Sustainable AI to Drive Global Health

A white paper summarizing opportunities of data and Artificial Intelligence in healthcare within the European Union and beyond

September 2023

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1. Executive Summary

In May 2023, thought leaders in information-driven healthcare gathered to examine and recommend best practices in accelerating healthcare delivery using Artificial Intelligence (AI) amidst the European legal landscape, There is tremendous potential for AI to support delivery of healthcare, including insights generation, diagnostics improvement, molecular drug target discovery, hospital administration, and more. The value of AI is global and dependent on our ability to understand and share data while respecting privacy and trust issues globally.

The development of a great variety of AI tools for healthcare and the general public is accelerating in both industry and research; therefore, maintaining trust and confidence in the industry is essential to continued delivery and improvement in healthcare. A triangle of trust between AI developers, healthcare professionals, patients and citizens is a distilled core of the larger, more complex network of trust across the individual, the community and society.

Successful deployment of data and AI in the European health system depends on clear navigation of the European Union's (EU) regulatory landscape. Regulations are beneficial to biomedical research and development, particularly in driving safety in high-risk applications. Striking a balance between regulation and innovation is crucial, to maximise the public value generated while safeguarding trust.
This white paper explores the intersection of two key upcoming European legislations- the AI Act (AIA) and European Health Data Space (EHDS). The AIA can provide a legal basis to enable accountability and rigour in the use of AI in healthcare, driving trust and adoption if enabled with the right support. The EHDS's implications on data usability can impact the quality, effectiveness and trustworthiness of AI in healthcare in several ways- enabling faster and more willing adoption of AI solutions, more accurate models that are applicable to a wider patient pool, increased interoperability of datasets, and increasing the triangle of trust as healthcare is transformed.
Several challenges and opportunities arise in information and AI-driven healthcare:

- Conflicting legislations across countries and regions
- Building and maintaining patient and public trust
- Training and upskilling of healthcare workers lags behind the technology
- Lack of dataset interoperability and clarity
- Navigation of European and global laws in health data & AI as health applications become globalised
- Accountability and liability of AI in healthcare, regarding harmful biases and explainability
- Optimising the human-machine system interacting together to harness AI accurately
- Solid metrics and measures to measure adoption and value of the AIA and EHDS legislations

A series of targeted calls to action have been developed in the health data & AI community toward understanding practical aspects of AIA and EHDS application, fostering trust in patients and healthcare workers, educating the workforce, and continued review and maintenance of legislations and tools and metrics for their successful application.

2. Introduction to data and AI in healthcare

According to the proposed AIA, an AI system is designed to operate with a certain level of autonomy and that, based on machine and/or human-provided data and inputs, infers how to achieve a given set of human-defined objectives using machine learning and/or logic- and knowledge-based approaches.[1] Healthcare and biomedical research has historically been a data-driven field, now being enhanced by numerous AI applications. Alongside these advances, legislations are being developed such as the EU's AIA and EHDS to harness the power of large-scale data and put guardrails on the application of AI in a safe and controlled manner. A sustainable use of AI systems can drive us towards a future global health intended as an area for study, research, and practice that identify as a priority the improvement of health and equity for all people worldwide. Such systems prioritise safety, ethics, and use of FAIR (Findable, Accessible, Interoperable, and Reusable) data.[2] Equity objectives are implicit in all the

information-driven activities discussed in the present paper and will also be made explicit at certain points. A 2023 report from the EU Health Policy Platform provides a comprehensive discussion of the AI issues for tackling health inequalities in the EU.[3]

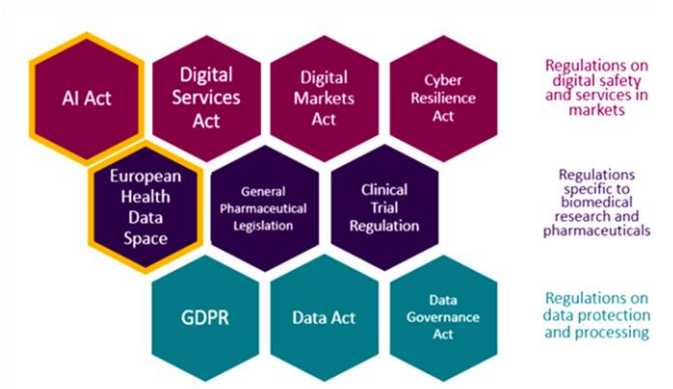

Figure 1. AI Act and EHDS among a network of legislations

Regulations are developing globally in artificial intelligence. Regulations in China, United Kingdom (UK), United States (US) and more are developing quickly, and other nations such as Singapore have already built AI governance and testing frameworks.[4] In parallel, several European legislations are active and in development, such as the Data Act, Data Governance Act, Digital Services Act and more (Figure 1). Successful deployment of data and AI in the European health system depends on clear navigation of this regulatory landscape.

This white paper explores the junction of the two legislations – AIA and EHDS – and the practical realities of implementation into health systems, biomedical research, drug development, and impact on patients.

The following will be examined:

1. What can be achieved with AI and Health Data whilst facing barriers and challenges arising from the European legal landscape on biomedical and healthcare fields in a globalised world?

2. What success factors can keep the EU globally competitive in biomedical development using data and AI?

3. How can a triangle of trust between AI developers, healthcare professionals, and patients and lay citizens be established and nurtured?

This paper explores the European ecosystem of healthcare, health research and relevant legislation impacting global health for the following reasons:

1. The "Brussels Effect"[5] is a well-known phenomenon of European policy and legislative frameworks influencing standards across the globe. The General Data Protection Regulation (GDPR) is becoming a global benchmark for privacy law, especially for multinational organisations, and the Brussels Effect is predicted for the AI legislative landscape as well.[6]
2. Europe's twenty-seven member states are united by common legislation but encompass diverse communities and localised policies within each state.[7] This is partially driven by Europe attracting global talent and innovation, and diverse history and culture across the region. Overcoming intercultural barriers in data interoperability and deployment of healthcare using data and AI within Europe creates best practice and sets an example for overcoming such barriers from global data standards.
3. Innovations from the EU having been developed using data and AI continue to demonstrate benefits to global health. Alongside the EU Global health strategy,[8] partnerships such as the European & Developing Countries Clinical Trials Partnership[9] actively work to improve public health beyond Europe, and many research programmes such as the European Institute of Innovation and Technology (EIT) Health[10] work to address healthcare challenges that extend beyond Europe.

Although there is a complex network of legislations effective and in development with the EU, this white paper will explore the interplay and implications of two.

This white paper was developed from the perspective of the experts at the Sustainable AI to Drive Global Health conference on 4 May 2023 in Gothenburg, Sweden, following the EU's event on

Sustainable AI and AI for Sustainability.[11] Cross-sector views were exchanged on the legislations and their impact on the EU and global health (Figure 2).

