HEALTHCARE DATA INNOVATION COUNCIL

Igniting Progress: Empowering Healthcare via the European Health Data Space and AI

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STRATEJAI

EXECUTIVE SUMMARY

The European Health Data Space (EHDS) is an EU initiative to transform healthcare systems using data. It aims to establish a framework to share electronic health data securely, benefiting patients, researchers, policymakers, and regulatory bodies. Aligned with the concept of "data altruism", the EHDS strives to create a cohesive European Health Union.

Among its key objectives, the EHDS aims to expand the primary and secondary use of health data; ensure individual control over electronic health data; and establish robust governance mechanisms at EU and Member State levels. The initiative seeks to harmonize digital health regulations, reduce barriers to innovation, and facilitate the cross-border exchange of digital health solutions to create an integrated market for such products and services across the EU.

> Investing in compliance and clear legal frameworks for data transfers.

However, there are challenges to address, including inconsistent regulations for electronic health record systems; uneven implementation of GDPR; fragmented national health IT systems; and unclear provisions for secondary data use. Stakeholders will need to work together to overcome these challenges.

The EHDS affects the various healthcare stakeholders differently. Individuals will get better access to their health records and improved healthcare systems. Healthcare professionals will see streamlined care at lower costs because patient records will be more readily accessible. Researchers can access health data more easily, but face challenges related to data access permits and regional jurisdiction. Comprehensive health data access will help regulators, but discrepancies between GDPR implementation and the EHDS framework must be resolved. Health data is more available to industry stakeholders (e.g. Medtech), but they must invest in compliance and clear legal frameworks for data transfers.

Generalist Medical AI (GMAI) models, a subset of foundational models, can perform a wide range of tasks with minimal labelled data, under self-supervision and using diverse datasets.

> Generative AI will enhance healthcare delivery, increasing access to quality care

GMAI models analyse various medical data types, such as imaging scans, electronic health records, lab results, and genomic data. They produce detailed outputs, including text explanations, spoken suggestions and image annotations, demonstrating a high level of medical understanding.

GMAI models could greatly enhance healthcare delivery by supporting doctors, improving communication, increasing access to quality care, and reducing administrative burdens.

In conclusion, the EHDS has the potential to revolutionize healthcare delivery, research, and policymaking in the EU. However, there are a number of issues to be addressed, in regulation, technology, investment, and skills development.

By addressing these concerns, the EHDS can transform the healthcare landscape in Europe. And as GMAI models continue to evolve, they can revolutionize healthcare by interpreting different data types, learning rapidly, and incorporating medical knowledge into their outputs.

THE RISE OF THE EUROPEAN HEALTH DATA SPACE

A European initiative for consolidating the use of healthcare data.

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1.1 THE EUROPEAN HEALTH DATA SPACE (EHDS)

Launched by the European Union, the European Health Data Space (EHDS) aims to harness the untapped potential of health data to improve healthcare systems.

The EHDS is an advanced framework to allow electronic health data to be used by patients and other stakeholders, including researchers, policy makers, and regulatory bodies.

By facilitating data-sharing in a controlled, secure and transparent manner, the EHDS improves decision-making in areas such as healthcare innovation, patient safety and healthcare statistics.

> EHDS is a key step towards achieving 'data altruism'.

The establishment of the EHDS marks a key milestone towards achieving 'data altruism' in healthcare, a concept that encourages the voluntary sharing of personal data for the greater good. Moreover, it lays the foundation for the formation of a cohesive European Health Union that can provide comprehensive, high-quality healthcare across the continent.

1.2 THE OBJECTIVE

The initiative significantly broadens the primary use of health data and enables its secondary use, thereby increasing the scope and depth of data insights. It also it reinforces EU citizens' individual control over their electronic health data, thereby ensuring privacy and promoting trust in the system.

Additionally, the EHDS helps to establish robust governance mechanisms at both the EU and Member State level. This ensures a secure data processing environment, balancing the demands of data accessibility and confidentiality. By safeguarding data integrity and privacy, these mechanisms bolster trust and confidence in the system's operation.

> By safeguarding data integrity and privacy, these mechanisms bolster trust and confidence in the system's operation.

