of data to consolidate the EU digital economy and support concrete actions in Digital Health. In particular, the Commission recognizes the challenges that exist for organizations to effectively share health data in research and to use this data to improve patient care. The creation of a common **European Health Data Space (EHDS)**, as an approach to facilitate sharing of data, represents a valuable building block. This new common platform would allow AI systems to automatically have easier (but appropriately protected) access to relevant data, leading to higher accuracy and better predictions and recommendations by the health system, resulting in higher quality of services for citizens and patients. Nonetheless, specifications on governance and structure of a EHDS still require a clear definition, building on contributions from different sectors.

In this context, on the 26 October 2022, the FEAM European Biomedical Policy Forum - with the support of AstraZeneca and the European Infrastructure for Translational Medicine (EATRIS) - organised a discussion with expert policymakers, academics, industry and civil society representatives to provide the opportunity to exchange opinions on the impact and challenges of using new digital health technologies and sharing of data, and to identify areas of consensus and/ or disagreement among experts. The event also featured lessons learned from the COVID-19 pandemic and the need for better cooperation in view of future health emergencies.

'It's not the data, it's advanced analytics (BDA). All the data has been there for a long time, but it is now that they are being analysed and interpreted. It is the most radical change that has happened in Health.' ***Eric Topol****, Director of the Scripps Translational Science Institute*

Introduction

In recent years, the vast collection of health data amongst European citizens has been matched by a growing capacity to analyse and exploit the information. In this sense, Europe can be said to be ready for the Artificial Intelligence (AI) and Digital Health revolution taking place in healthcare. However, firstly, it is important to clarify the wide concept of AI. AI can be defined as the general capacity that computers have to mimic human intelligence for the performance of a specific task. In the context of AI interventions in healthcare, the focus is on machine learning, which is a recent subset of AI that learns to perform given tasks from data and improves with experience. The last twelve months have been extraordinary for the development of AI in healthcare, with the publication of four key documents of note:

1. **Artificial Intelligence in Healthcare: applications risks and societal impacts (EU Parliament)** (www.europarl.europa.eu/RegData/etudes/STUD/2022/729512/EPRS_STU(202)729512_EN.pdf)
2. **The 2017/745 Medical Devices Regulation (MDR) and 2017/746 In vitro Diagnostic Medical Devices (IVDR) regulation** (eur-lex.europa.eu/eli/reg/2017/745/2020-04-24 ; eur-lex.europa.eu/eli/reg/2017/746/oj)

3. **The EU proposal on the regulatory framework for AI**
   (digital-strategy.ec.europa.eu/en/policies/regulatory-framework-ai)
4. **The Ethic guidelines for Trustworthy AI**
   (digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai)

Although there have been advances in research and development (R&D) in all AI fields, the advance of machine learning in healthcare over the past few years has been particularly impressive. Its strong impact can be measured in the varied applications of AI in healthcare: outbreak prediction, diagnosis of diseases, medical image diagnosis, drug discovery, personalized medicine, medical robots, electronic health records and clinical trials to name but a few. After reaching a certain level of sophistication of AI in the health domain, it is necessary to begin to bring structure to this complex landscape. The AI tools in the healthcare domain can be broadly categorized into four areas: clinical practice, biomedical research, public health, and health administration. However, despite all the progress, it is important to note that considerable risks in healthcare remain:

- **Patient harm due to AI errors**
- **Misuse of medical AI tools**
- **Risk of bias in medical AI and perpetuation of inequities**
- **Lack of transparency**
- **Privacy and security issues**
- **Gaps in AI accountability**
- **Obstacles to implementation in real-world healthcare**

The medical consequences of AI errors can be severe, ranging from missed diagnosis of life-threatening conditions, false diagnosis and thus inadequate treatments and incorrect scheduling or prioritization of interventions. In order to mitigate these challenges, several measures should be prioritized. Firstly, there should be comprehensive multi-centre evaluation studies to identify instabilities in the datasets. Secondly, there should be a consensus that AI is an assistive solution to the human process, and it should be used to assist and complement clinical decision making. For example, if there is limited involvement of clinicians and citizens in AI development and a lack of training in medical AI among healthcare professionals, the likelihood of potential misuse increases. Therefore, it is crucial that certain measures are taken to mitigate misuse, such as prioritizing a user-centred design, integrating AI education and training in medical schools and introducing new literacy programmes to increase medical AI knowledge in society.