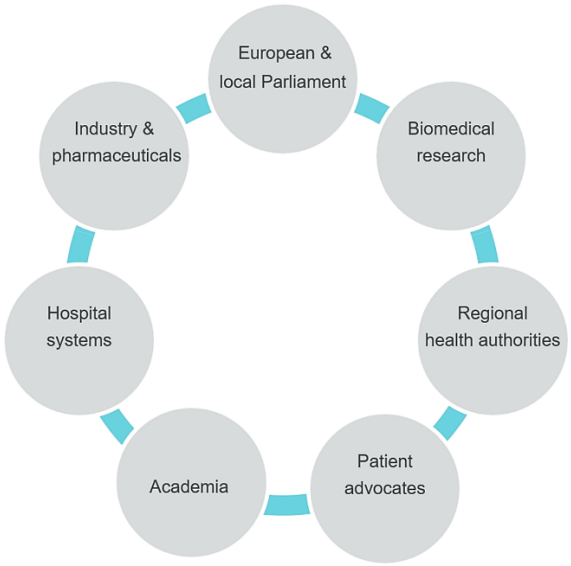

Figure 2. Active participants represented in this white paper

The intended audiences for this white paper are multifold:

1. **REGULATORS and POLICY MAKERS**: those involved in developing, forecasting impacts, and measuring adoption metrics of the AI Act and EHDS, alongside above-mentioned legislations on a European level and on a global impact scale.

2. **CHANGEMAKERS and INTEREST GROUPS**: those who work to facilitate implementation of new and updated legislation around big data, AI, and digital in healthcare. This paper characterises the realities of navigating legislation while implementing and realising benefits of digital and AI solutions in public health and provides guidance on what will enable greater success.

3. **MULTINATIONAL ORGANISATIONS and RESEARCH FUNDERS:** those who enable research and development of medical interventions and diagnostics within Europe and beyond, those who shape strategic plans and programmes toward digitisation of healthcare research and practice.

4. **PUBLIC and PATIENTS**: those who are using or considering digital solutions to manage their own health and well-being and wish to get involved in shaping their digital future to drive adoption and trust.

3. Why it matters: sustainable AI and global health

Sustainable AI driving global health is directly aligned to the United Nations' Sustainable Development Goal Number 3 – Good Health and Well-Being.[12] The core importance of sustainability is implicit in many of the issues discussed in this white paper but a comparison of the different dimensions of sustainability (e.g., for health, environment, business models, society) is beyond our present scope. Here, sustainable health refers to the continued and improving ability to develop and implement medical innovations in healthcare globally into the future. This also aligns with AstraZeneca's sustainability pillar on enabling global access to healthcare.[13]

3.1. AI in biomedical research and development

AI technologies are not new, but their uptake and application has accelerated rapidly over the last several years, particularly with the advent of widely available generative AI. AI and machine learning (ML) are being utilised in medical research in various ways, providing novel insights and accelerating outcomes and development pipelines. The focus is on pushing boundaries, seeking purpose-driven applications, and ensuring responsible use. There is an inherent tension between innovation and responsibility, which requires a constant balancing act and risk-benefit assessment.

AI has great potential across the entire value chain of healthcare, from understanding of basic biomedical science to target discovery to delivery of treatment and monitoring of care. It offers opportunities for faster drug development and delivery, as is widely acknowledged across the sector. Different organisations adopt AI to varying degrees, but for many AI is a deeply embedded in their core strategy.

One example of AI's potential is in drug discovery.[14] AI can enhance our understanding of biology facilitating pathway exploration and target identification. AI has delivered some remarkable improvements, in some cases doubling the speed of small molecule lead generation and greatly accelerating antibody discovery. AI and ML are also transforming areas like image analysis, providing higher quality and more reproducible results. Generative AI has great potential to revolutionise the drug discovery landscape e.g., in silico drug discovery at scale.

AI is viewed as a core technology for biomedical companies and research institutions across public, private and third sector. It enables and enhances the ability to tackle the most challenging medical needs with the aim of delivering a societal shift from "sick care" to "healthcare." AI can potentially facilitate earlier medical interventions and precision medicine strategies. Furthermore, AI's potential will extend beyond current applications. In the near future it may be used in a variety of predictive applications, such as retinal scanning to identify cardiovascular risk factors or detect aggressive prostate tumours. This potential could particularly benefit underprivileged regions with limited access to healthcare resources. This has implications for both public and private sector Research & Development (R&D), e.g., in training algorithms with data obtained from the relevant community and in ensuring equitable access.

The value of AI in medical research is measurable, both financially and non-financially and can drive indicators like the number of projects, access to data, people, and training. Responsible use of AI and data is a priority, as is collective knowledge sharing and engagement with regulators to ensure responsible practices as both the field and regulations evolve.

Regulations are beneficial to biomedical research and development, particularly in driving safety in high-risk applications. Striking a balance between regulation and innovation is crucial. Overall, AI and ML in medical research offers immense potential and requires a collaborative approach to deliver responsible and beneficial outcomes.

3.2. The EU and competitive landscape

As healthcare and health data becomes increasingly globalised, research occurring in different areas of the globe can be made applicable within Europe. The maturing legal landscape, applications, and accessibility will greatly influence organisations and research funders' decisions to conduct research and innovation in the EU.

To harness the value AI can bring while safeguarding against potential risks, it is important that the legal frameworks and associated administrative burden are fit for purpose. Thus, research and delivery in healthcare enhanced by AI, should be enabled without the excessive added time and administration. Therefore, this document aims to illustrate the opportunities, challenges, realities, and suggest practises to implement the AIA and EHDS in practical, smart, and relevant ways while managing risks, so that research and clinical practise may be enhanced to improve the lives of patients. Practical needs and models of continuous improvement are needed to ensure the value of these new legislations while keeping the EU globally competitive in healthcare and AI research.

3.3. The “triangle of trust”

Three key players in this space are interconnected – the AI developer, the health care provider, and the patient. In addition, trust by other citizens (who are not currently patients) is critically important and the dimensions of trust are discussed subsequently. Promoting and maintaining trust has important implications for education and communication initiatives as well, of course, as for all the other actions by stakeholders in AI R&D and its healthcare provision. Historically in biomedical research, decisions and research aided by AI was not exchanged broadly across disciplines and roles- the data scientists were the developer, user, and decision-maker. In today's world, AI tools developed by an organisation or purchased externally can be incorporated into a device and used by healthcare providers and patients.

A healthcare practitioner may use AI systems in the screening, diagnosis or monitoring of patients and make decisions based on the systems inputs. In research, AI technologies may be used to understand a patient's physiology, treatment progression or guide compliance of care, and even help to build new decision-making criteria for the safety and efficacy of a drug or device. However, trust and explainability is essential to making this work. Trust between the developer of the AI system, the healthcare provider using it in clinic, and the patient. All three must also understand the strengths and limitations of the AI system and quality of associate data, and its relevance to operate it effectively during the conduct of research or healthcare administration. This requires transparency and pedagogic efforts to safeguard from inequality driven by unevenly distributed data literacy among users.