The EHDS paves the way for a truly integrated market for digital health products and services to be created. It does this by harmonizing rules across the EU, reducing barriers to innovation, and facilitating the cross-border exchange of digital health solutions.

It is anticipated that this uniformity in digital health regulations will boost efficiencies within healthcare systems, improving healthcare delivery and outcomes across the Union.

1.3 THE TWO AREAS OF THE EHDS MYHEALTH@EU

MYHEALTH@EU

The EHDS seeks to build a cross-border digital infrastructure that will serve as a conduit for the seamless exchange of health data to optimize healthcare delivery across the European Union. MyHealth@EU will enable patients to readily access their electronic health data through designated access points, established by individual Member States.

The interconnected infrastructure designed for primary data use will link Member States, allowing patients to readily share their health data across borders.

Patients will be able to control, manage, and share their electronic health data with their chosen healthcare providers, regardless of geographical boundaries. This will not only enhance patient engagement in healthcare decisions but also foster more personalized

and effective care delivery system across the European Union.

HEALTHDATA@EU

Participation in HealthData@EU by all EU Member States is mandatory.

HealthData@EU forms a critical part of the European Union's strategic roadmap, centring on the establishment of a decentralized EU infrastructure that enables the secondary use of health data. This innovative infrastructure will serve as a hub, connecting health data access bodies that will be established in all Member States.

Participation by all Member States in this EU infrastructure is mandatory to ensure a pan-European approach to health data management.

The ultimate aim is to facilitate cross-border health studies that will improve our collective understanding of diverse health trends and challenges across the continent.

We will focus our findings on this second part (HealthData@EU), as it is more aligned with the goals of the Health Data Innovation Council.

1.4 EHDS AND THE REGULATORY SCENARIO FOR SECONDARY USE OF HEALTH DATA

The European Health Data Space (EHDS) has the ambitious goal of streamlining the application of data analytics and artificial intelligence (AI) within the healthcare sector.

The strategy seeks to establish robust structures and effective governance mechanisms that clarify and standardize protocols for data usage across the EU. The overarching aim of this effort is to help create a future where healthcare systems are driven by data.

This transition is anticipated to revolutionize healthcare delivery, enable predictive and personalized care and improve health outcomes across the continent.

This vision aligns with the long-anticipated shift towards data-driven healthcare, reinforcing the EU's commitment to spearheading innovation and excellence in healthcare.

1.5 HINDERING FACTORS

However, there are potential impediments that could prevent these ambitious goals being met. Key among these challenges are:

+ Regulation gaps in Electronic Health Record (EHR) systems – the current lack of consistent regulations for EHR systems across Member States is a significant hurdle. Without harmonized rules, cross-border data exchange and secondary usage of data may be unnecessarily complex.

+ Uneven GDPR implementation – the inconsistent implementation of the General Data Protection Regulation (GDPR) across Member States presents another substantial barrier. A standardized approach to data protection and privacy is essential for a pan-European health data infrastructure to function smoothly.

+ Disconnected centralized national systems – presently, many EU Member States have national health data systems that operate in isolation. These disjointed systems could stop health data being flowing seamlessly across borders, preventing a unified health data space from being established.

+ Unclear provisions for secondary use – the proposed regulations currently fail to clearly define the rights and rules for the secondary use of health data. A lack of explicit guidelines could stifle innovation and cross-border health studies, slowing the transition towards a data-driven healthcare system.

A future where healthcare systems are driven by data

Addressing these challenges requires all stakeholders to make concerted efforts and collaborate, to ensure the EHDS is successfully implemented and a truly unified and effective framework for sharing and using data is created.

1.6 EHDS IMPACT ON DIFFERENT HEALTHCARE STAKEHOLDERS

Given the expansive reach of this initiative, several stakeholders could potentially reap substantial benefits from its successful implementation. However, these stakeholders are still advocating for the existing regulatory framework to be refined. They are calling for a tailored approach that incorporates elements specifically relevant to their domains.

> A future where healthcare systems are driven by data

These are the key stakeholders and their specific concerns.

PATIENTS

With the rollout of MyHealth@EU, individuals are poised to experience both immediate and secondary advantages.

At the forefront, patients can enjoy greater health data portability. This means they can access their health records seamlessly across borders, encompassing data they've personally recorded.