The risks of AI in healthcare can be categorized into different domains:

- **Bias in medical AI and perpetuation of inequities**
  Possible solution: Representative datasets, enhancing diversity and inclusion, diverse development team

- **Lack of transparency**
  Possible solution: AI passport for documenting the model deployed, including traceability and explainability as prerequisites for certification
- **Privacy and security issues**
  Possible solution: Regulations to address accountability and the use of a federated approach
- **Gaps in AI accountability**
  Possible solution: Unified regulatory frameworks including the involvement of manufacturers
- **Obstacles to implementation in real-world healthcare**
  Possible solution: Development of data standards and data interoperability (EHDS)

Recently, the European Commission published the long-anticipated regulation on artificial intelligence (AI), as a regulatory framework. The EU AI Act is a proposed European law on AI; it is the first law on AI by a major regulator anywhere. Although it is still in the draft stages, the law assigns applications of AI to a pyramid of risk categories. Firstly, applications and systems that create an **unacceptable risk**, such as government-run social scoring, are banned. Second, **high-risk applications**, such as a CV-scanning tool that ranks job applicants, are subject to specific legal requirements such as a conformity assessment. Lastly, applications not explicitly banned or listed as high-risk are largely left unregulated. Most of the machine learning solutions in healthcare are assessed as high-risk, thus they will require a conformity assessment. Crucially, the act includes a proposed regulatory workflow, which ensures that if there are substantial changes observed in the way the AI tool is implemented, it must go back and undergo the conformity assessment and comply with AI requirements again. This ensures that once a tool is launched into the market, it is still subject to strict regulation and there is space for governmental intervention, if necessary.

There are significant obligations placed on the organisations that are creating and implementing these AI tools. For example, they must establish a quality management system, keep up to date with technical documentation, undergo a conformity assessment and register the AI system in the EU database. This strong regulatory process is evolving together with an ethical dimension, which aims to ensure that AI reflects European values. These values include:

- **Human agency and oversight**
- **Technical robustness and safety**
- **Privacy and data governance**
- **Transparency**
- **Diversity**
- **Non-discrimination & fairness**
- **Societal and environmental well-being**
- **Accountability**

In order to facilitate the use of data, the European Commission has identified the creation of the European Health Data Space (EHDS) as a top priority of the European Health Union. In May 2022, the regulatory framework was published, and the process of pre-implementation is well underway. Very recently, the European Commission has funded two prefigurative instruments which should help define some key elements for the future implementation of the EHDS:

1. TEHDAS joint action – provides studies, concepts, recommendations on secondary use of health data on a European scale
2. EHDS pilot- creates and tests a first version of European Health Data Space network

A further example of an infrastructure underway is the EUCAIM project, a pan-European digital federated infrastructure facilitating the discovery of new findings, accessing harmonized cancer images and related patient data. This aims to be a proof of concept that the principles laid out in the EHDS can indeed be transferred easily into clinical practice. We have arrived at the border of a potentially new era of medicine, and the EHDS will help to allow citizens to have better control over their own health data.