3.4. Advancement of global health interests outside the EU

Key players in global health such as multinational corporations and academic research teams operate cross global legal and ethical and cultural borders when developing and delivering health solutions. They also develop, store, retrieve, and reuse datasets across global data centres and in teams. These entities set global policies according to the ability to operate realistically in their key locations. If Europe is to remain a key location, these organisations must incorporate the AIA and EHDS regulations into their global ways of working and implement them effectively without overburdening the organisation, allowing realistic change management, administration, and avoiding process upheaval. Again, trust and strong interactions across roles, disciplines and professions are key success factors.

4. The state of AI in healthcare - present and future

There is tremendous potential in AI in supporting information-driven delivery in healthcare, including but not limited to:

- There is a wealth of data in healthcare that could be exploited to develop AI solutions. Only a fraction has so far been used for this purpose due to accessibility, FAIRification, proprietary and legal roadblocks, privacy considerations, consent and intended use. Much of this patient-derived data but also data from hospital operations in general could be used.
- Several AI solutions have been developed to address better treatment of patients, most notably in diagnostics and monitoring. AI is also being used for patient outcome predictions for increased precision and personalization.
- Health care is heavily regulated and developing AI solutions in the administrative/ operational aspects is an easier area to incorporate AI solutions to increase efficiency because patient safety risks are relatively lower.
- Hospital operations, such as planning, scheduling, capacity management, and maintaining stores of equipment and medicines.

The following is a deeper look at the hospital operations aspect. Active involvement in AI development is necessary to determine the types of data and algorithms that are most effective for aiding patients, ensuring information privacy protection, and addressing other key healthcare factors. One notable benefit of AI implementation is the reduction of operational and administrative burdens. For example, AI can be used to predict sick leave for staff members and develop forecast models for managing patient influx, especially during events like the COVID-19 pandemic. This enables better resource planning and utilization.

Testing algorithms that may be commercially available is crucial, and a test bed or sandbox environment can be utilized to assess cultural nuances and scalability across the European Union. They may also provide a safe environment to navigate regulations and their implications that are still developing.[15]

Handling sensitive health behavioural data requires careful consideration. Pooling data from different organizations poses challenges due to some EU nations' current national legislation which limit a central model. Instead, multiple ML nodes could be placed at each healthcare provider, allowing them to pool insights from their respective federated ML models while preserving privacy. The approach could work well with open-source or synthetic data but has not yet been tested with live data. Legal interpretations can be challenging during implementation phase. A regulatory pilot testbed would support resolution of such challenges. Synthetic data can also be used for pilot testing and open new avenues of risk measurement in data sharing whilst preserving privacy. Also, trusted parties could be formed to connect data from different data holders before anonymising and possibly synthesising it as a service with safeguards around.

Regarding large language models, there is great potential in applications in healthcare administration. However, the current landscape relies on cloud-based solutions provided by global technology companies that may over-represent localities outside of the EU. Sweden is exploring the establishment of a Swedish national large language model called GPT3-SW3 to ensure contextual relevance and benefits within the country.[16] Validation projects are underway to assess its potential, and the next step is implementation in hospitals to utilize patient data without transmitting it outside of Swedish healthcare facilities. A structured approach to deployment and maintenance is critical to success.

In terms of legislation, obtaining operational data can be challenging, particularly when dealing with patient data due to its sensitive nature. Other types of data may pose fewer difficulties. However, technical obstacles exist, as data is often fragmented, unstructured and housed in silos with limited interoperability and without adequate export solutions. Additionally, a culture of operational data sharing is not yet prevalent. Furthermore, the culture of AI development and innovation is often exploratory and can conflict with principles such as data minimisation (GDPR Article 25).[17] Developed data infrastructures including defined data formats and interoperability requirements could help overcome critical issues in relation to silo problems. In conclusion unleashing the value in data with the help of AI should direct substantial effort to the handling of data in addition to the AI development and application itself.

There is a clear distinction between information-driven healthcare and data-driven healthcare: whilst data-driven care is quantifiable and based on findings, it is often in raw format and not readily usable. Information driven care also relies on data which is processed, formatted and presented in an understandable way. It works along the value chain of knowledge, from data to information, insights, altered behaviours, and eventual patient value.[1819] A hybrid approach is recommended in translating data to information, acknowledging that AI will progressively improve the conversion of data into actionable information.

5. Trust for data and AI in healthcare

Trust is essential to the successful integration of AI in health research, care, and provisioning. A triangle of trust between AI developers, healthcare professionals, and patients is a distilled core of the larger, more complex network of trust across the individual, the community and society. Trust is clearly not uniform, and all three aspects of trust (benevolence, integrity, and ability) interact in different ways:

- **Altruistic:** do I trust that you will do general good with my data?
- **Transactional:** do I trust that you will handle my data well for my treatment and respect my wishes with my data?
- **Representational:** do I trust that you will use my data so that I will benefit?

6. Upcoming European legislations and their relationship in a global health context

6.1. European Health Data Space (EHDS)

The EHDS is a legislative initiative aimed at creating a unified system for sharing and utilizing health data across the EU. Currently, the EU consists of twenty-seven member states, each with their own data systems, protocols, and interpretations of data regulations such as the GDPR. Regional diversity in culture and requirements also exists in some EU countries. This fragmentation makes it challenging to use health data in cross-border settings and conduct research using large health datasets. Additionally, early misconceptions and differing interpretations of the GDPR led to refusals of legitimate data sharing requests from healthcare systems.

The primary objective of EHDS is to establish common standards, protocols, and rules for the use of health data within the EU. The legislation focuses on two dimensions: primary use and secondary use of data (Figure 3).

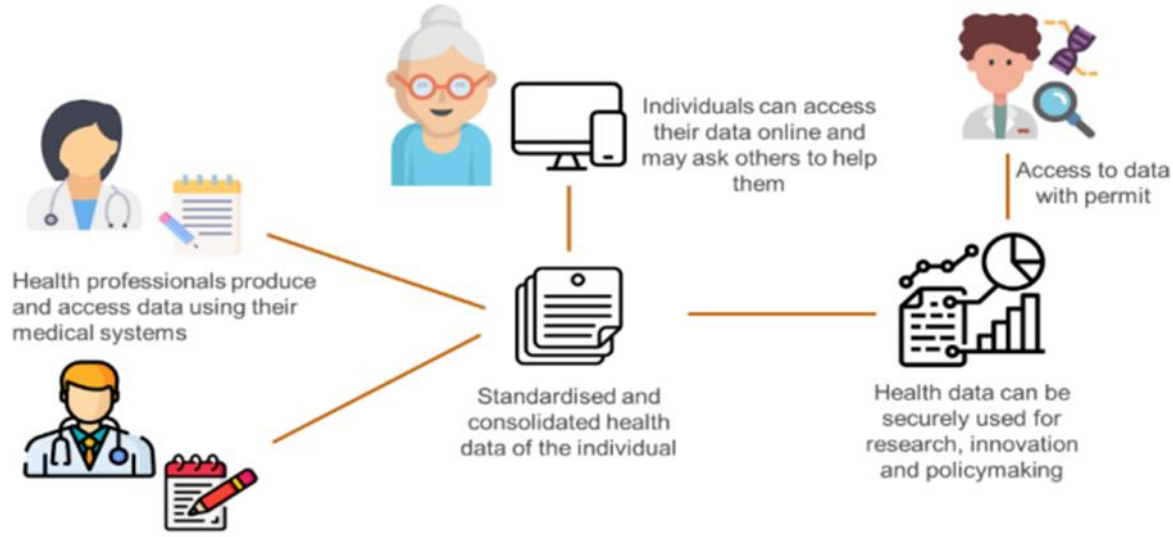

Figure 3. Primary and secondary use of data[20]

The primary use of data refers to the digitalization of health data for healthcare professionals, creating a standardized electronic health record accessible to medical professionals throughout the EU. This facilitates efficient healthcare provision, as doctors can access a patient's medical history, diagnoses, treatments, and allergies, regardless of their location within the EU.