It's essential to address the significance of such patient-logged data; neglecting it could marginalize patients, sidelining them from the collaborative process of health service design and delivery. Additionally, it's noteworthy that several health data devices, like Fitbit and Garmin, are intentionally left uncertified by their creators for CE approval. The lack of stringent regulations also means valuable nutritional data often gets overlooked.

On a broader scale, the initiative promises systemic improvements. By harnessing the power of comprehensive health data and cutting-edge analytics, healthcare systems stand to evolve for the better.

Yet, there's a call for clarity. Organizations such as the European Patient Forum (EPF) stress the need to specify the intentions behind data re-purposing. Their advocacy centers on ensuring that such endeavors prioritize the well-being of patients and the greater community

HEALTH PROFESSIONALS AND HEALTHCARE PROVIDERS

> Increased investments in enhancing data collection systems and improving interoperability-EUHA

The successful implementation of the EHDS will improve interoperability of health records across borders and increased the evidence base for medical decisions pertaining to diagnoses and treatments. This will not only streamline patient care but also avoid unnecessary duplication of tests, reducing costs and improving the efficiency of healthcare systems.

Despite these benefits, the European Union Hospital Alliance (EUHA) has voiced specific concerns and suggestions for improvement. Primarily, they call for more investment to enhance data collection systems and improve interoperability of data already for their primary use. They also emphasize the need for patients to be able to opt out of secondary and tertiary use of data, ensuring that they retain control over their personal health information. Nevertheless, the possibility to dynamically opt out, does not seem feasible in practice. Lastly, the EUHA highlights the need to address the cultural gap among stakeholders regarding the usage and sharing of health data. They stress the importance of fostering an inclusive culture where data-sharing is seen as a tool for improving healthcare outcomes rather than

as a breach of privacy. A strategic approach to these issues is crucial to ensuring the long-term success of the EHDS.

RESEARCHERS

For researchers, EHDS promises to significantly improve access to health data within a trusted and secure framework, accelerating the pace of medical research and leading to faster development of medical treatments, technologies, and healthcare policies.

However, the European Advanced Translational Research Infrastructure in Medicine (EATRIS) raises concerns around the administrative complexities associated with a permit-based system for data access . Specifically, they note the challenges that may arise given that health data management often falls under regional jurisdiction rather than national control. This divergence could lead to inconsistencies in health data access and usage.

Additionally, EATRIS suggests that competence centres for managing secondary data should be established at the Member State level. These centres would effectively manage citizen opt-out systems, ensuring that individuals retain control over their personal health data and its usage. Such an approach would uphold individual privacy rights and help build trust in the data management system, which will be crucial for the successful implementation of EHDS.

REGULATORS

From a policy-making perspective, EHDS significantly eases access to comprehensive health data. This streamlined access is expected to lead to better health policy decision-making and improve the functioning of the healthcare system, resulting in more efficient and effective patient care across the EU.

> Discrepancies between the General Data Protection Regulation (GDPR) and the EHDS framework- TEHDAS

Meanwhile, the Joint Action Towards the European Health Data Space (TEHDAS) identifies specific regulatory challenges that need addressing.

These include the discrepancies between the General Data Protection Regulation (GDPR) and the EHDS framework, which can lead to conflicts and complexities in data management.

TEHDAS also points out that overlapping norms and national peculiarities lead to a lack of clarity. This can cause confusion and create barriers to the smooth operation of a pan-European health data space.

Consequently, more precise guidelines and regulations are needed that take into account these national nuances while maintaining the overarching objective of an integrated, efficient, and secure health data infrastructure across the EU.

INDUSTRY

Substantial industry investments will be needed to fully comply with the EHDS framework.

EHDS promises to significantly increase the availability of electronic health data, leading to significant improvements in health outcomes. This enhanced access to health data could also streamline the production of medical products and devices, leading to advances in medical treatments and technologies.

However, Digital Europe, a leading digital technology association, says the industry will need to make substantial investments to fully comply with the EHDS framework.

MedTech Europe, a trade association for the medical technology industry, identifies the absence of a clear legal framework for international data transfers and data governance as a potential challenge. It recommends significant investment in technical infrastructure to ensure smooth,

secure, and efficient data management. Additionally, it underscores the importance of upskilling digital health workers to manage and leverage the EHDS effectively.