European Parliament perspective

In the twenty-first century, access to quality health services should be a fundamental right, yet, according to recent studies from the European Commission, WHO and the OECD, there is still unequal access to healthcare within the EU and some member states still have an inadequate primary care structure. For examples, many European patients still move with paper dossiers from one physician to another, when receiving treatment. These types of issues could be alleviated if we transition to digitalisation in healthcare, which means a greater role for AI and more data sharing that can improve citizens health, transform health care systems, and speed up the development of new medical tools. The EHDS is an important proposal, which will build on the Data Governance Act and the Data Act, ensuring that a patient's data can be exchanged in a safe environment and it can improve access to healthcare and medicine across the union. However, the EHDS implementation requires clear rules to be enforced on the interoperability and security of the data. The European Parliament welcomes the active engagement, participation and expertise of citizens, as the EHDS legislation passes through the Committee on Civil Liberties, Justice and Home Affairs (LIBE) and the Committee on the Environment, Public Health and Food Safety (ENVI).

Panel Discussion

The Panel was comprised of high-level, cross-sector experts and representatives, ranging from the European Commission, academia, civil society organisations, industry, as well as physicians and pharmacists. The discussion covered a wide range of key topics, such as implementation of AI in healthcare in Europe, legislation such as the AI act and the EHDS, the impact of COVID on AI and the practical benefits of AI.

Key challenge/focus

Firstly, the discussion began around the topic of key challenges facing AI in healthcare and the important areas in need of attention. From the **Physician's perspective**, an important challenge is the mismatch between exciting research and clinically useful and validated technology. Therefore, it is imperative to find clinically and cost-effective ways to use the technology for people's benefit. From the **European Commission's perspective,** it is important to look at both challenges related to the development, as well as deployment, of AI in clinical practice. The key focus from the **industry perspective** is the AI act and how it can help put appropriate safeguards in place, without introducing unnecessary high thresholds for research, innovation and already established ways of working. From the **civil society perspective,** the crucial challenges will be centred around building trust with citizens and ensuring that patients receive education and training about their health data. The TEHDAS project was cited as a strong example of consulting citizens and involving them in the process. The **academic perspective** singled out the shortcomings of the AI act in its current form, expressing concern about its scope, accountability, and assessment. Finally, from the **pharmacist's perspective,** a key focus should be on integrating the AI tools effectively into clinical care.

Effective implementation of AI in healthcare

Although Europe performs strongly in the discovery of potential AI products, there is still some doubt around its performance in AI implementation. In this discussion, various suggestions were made to improve the effective implementation of AI in healthcare across Europe. From the **physician's perspective**, the technological environment into which these AI systems are deployed needs to be improved. Technology in healthcare is currently very fragmented and this has not been viewed as a priority until very recently. Chiefly, addressing the technological environment in the healthcare system would improve connectivity and interoperability. From the **translational researcher's perspective**, the difficulty in implementation reflects the inherent complexities of the EU project, which must always consider different countries and perspectives. The challenge of interoperability of the AI tools is not only cross-border, but there are also challenges within borders. For example, in Catalonia, there are 42 public hospitals with over 32 different operative systems in the healthcare structures.

From the **pharmacist's perspective**, an example was noted of the historically low levels of investment in AI infrastructure in some jurisdictions. However, the National Cancer Information System (NCIS), a single national computerised system that records and stores information relevant to a patient's health care in a single longitudinal record, was heralded as a promising example of effective information technology implementation in healthcare. The need to better educate healthcare professionals and the public on the AI tools was raised. Chronic disease patients are very knowledgeable about their disease but with matters of health data and AI, there is a huge knowledge gap, which needs to be addressed. From the civil society perspective, there is not a one size fits all solution. Given the diversity of opinions across the EU, it is a real challenge to agree on a consensus. However, it is clear that there is a massive burden on healthcare professionals and increasing AI training for them could reduce their workload and improve effective implementation of AI in healthcare.

AI Act

The discussion also touched upon the AI Act and its implications for healthcare in Europe. From the **European Commission perspective**, it is worth reflecting on the widespread scepticism and concern which existed when conversation began about the AI Act in 2017. Now, at the EU level, the AI Act and the EHDS are providing some solid foundations in place and clarified the vision of AI in healthcare in Europe. The AI Act also clearly highlights the concerns and the issues which need to be considered. Since 2017, a lot of initial concerns have been addressed.