The secondary use of data pertains to research purposes. Researchers seeking access to large datasets from across Europe can submit requests to National Health Data Access Bodies or data sharing infrastructures in each member state. These bodies evaluate the research purpose, expected results, and justify the need for data access. Access is granted only to anonymised or pseudonymised data, ensuring patient privacy and preventing re-identification. The aim is to enable research and innovation by providing a broader range of datasets across the EU, overcoming the current limitations imposed by national rules and regulations. Complementary efforts such as the Innovative Medicine Initiative's FACILITATE project will also drive data sharing and re-use in practice, whilst driving patient centricity.[21]

One issue with the initial proposal was the absence of a consent mechanism for the secondary use of data. To strike a balance between patient choice and the need for representative and useful data, an opt-out mechanism was suggested. This allows patients to decide whether their data is used for secondary purposes but ensures that enough data is available for research and analysis. An opt-in

model would limit the amount of data collected and potentially lead to biased or incomplete datasets. How patients/citizens may gain access to their data in the EHDS will influence data access for companies and research and is yet to be seen. Data donation, patient control and lending of data to different causes are current options discussed.

The EHDS implementation also involves the establishment of health data access bodies at the national level and health data authorities at the EU level. The participation of patient groups and industry representatives is proposed to streamline the implementation process and ensure a unified and well-governed ecosystem.

The involvement of patient groups, health authorities, and industry and small and medium-sized enterprises (SME) representatives is crucial for successful implementation, also enabling identifying potential unintended bottlenecks, risks, or excessive administrative burdens. Patient representatives have been largely supportive of the legislation and understand the importance of data sharing in improving health, especially those in rare disease research.

6.2. Potential value from the EHDS

For secondary use of health data, the EHDS can yield enormous benefits to all sectors if implemented and taken advantage of to its full potential. The content, currently under formation, will enable great potential if stakeholder from all sectors can align on underlying goals. Its implementation, however, depends on softer values and behaviours than cannot be legislated, regulated, and controlled from authorities. Strengthening citizen and patient organisations to use and take advantage of the new opportunities is an important and longstanding task.

Patients' contribution of data in the altruistic fashion, as known from blood and tissue donation today, will most likely continue.[22] However, the opening of a data marketplace where patients also directly benefit and draw from a data source to create value for themselves, or their community is key. The improvements in the case of primary use of health data is unifying, simplifying, and promoting mobility for citizens and society and should when in function, not be controversial in terms of value creation. Furthermore, it is important to understand the value and potential value of data collected in the past in health research, considering inability to re-contact the patients. Data re-use has demonstrated enormous value within organisations, with FAIR considerations pivotal to the re-use value.[23] [24] [25] [26]

Regarding secondary use, both the public and private sectors today are strained by the lack of access to health data and suffer from the long lead times and complicated procedures for gaining access. The EHDS will, as today, mandate a special withdrawal licence and the lead times are likely to be relatively long although this remains to be seen. To shorten development cycles and timelines to clinic implementation, and provide a better base for clinical trials, the private sector will need:

1. metadata catalogues and uniform, structured data
2. in-house competency to generate value from the retrieved data

Knowledge of customer needs and understanding how these may develop over time will likely be key to open new markets for products and services.

The collection of healthcare data across Europe facilitated by the EHDS can present further opportunities to improve "sick care" and "healthcare" in community health. One possibility is to enable data-driven understanding of the increasing demands of healthcare staff, skills and equipment and fortify resources accordingly. For instance, if there is a predicted increase in obesity, there could be a focus on placing countermeasures such as more diabetes nurses in specific areas. This data sharing can also support studying the effectiveness of new healthcare practices or interventions applied on a small scale, then adapted in kind to similar scenarios. To determine if the EHDS is effective in achieving prevention strategies, it is important to measure and evaluate the changes it enables in a culturally sensitive way.

There is potential the EHDS may foster a competitive and collaborative platform where countries or regions can give and receive tailored support, guidance for improvement, and evaluation of healthcare interventional strategies, based on data-driven evidence. This is more likely to be achieved through multi-regional collaboration rather than through monitoring or surveillance measures.

6.3. Measuring value gained from the EHDS

The EHDS has high potential to generate value across many communities, and its success depends on developing benchmarks and metrics to measure benefit realised. Examples of potential benefits include:

- **patients and citizens:** empowerment and health-related value (comfort, access to care, speed of care delivery, quality of life)
- **private sector:** increased competitiveness and growth which is of national interest
- **health authorities and health care providers:** increased possibility to govern effectively
- **academia:** evaluating the generation of new knowledge as a fundamental resource that serves as the basis for all health innovation

These are all based on data mirroring the real-world enabling insights and actions leading to the expected result. While comprehensive discussion of all of the opportunities for progressing basic science is beyond the scope of this paper, the recent discussion of AI for better brain and mental health provides one illustration of the ambitions for linking fundamental research and therapeutic applications.[27]

These outcome measures ultimately have the same goal: 1) maintained health for oneself or the population and 2) resource efficiency and 3) competitiveness. The metrics for the evaluation grounds remain to be clarified. Most likely the softer values and cultural uptake will influence sectors where the access to health data might remain a nice-to-have commodity. However, in the need-to-have sectors the behaviours are more likely to change more rapidly. How incentives and business models might shift groups or individuals between nice-to-have and need-to-have will be interesting to follow. Until the shifts occur, sense of urgency is a likely driving force behind who will use the EHDS to its fullest extent.

Sharing of resources as in the case of EHDS will allow a more even distribution of access to health data than ever before. The goals and ambitions to yield results and generate value are high. The factors determining who is most equipped to harness the powers of data access and to generate the intended value will play a key role. Success will hinge on keeping a uniform code of conduct, transparent and easy to follow regulatory paths and established semantics so that the comparisons made are relevant, and any conclusions truly are aimed at the intended goals.

6.4. The AI Act and relationship to EHDS

Access to representative and useful data are essential for building trustworthy, accurate, and effective AI systems in healthcare. Where the EHDS enables access and secondary use of data to train AI systems, the AIA is intended to help build trust in high-risk AI systems such as medical devices, wearable AI tools, or those used in clinic settings.

The AIA aims to drive the EU's seven ethical requirements for trustworthy AI[28] into law, which ultimately enable quality and trust in a healthcare AI system.

The EHDS aims to address several issues which can affect the quality, transparency, and trust of a healthcare AI system (Table 1).

Goal of EHDS	Impact on AI
Acquiring diverse data from all over Europe to fulfil obligations under the AIA and ensure systems benefit all European citizens.	AI model more accurate and applicable to patients of different communities.
Ensuring trustworthiness of AI systems in different geographical, behavioural, and functional settings.	Faster adoption of AI solutions in disease control, prevention, diagnosis, and treatment.
Differences in training, validation, and generalization of algorithms across different regions.	Algorithms can be used more confidently within the context of local cultures and medical systems, and unintentional or harmful bias avoided.
Balancing data privacy and protection with facilitating the use of data for meaningful health improvements.	Driving trust from patients in digital and AI solutions to be used in healthcare.
Building a return to patients and society when industry gains access to health data.	Maintaining trust and continued willingness to share data with industry researchers.
Harmonizing data standards and facilitating comparative research across the EHDS.	Increased interoperability of datasets, leading to more robust training data and more accurate algorithms.
Cultural and contextual differences in data processing and healthcare systems across the EU.	Increased interoperability of datasets.

Table 1. Interrelated concepts between EHDS and AI Systems in Healthcare

7. Features that differentiate data and AI in health

7.1. Data decentralisation and global storage, access, applications

The biomedical and health sector has a long history of dealing with sensitive data and managing data quality. They are used to identifying and mitigating risks in this space. Healthcare has always operated in a regulated environment, with bioethics and trust being essential to success. AI ethics and bioethics have many overlapping principles - respecting autonomy, doing good, preventing harm, and promoting justice. Additionally, developing new drugs is a data-driven and resource-intense endeavour. In Europe, over €39 bn is spent on pharmaceutical R&D each year.[29] There are strong incentives to improve R&D and healthcare delivery through AI systems by making it faster and cheaper, while maximising patient safety.

7.2. Health data use and reuse within and across organisations

In biomedical research, health data, once collected and used for a trial, is traditionally left in cold storage and untouched. Reuse enables scientists to harness the power of the data at lower cost compared to regenerating the dataset again.

The health and biomedical sector's interest in data and AI goes beyond activities like consumer browsing and other behavioural data. Using health data in AI impacts both individual and community health. People are affected by AI activities in the drug development pipeline, from lab bench to medical bedside. AI tools used in decision-making may not be a marketable product, but the use cases of a medical product or process improvement within R&D, may have an impact on individual citizens and their health.

7.3. The evolving definition of health data

Healthcare is not limited to disease; equally important are prediction and prevention to drive overall health. Children's health status is known to be linked to the socioeconomic conditions of their upbringing and predictive of their adult health status. It may be argued that the definition of health care can be broadened to include social care, enabling the sharing and use of social care data in a health context. However, predictive analytics in social-behavioural situations are delicate and difficult to address proactively. Data provided by citizen science initiatives are also likely to increase considerably with potential applications for use of AI. The multiple issues involved in citizen science and AI are beyond the scope of this white paper but have been discussed in literature elsewhere appertaining to health care opportunities and threats, e.g., see articles 'Opportunities and Risks for Citizen Science in the Age of Artificial Intelligence'[30] and 'The Partnership of Citizen Science and Machine Learning: Benefits, Risks, and Future Challenges for Engagement, Data Collection, and Data Quality'.[31]

The EHDS is clear on the purposes and ways in which health data can be used (e.g., prohibiting the use of data for insurance calculations).The list of permitted uses may grow in the future but will be limited to the provisions of healthcare. However, technology giants' collection and use of health data is difficult to contain in this law. The Digital Services Act (DSA) and Digital Markets Acts (DMA) were enacted to limit what data giants can do with health data they collect.[32] Third countries have expressed interest in emulating the DSA and DMA, however, their implementation will be dependent on their legislative framework and court systems.

7.4. Boundaries and competitive advantage of data sharing

Regarding access to data from third countries, European citizens' health data is not to be stored outside of Europe, through the extraterritoriality of EU laws extending outside of borders (and the opposite) cause exception. The European Commission wants collaborators to hold very similar standards and level of protection as those of Europe. Other players who want access to the European market should have the same reciprocity. In consequence of the implementation of GDPR provisions, there are increasing obstacles for both the public and private sectors to share data for research outside the EU/European Economic Area (EEA). Of course, it is vitally important to ensure protection of privacy, but it is becoming increasingly difficult to maximise the value of the contribution made by patients and volunteers in providing data. Problems with sharing data for research internationally result in unnecessary duplication of research and slowing health care innovation.

This can potentially affect large multinational corporations who store and reuse data and algorithms globally. Data typically hosted in global servers and accessed by global teams would have limitations, adding administrative overhead in adoption and change of policies. Additionally, any further research would need clear applicability in EU populations, which may limit the power of datasets used to build healthcare algorithms intended for the Global South or other third countries. Significant problems for public sector researchers in the EU/EEA have been described in detail by the Federation of European Academies of Medicine (FEAM) together with the other European academy networks, the European Federation of Academies of Sciences and Humanities (ALLEA) and the European Academies' Science Advisory Council (EASAC). It remains urgent to address the recommendations made by the academies in 2021, see report 'International sharing of personal health data for research'.[33]

A key factor of success is to prevent out-competing the EU by enabling access to data from a third country with intents to apply findings to European residents' benefit without the same reciprocity.

8. Challenges and opportunities in data and AI-driven global health

8.1. Conflicting legislations and guidance across countries and regions

The Towards European Health Data Space (TEHDAS) joint action committee's study on the EHDS implementation and the European Cancer Imaging Initiative's (EUCAIM) development of a medical

image database show that legal uncertainty is a significant barrier to data sharing. This highlights the importance of establishing a standard for data management within the EHDS framework. Shifting from project-based to operational-based data management mindset and federated approaches are crucial to ensure effective interoperability. Lessons may be learned from biomedical industry and academia as data stewardship is changing from a researcher-based asset to an institutional asset.

The Need for Guidance and Clear Processes: To drive adoption, it is imperative to have clear guidelines and processes in place. The success of FINDATA, an example of such a framework, demonstrates the importance of evaluating research plans based on legal principles, like the GDPR's minimization principles. FINDATA provides robust and effective guidance for data management.[34]

Dynamic Interpretation and Collaboration: Interpreting data sharing rules is not a static process. It requires continuous development, maturity, best practices, and societal advancements. Enhanced cooperation on a European level and national levels are essential to foster shared understanding and harmonize interpretations across different jurisdictions.

Navigating conflicting legislations and advice regarding data sharing requires a proactive approach. Establishing clear processes, guidelines, and interoperability standards, as demonstrated by FINDATA, can help overcome legal uncertainty. Continuous collaboration and shared learning at a European level are key to addressing evolving challenges and ensuring the effective implementation of data sharing practices.

8.2. Developing and maintaining trust of patients

Continued trust of patients is crucial to the value of data sharing and AI in healthcare and to prevent healthcare hesitancy. Recent findings suggest that patients largely agree with the EHDS's opt-out model of secondary use but only in conjunction with other safeguards, including digital literacy for patients and the healthcare professionals (HCP), data privacy and protection, and more.