The **academic perspective** posed a simple question to consider: '*Who does what for what purpose?*' When discussing AI and the AI Act, it is important to consider this question, as well as '*who controls who does what for what purpose?*' The AI Act is based on a product philosophy. However, we should not be regulating the product itself, but rather its behaviour, actions, and output. An illustrative analogy was provided: '*We should be regulating the cooking of the microwave and not the microwave itself. We are addressing the wrong thing*.' Furthermore, there is still a disciplinary language barrier. There needs to be greater integration between groups of clinicians and groups of computer scientists in the development of proposals, such as the AI Act, so that there is genuine cross-sectoral collaboration, which will improve the policy outcome. From the **industry perspective**, the AI Act provides a good basis, yet for it to be effective where it matters the most, it is essential to clarify risk management. The current draft of the AI act is still prescriptive in terms of identifying high risk AI systems, and it is necessary to better define the criteria for determining high risk AI systems.

In addition, the act's definition of AI is broad and brings into scope other activities that have long been performed e.g. analytics and biomedical statistics. These are already subject to regulations (GxP) or otherwise heavily validated before a medical intervention is submitted to the EMA for approval. Duplication or over-regulation should be avoided. Industry players use health data and AI in a global environment well beyond the EU. Industry would therefore also welcome consideration of other guidance and regulations on AI globally to avoid conflicting definitions, guidance and regulations. They need the AI Act to be complementary and interoperable with other global regulations for multi-national industry partners who wish to benefit global health using AI. Incongruent regulations cause great business impact, delaying the industry's efforts in bringing the right medicines to patients in an equitable and fair manner.

AI and COVID-19

The emergence of the COVID-19 pandemic accelerated the shift towards the use of AI in healthcare. From a clinical perspective, COVID-19 was a special case, and it was a pioneering period. Although there are normally barriers in the routine health infrastructure, the COVID trials were conducted in spite of the insufficient infrastructure in place. The underlying health infrastructure remains the key problem, as many hospitals lack basic business intelligence. The pandemic really highlighted the inadequacies in the healthcare system, relating to attention to infrastructure and informatics. This is an area where targeted policy attention could make a huge difference. From the pharmacist's perspective, health systems went through substantial innovation during the pandemic.

Clinicians began collecting data as part of their daily workflow and therefore it was simple and non-bureaucratic. The usability of the products on the ground should always be prioritized.

European Health Data Space (EHDS)

The EHDS is of critical importance in shaping how digital health and AI will be implemented in the European context. However, it is important to consider the obstacles that the EHDS is likely to face and how they can be overcome. From the **civil society perspective**, a keen focus is more on the secondary use of data, rather than the primary use. The primary use of data is how you will use data for the patient's (or citizen's) personal health, and this is well understood. However, the secondary use of data needs to be better understood. Simply, the secondary use of data is when a public body or organization takes personal information it has collected for one purpose and uses it for a different purpose – research in many cases involves this secondary use of data.

A remaining obstacle with the EHDS is the lack of clarity and the lack of understanding about how the health data will be used for secondary purposes. Health data means more to citizens than other types of data collection and we need to grasp and address citizens' concerns. From the **industry perspective**, there is a need for all parties to understand the concept and practicalities of the EHDS, as well as their incentives to contribute. Another discussion point was around ensuring transparency and trustworthiness in the implementation of the EHDS. From the **European Commission perspective**, one of the overriding goals of the EHDS is to provide concrete benefits to individuals, including patients. The industry perspective also emphasized explainability and transparency as key values. A comment was made considering whether the AI space will become too convoluted and fragmented. There is a tight balancing act between maintaining innovation and avoiding fragmentation.