Digital health literacy is manifested when data and AI elements of personal health plans are explained to the patient, giving them agency, and ultimately trust. Lawmakers and healthcare providers are advised to understand patient literacy and develop outreach and communication strategies to patients at different levels of technological literacy.

Patient-reported data also needs to be shared in a secure and privacy-preserving way. Patient involvement in the design process can support trust-building and reduce fear and is encouraged in the GDPR by way of public participation. Patient trust can also be built by sharing best practices, to demonstrate what worked well and how value is created for a patient or their community. Novel privacy preserving techniques may also facilitate trust but must be understood and accepted to a higher degree first.

Accessibility of consent information and details is another way to build patient trust. The current management of patient consent collection is predominantly analogue and paper-based, which is difficult to revisit and understand for patients. However, most patients express willingness to have their health data used, which suggests that the consent process, especially for primary use of data, could be simplified. A simplified consent process would also need to consider situations where consent is deferred or not collected (e.g., emergency medicine or legal obligation).

8.3. Building trust in AI models from scientists and lay operators

Healthcare as an industry is accustomed to dealing with risk because health data is sensitive in nature and has high-risk activities like surgeries. However, the use of AI may trigger scepticism in the public as it pertains to their healthcare. A robust regulatory framework is a starting point to build trust in AI models.

Access to training data and understanding training methods of models are key transparency practices that can build trust in an algorithm. This is not always possible for consumable technologies; consumers need a process of validating important aspects of the model to build trust and confidence in using it.

Training and development of employees is paramount to make sound decisions and use AI tools wisely. Organisations can build trust in their own interactions and practices with AI by running a self-audit to understand their compliance, risk management and ethical practices with AI. Reflecting and improving through lessons learned sharing, fosters a culture of employees questioning their own practices, focussing on accuracy rather than the development race. Employees and users can be trained on understanding AI limitations and appropriate use. The general workforce will require greater skills on interacting with AI such as prompt engineering, bias recognition, and better understanding of the human-machine system relationship, as evidenced by numerous analyses into corporate workforce by consulting firms.[35] Health systems can also develop learning plans to build healthcare workers' confidence in AI, such the UK's National Health Service report.[36]

Defining interaction methods with AI models can also build trust. A model can be deployed with the intent of a human in the loop, or a human looking for a minimum score, or completely separate from a human – these have vastly different accuracy profiles. If the human and machine system does not interact properly, accuracy and trust can suffer.

Physicians who use AI systems are not always aware of how the decision is made or how the AI tool was developed; regardless, they are required to trust the model in order to operate it. There has been increased awareness of clinical AI in healthcare practice and education, but insufficient understanding and knowledge means trust is lagging.[37] A framework for healthcare providers to understand the risks and benefits toward laypersons will enable the physicians to opt into using medical AI solutions more confidently.

8.4. Training and upskilling of healthcare providers

The goal is to establish a seamless path for patients to receive treatment while ensuring the system is user-friendly for doctors, patients, and researchers and supports health equity. Overcoming natural barriers is an essential aspect of this endeavour. An in-depth analysis of healthcare in primary care is underway, focusing on the entire process from initial contact to medication dispensing. It is hoped that a new law will be enacted next year to support these efforts.

To embed and improve data sharing and medical AI in clinical practice, education and training play a vital role. Medical schools are a starting point for implementing changes in the way patients are approached. Patients should feel they are central in the process, even when AI techniques are utilised. Allowing patients to provide answers and share reports before appointments can make the process more informative and efficient. It is important for patients to understand that their data belongs to them and is simultaneously valuable for research purposes.

The EHDS implies major changes in the way medical professionals operate and their relationships with data. The extended implementation period of the EHDS will support the change for HCPs. A special additional implementation period will be also granted for individual and/or private healthcare practices. It will accommodate and support the creation of new roles, organisational mandates and perhaps even new professions as the cultural changes resulting from the EHDS manifest in the health systems.

8.5. Lack of data interoperability

The EUCAIM project is developing a tool to build federated infrastructure of cancer imaging data, where clinicians, researchers, innovators can access, process and research. This will include a marketplace to train, execute models, and annotate data. A key challenge is to connect existing repositories because the nature of the data and images are heterogenous and rarely connected to ground truth outcomes. They may come from different scanners, protocols, formats, and more. The medical imaging modalities need a common data model and ontology to combine interoperable models.

The EHDS has an opportunity to provide a standard of how data is annotated and collected, moving data generators from a project based to operational based mindset. To enable interoperability, robust guidance and clear processes are required, if EU is to keep a competitive edge.

For example, Sweden aims to become a leader in healthcare, life sciences, and precision medicine. However, the country faces challenges in sharing health data among its 21 regions[38] and there is a lack of interoperability within the national health systems. Interestingly, it is sometimes easier to exchange data across country borders than within Sweden itself. To address these issues, the goal is to establish a seamless path for patients to receive treatment while ensuring the system is user-friendly for doctors, patients, and researchers. Overcoming natural barriers is an essential aspect of this endeavour. Several government investigations are on the way to suggest appropriate measures to change legal frameworks and pave the way for achieving interoperability.

8.6. Global impacts of AI in healthcare

The value of AI is global. The value is dependent on our ability to understand and share data while respecting privacy and trust issues globally. Sharing of ways of working alongside of data and models is important as the European and global AI transformation matures. This white paper has explored some of the global implications of EU actions for EU patients, but it is also providing an opportunity to emphasise that the EU can help to take a lead in global R&D to develop AI products and services that are relevant and accessible worldwide. The broad issues for AI in the future of global health have been discussed extensively in recent literature, e.g. the 'Artificial intelligence and the future of global health' article.[39]

8.7. Accountability and liability in AI for healthcare

Liability is difficult to resolve for models that are continuously developing themselves. Today's approach with Large Language Models (LLMs) in practice is keeping clinicians in the loop to take responsibility for the output of the models. Society will consider this a safeguard in the near term, as long as patients trust the doctor more than the model. Over time, the situation may change, as doctors are already starting to trust AI-based models more than the responses of other doctors when it comes to patient care, as models might provide better accuracy in predictions and risk assessments than the physicians alone. This alters the ethical ground. However, clinical decision support systems and tools are not new to healthcare and new AI tools should be considered in the light of the already existing scoring systems and the validity.

In a research and pre-clinical setting, liability is typically assigned to an accountable human - whether it be the research sponsor, vendor, partner, or a product-accountable party. This is less straightforward with publicly available and consumable models that can be accessed online, or when multiple AI tools are used in a pipeline of decision-making, sourced separately and may be off the shelf. Assigning accountability to the user or operator means training, education, confidence-building, and clear escalation, change, or human override routes if inconsistencies or accuracy doubts are raised.

8.8. Management of AI biases in healthcare

It is currently difficult to track and measure biases in a model when data used to train an algorithm is not transparent. Protecting patients' consent, identities, equitability, and data access rights needs to be balanced with maintaining transparency of data used to train an algorithm, to enable confidence and context in applying the algorithm appropriately.

9. Calls to action

As the AIA and EHDS grow closer to implementation, data and AI usage continue to evolve. A greater variety of AI tools are expected to be available in healthcare and the general public, therefore, maintaining trust and confidence in the industry is essential to continued delivery and improvement in healthcare.

The following calls to action have been developed for specific actors:

1. **ASK TO THE PUBLIC AND PATIENTS**: involved in the ongoing development and implementation of the AIA and EHDS. Be and stay informed. Ask to use new technologies to help diagnose and manage their disease and care.

2. **ASK TO REGULATORS**: to continually revisit and renew the AIA with consultation of key representatives from multiple sectors. The technology, public expectations, and trust continue to evolve rapidly, and risks and opportunities must not be assessed separately.

3. **ASK TO GLOBAL LEGISLATORS**: to cooperate on how to interpret regulations across country- and local-level governments and cross-sector. So best practices emerge, enabling greater interoperability and collaborations between EU healthcare entities. Support a developed technical health data infrastructure to enable scaled deployment of novel products and services.

4. **ASK TO LEGISLATORS AND AFFILIATED INTEREST GROUPS:** to engage stakeholders on understanding the practical impacts of implementing the proposed regulations. Identify and articulate value drivers for the healthcare sector associated with the legislation, e.g., benefits and return on compliance with the EHDS. Build incentives for innovators to develop AI solutions to drive global health based in the EU and to the EU's economic benefit. This will drive and accelerate changes in creating and sharing datasets, in turn driving quality, trustworthy, and compliant AI.

5. **ASK TO RESEARCHERS:** to generate the knowledge resource to develop AI applications and underpin innovation, education, policy development and practice with objectives for health equity, sustainability, and global relevance.

Trust is a key pre-condition for and enabler of sustainable AI for sustainable health. Toward developing the triangle of trust, two greater asks to all actors in the AI healthcare space:

1. **ASK TO OPERATIONALISE THE MECHANISMS OF BULDING AND MAINTAINING TRUST.** This is a call to develop best practises across the European Union on trust management, connected to the emerging data stewardship capabilities that are currently supported. AI is broader than just the data, and trust is currently not uniformly available of a similar nature. The implicit contract between the individual and society needs to be extended for the era of AI and health.

2. **ASK TO PRIORITISE AI EDUCATION TO THE PUBLIC AND THE WORKFORCE.** Risks in data sharing and risks in AI in the health space cannot, and should not, be eliminated. Rather, we aim to have a long-term method to continually evaluate the risk and benefit balance of sharing and reusing data and developing or deploying AI toward the advancement of human health. Guidance and best practices will help users and recipients balance risk and benefits, ultimately driving confidence in the use of data and AI.

10. Annex 1. The agenda of the conference "Sustainable AI to drive Global Health"

Conference: Sustainable AI to drive Global Health. 4 May 2023, 09.00 – 14.00 (CET)
Gothenburg, Sweden
Link to access recording
Agenda

Time	Event	Speakers
9:00	Welcome: Moderator remarks and introduction of Hosts Vision and value: Artificial Intelligence in biomedical Research and Development	Hosts- AstraZeneca, AI Sweden, KTH Royal Institute of Technology, FEAM Moderator- SEBASTIAAN MEIJER, KTH Royal Institute of Technology | The European Digital Innovation Hub Health Data Sweden Vision and value- PEDER BLOMGREN, AstraZeneca
9:25	Opening remarks and presentations from esteemed politicians	TOMISLAV SOKOL, EHDS rapporteur European Parliament TOLIAS YIANNOS, Legal lead on AI and AI liability, DG Sante EU commission (virtual) MARIE-LOUISE HANEL SANDSTROM, Member of the Swedish Parliament
10:00	Presentation: Information-Driven Healthcare	MAGNUS KJELLBERG, Sahlgrenska University Hospital
10:40	Panel Discussion: Articulating needs, barriers, and value for the EHDS legislation	LEONOR CERDÁ ALBERICH, Medical Research Institute La Fe University of Valencia MILANA TRUCL, Policy Officer at European Patients Forum (EPF) MARKUS KALLIOLA, TEHDAS Finland TOMISLAV SOKOL, EHDS Rapporteur, European Parliament ANNEMIEKE ÅLENIUS, The Swedish eHealth Authority
11:40	Panel Discussion- Implementing the AI Act in a global context | Practical challenges and opportunities across sectors	ROBIN FEARS - Biosciences Programme Director at EASAC - European Academies' Science Advisory Council MARGI SHETH, AstraZeneca MAGNUS KJELLBERG, Sahlgrenska University Hospital MARKUS LINGMAN, Region Halland
12:40	Summary, call to action and closing remarks	FREDRIK HEINTZ, AI Sweden SEBASTIAAN MEIJER, KTH Royal Institute of Technology

11. Annex 2. Acknowledgements

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12. References

[1] European Union. (2021). Document 52021PC0206: Proposal for a regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain union legislative acts. [URL] https://eur-lex.europa.eu/legal-content/en/txt/?uri=celex%3a52021pc0206 [Accessed 20 July 2023]

[2] Wilkinson, M., Dumontier, M., Aalbersberg, I., et al. (2016). The FAIR Guiding Principles for scientific data management and stewardship. Scientific Data, 3, 160018. https://doi.org/10.1038/sdata.2016.18

[3] Kania, E. (2023). Dr Pin Lean Lau's joint statement at EU Health Policy Platform Annual Meeting. [URL] https://www.brunel.ac.uk/about/brunel-public-policy/news-and-events/news/Dr-Pin-Lean-Laus-joint-statement-at-EU-Health-Policy-Platform-Annual-Meeting [Accessed 25 July 2023].

[4] Personal Data Protection Commission Singapore. (n.d.). Singapore's Approach to AI Governance. [URL] https://www.pdpc.gov.sg/help-and-resources/2020/01/model-ai-governance-framework [Accessed 25 July 2023].

[5] Bradford, A. (2012). The Brussels Effect. Northwestern University Law Review, 107(1). Columbia Law and Economics Working Paper No. 533. Available at SSRN: https://ssrn.com/abstract=2770634

[6] Siegmann S, Anderljung M. (2022). The Brussels Effect and Artificial Intelligence. [URL] https://www.governance.ai/research-paper/brussels-effect-ai [Accessed 25 July 2023].

[7] European Union. (n.d.). Country profiles. [URL] https://european-union.europa.eu/principles-countries-history/country-profiles_en. [Accessed 25 July 2023].

[8] European Commission. (2022). EU Global Health Strategy to improve global health security and deliver better health for all. [URL] https://ec.europa.eu/commission/presscorner/detail/en/ip_22_7153. [Accessed 25 July 2023].

[9] The European & Developing Countries Clinical Trials Partnership (EDCTP). (n.d.). About us. [URL] https://www.edctp.org/about-us/ [Accessed 25 July 2023].

[10] EIT health. (n.d.). Who we are. [URL] https://eithealth.eu/who-we-are/. [Accessed 25 July 2023].