The panel also discussed whether digital health would narrow the health equity gap between disadvantaged communities and the wealthy communities. From a **patient's perspective**, the digitalization will help ensure a greater quality of data, thus this should translate into better quality healthcare. However, it is vital that citizens are digitally informed and literate. From the **European Commission perspective**, it is also seen of great importance that patients' health data are protected, securely processed, and used for specific purposes. The EHDS provides clear rules on which types of data can be securely shared in compliance with GDPR rules and for what purpose, such as the training, testing and validation of AI algorithms. There are strict security measures in place, where you need to apply for the data access body and explain why you require the data and for what purpose, before being allowed to use data for this purpose in secure processing environments. Therefore, the EHDS provides a secure environment for data sharing and digital health. From a pharmacist's perspective, it is important to be aware of the ongoing challenge of maintaining a digital system as well.

Finally, another discussion point regarding the EHDS included **patients and citizens' needs**. Before the implementation of the EHDS, it is necessary to have multi stakeholder discussion where patients can be actively involved in the discussion. It is important to understand that the EU is not a country, so there will inevitably be a different application in different countries and a different speed of implementation. As well as considering what citizens want from the EHDS, it is equally important to

consider what they want from the re-use of their health data. We generally think that citizens are sceptical about the use of their health data, but in reality, we find that citizens are eager for the potential health benefits to be actualized, provided their privacy is protected.

Practical benefits of AI in healthcare

The discussion also touched upon the practical benefits of AI application in healthcare. From the European Commission perspective, the proposals envisaged in the AI Act, EHDS and liability (Products Liability Directive and AI Liability Directive) would aid trust in these technologies and their safe use would allow individuals, including patients, to reap the benefits of AI. From the **industry perspective**, a key area of benefit will be in assisting and enhancing what citizens and patients are already accessing, such as in diagnostics and personalized medicine. From the **pharmacist perspective**, a lot of physicians' time can be freed up by offloading their bureaucratic and repetitive tasks, such as paperwork, to an AI tool. This would bring great practical benefits for patients.

Concluding remarks

Finally, a few conclusive remarks were offered to summarize the discussion. Evidently, real world data is becoming more and more important, as well as research based on clinical trials. If this data is utilized properly, we could collectively construct the future of medicine. This could open a new era in the way healthcare is performed, which would ultimately benefit all of us. However, it is critical that we continue to share expertise, foster policy and advise policy makers on the structure and implementation of AI. In healthcare, AI can provide an intellectual turbo boost and stimulate improved drug discovery, diagnostics, and personalized medicine. An exciting development was noted, which is an AI system called AlphaFold by Deepmind that predicts a protein's 3D structure from its amino acid sequence. There will be impressive results as we embed AI within clinical systems. Crucially, the interoperability of the health systems needs to be urgently prioritized and patients need to be always protected, rather than the data, in the pursuit of advanced 21st century medicine.

Additional material available:

1. **Agenda and speaker information**
2. **Full Recording of the event**

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Disclaimer: *The summary report is a neutral reflection of the discussion which has taken place and it does not represent the views of any particular organization, supporting parties (AstraZeneca / EATRIS) or individual. Those opinions may not be shared by all participating companies and attendees.*

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FEAM is the European umbrella group of national Academies of Medicine, Pharmacy and Veterinary Science, or national Academies via their medical division. It brings together under one umbrella 23 National Academies representing thousands among the best scientists in Europe. FEAM's mission is to promote cooperation between National Academies of Medicine and Medical Sections of Academies of Sciences in Europe; to provide a platform to formulate their collective voice on matters concerning human and animal medicine, biomedical research, education, and health with a European dimension; and to extend to the European authorities the advisory role that they exercise in their own countries on these matters.

About the FEAM European Biomedical Policy Forum

The FEAM European Biomedical Policy Forum provides a platform for discussion on key policy issues for the biomedical community. The Forum is an initiative from the Federation of European Academies of Medicine (FEAM). It aims to bring together representatives from academia, research charities, industry, European and national trade associations and professional bodies, regulators, public health bodies, and patient and consumers groups. If you would like further information or becoming a partner, please contact elisa.corritore@feam.eu