[11] FEAM. (n.d.). News & Events. Recording of the conference "Sustainable AI to drive Global Health" available. [URL] https://www.feam.eu/recording-of-the-conference-sustainable-ai-to-drive-global-health-available/ [Accessed 25 July 2023].

[12] United Nations. (n.d.). Ensure healthy lives and promote well-being for all at all ages. [URL] https://sdgs.un.org/goals/goal3. [Accessed 25 July 2023].

[13] AstraZeneca. (2023). Access to healthcare. [URL] https://www.astrazeneca.com/sustainability/access-to-healthcare.html [Accessed 25 July 2023].

[14] Paul, D., Sanap, G., Shenoy, S., Kalyane, D., Kalia, K., & Tekade, R. K. (2021). Artificial intelligence in drug discovery and development. Drug Discovery Today, 26(1), 80-93. https://doi.org/10.1016/j.drudis.2020.10.010

[15] OECD. (2023). Regulatory sandboxes in artificial intelligence. OECD Digital Economy Papers, No. 356, OECD Publishing, Paris. https://doi.org/10.1787/8f80a0e6-en

[16] AI Sweden. (n.d.). GPT-SW3. [URL] https://www.ai.se/en/node/81535/gpt-sw3/ [Accessed 25 July 2023].

[17] Information Commissioner's Office. (n.d.). Data protection by design and default. [URL] https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/accountability-and-

governance/guide-to-accountability-and-governance/accountability-and-governance/data-protection-by-design-and-default/ [Accessed 25 July 2023].

[18] International Forum on Quality & Safety in Healthcare. (2022). Information driven healthcare – turning data into health for patients and quality of care. [URL] https://internationalforum.bmj.com/wp-content/uploads/2022/06/D9_-220622-IHI.pdf [Accessed 25 July 2023].

[19] AI Sweden. (2021). En handbok för informationsdriven vård. [URL] https://www.ai.se/en/handbok-informationsdriven-vard [Accessed 06 July 2023].

[20] European Commission. (2022). A European Health Data Space: harnessing the power of health data for people, patients and innovation. [URL] https://health.ec.europa.eu/system/files/2022-05/com_2022-196_en.pdf [Accessed 25 July 2023].

[21] Innovative Medicines Initiative. (n.d.). FACILITATE. [URL] https://www.imi.europa.eu/projects-results/project-factsheets/facilitate. [Accessed 25 July 2023].

[22] AI Sweden. (2021, September 6). En handbok för informationsdriven vård. [A Handbook for Information-Driven Healthcare]. https://www.ai.se/en/handbok-informationsdriven-vard [Accessed 2 July 2023].

[23] Hughes, L.D., Tsueng, G., DiGiovanna, J., et al. (2023). Addressing barriers in FAIR data practices for biomedical data. Scientific Data, 10, 98. https://doi.org/10.1038/s41597-023-01969-8

[24] Queralt-Rosinach, N., Kaliyaperumal, R., Bernabé, C.H., et al. (2022). Applying the FAIR principles to data in a hospital: challenges and opportunities in a pandemic. Journal of Biomedical Semantics, 13, 12. https://doi.org/10.1186/s13326-022-00263-7

[25] Chlebus, M. (2021). IMI Impact: Driving healthcare's digital future. Retrieved from [URL] https://www.efpia.eu/news-events/the-efpia-view/blog-articles/imi-impact-driving-healthcare-s-digital-future//. [Accessed 25 July 2023].

[26] Yin, P.T., Desmond, J., & Day, J. (2019). Sharing Historical Trial Data to Accelerate Clinical Development. Clinical Pharmacology & Therapeutics, 106(6), 1177-1178. doi:10.1002/cpt.1608

[27] University of Cambridge. (2023). Artificial Intelligence systems in brain health. [URL] https://www.csap.cam.ac.uk/news/article-artificial-intelligence-systems-brain-health/. [Accessed 25 July 2023].

[28] European Commission. (2019). Ethics Guidelines for Trustworthy AI. [URL] https://digital-strategy.ec.europa.eu/en/library/ethics-guidelines-trustworthy-ai. [Accessed 25 July 2023].

[29] European Federation of Pharmaceutical Industries and Associations. (2023). Review of Pharmaceutical industry research and development in Europe. EFPIA. [URL] https://www.efpia.eu/publications/data-center/the-pharma-industry-in-figures-rd/rd-in-europe/. [Accessed 25 May 2023].

[30] Ceccaroni, L., et al. (2019). Opportunities and Risks for Citizen Science in the Age of Artificial Intelligence. Citizen Science: Theory and Practice, 4(1), 29, pp. 1–14. DOI: https://doi.org/10.5334/cstp.241

[31] Lotfian, M., Ingensand, J., & Brovelli, M. A. (2021). The Partnership of Citizen Science and Machine Learning: Benefits, Risks, and Future Challenges for Engagement, Data Collection, and Data Quality. Sustainability, 13(14), 8087. https://doi.org/10.3390/su13148087

[32] European Commission. (n.d.). The Digital Services Act package. [URL] https://digital-strategy.ec.europa.eu/en/policies/digital-services-act-package/ [Accessed 25 July 2023].

[33] Federation of European Academies of Medicine. (2021). International Sharing of Personal Health Data for Research. [URL] https://www.feam.eu/wp-content/uploads/International-Health-Data-Transfer_2021_web-1.pdf [Accessed 25 July 2023].

[34] FINDATA. (n.d.). Finnish Social and Health Data Permit Authority Findata. [URL] https://findata.fi/en/ [Accessed 25 July 2023].

[35] KPMG. (n.d.). Preparing your workforce for generative AI. [URL] https://kpmg.com/si/en/home/insights/2023/05/preparing-your-workforce-for-generative-ai.html#:~:text=Organizations%20also%20need%20to%20consider,a%20safe%20and%20controlled%20environment [Accessed 25 July 2023].

[36] NHS Health Education England Digital Transformation. (n.d.). Developing healthcare workers' confidence in artificial intelligence (AI) (Part 2). [URL] https://digital-transformation.hee.nhs.uk/building-a-digital-workforce/dart-ed/horizon-scanning/developing-healthcare-workers-confidence-in-ai [Accessed 25 July 2023].

[37] Chen, M., Zhang, B., Cai, Z., et al. (2022). Acceptance of clinical artificial intelligence among physicians and medical students: A systematic review with cross-sectional survey. Frontiers in Medicine (Lausanne), 9, 990604. [URL] https://doi.org/10.3389/fmed.2022.990604 [Accessed 25 July 2023]

[38] Towards European Health Data Space. (2023). Country visit – Sweden. [URL] https://tehdas.eu/app/uploads/2023/03/sweden-country-visit-factsheet-03-2023.pdf [Accessed 25 July 2023].

[39] Schwalbe, N., & Wahl, B. (2020). Artificial intelligence and the future of global health. The Lancet, 395(10236), 1579-1586. https://doi.org/10.1016/S0140-6736(20)30226-9 [Accessed 24 July 2023]