This suggests the need for a comprehensive approach, involving both infrastructure development and capacity building, to successfully implement the EHDS.

As we have seen, the EHDS promises to revolutionize how health data is managed and used across the European Union. It could transform healthcare delivery, research, and policymaking, benefiting a wide array of stakeholders from individuals to industry players.

However, realizing this potential hinges on the current framework being refined in areas such as legal clarity, technical infrastructure, investment considerations, and skills development.

For instance, a clearer and more harmonized regulatory environment is needed that aligns GDPR implementation with the EHDS framework across Member States. The technical infrastructure must be robust, secure and able to manage vast quantities of health data efficiently.

Moreover, both public and private sector investments are required to ensure the EHDS guidelines are adhered to. Lastly, upskilling the digital health workforce is critical to ensure the full potential of the EHDS.

By addressing these considerations and evolving based on stakeholder feedback, the EHDS can become more effective and efficient, deliver value to all stakeholders and transform the EU's healthcare landscape.

1.7 ACTUAL EHDS IMPLEMENTATION AND PILOTS

Many projects being developed could become effective lighthouses for the implementation of the EHDS, guiding its adoption in practice, such as the HealthData@EU examples below.

HEALTHDATA@EU PILOT

This practical trial will provide crucial insights into the operational efficiency of the system, leading to further optimization in subsequent phases.

This pilot project is a collaborative venture involving 17 partners including health data access bodies, health data sharing infrastructures, and various European agencies. The primary aim is to establish a pilot version of the EHDS infrastructure specifically for the secondary use of health data, covering research, innovation, policy making, and regulatory needs.

The HealthData@EU project intends to establish a network connecting data platforms across various EU Member States. The project will develop user support services to aid research projects that harness health data from multiple EU nations. This multi-faceted approach ensures seamless and secure access to diverse health data, promoting cross-border co-operation and innovation.

The project will establish guidelines in areas such as data standards, data quality, data security, and data transfer. These guidelines will provide a comprehensive framework to support this cross-border infrastructure, ensuring that all activities conform to the highest standards of data management and security, fostering a trusted environment for the secondary use of health data.

EUROPEAN FEDERATION FOR CANCER IMAGES (EUCAIM)

EUCAIM represents a pivotal element of the European Cancer Imaging Initiative, a project initiated by the European Commission under the umbrella of Europe's Beating Cancer Plan (EBCP). The EBCP aims to foster innovation and increase the use of digital technologies in cancer care. This initiative aims to facilitate more accurate, rapid clinical decisions,

diagnostics, treatment, and predictive medicine for cancer patients across Europe.

EUCAIM will establish a pan-European digital infrastructure. The platform will host a comprehensive collection of FAIR (Findable, Accessible, Interoperable, Reusable) pan-cancer anonymized images derived from Real-World Data, while preserving providers' data sovereignty.

EUCAIM plans to create an Experimentation Platform dedicated to developing and benchmarking AI tools. This will support precision medicine in cancer diagnosis and treatment, paving the way for more personalized and effective cancer care.

One of EUCAIM's primary aims is to tackle the fragmentation of existing cancer image repositories by constructing a distributed atlas of cancer images, encompassing both common and rare types of cancer. These images will be drawn from existing initiatives, including networks of related research infrastructures and successful Horizon 2020 projects.

EUCAIM's target audience includes clinicians, researchers, and innovators. It will provide them with the resources needed to construct reproducible clinical decision-making systems that support diagnosis, treatment, and predictive medicine. This infrastructure promises to stimulate the European market through the development of new tools and services and have a profound impact on cancer care and healthcare across Europe.

AIDA PROJECT

The AIDA project aims to develop an artificially intelligent diagnostic assistant for gastric inflammation to help researchers, clinicians, patients and the general public understand, diagnose and treat chronic gastric inflammation and gastric cancer.

> Aida: a healthcare data space in the field of gastric cancer

Most cases of gastric cancer are detected at a late stage when patients have a life expectancy of a year. Diagnosing people at risk of developing gastric cancer at the pre-symptomatic stage could significantly improve their outlook.

Aida will consider multiple data sources from the same individual to help diagnose pre-cancerous inflammation, suggest personalized medical treatment and follow-up, and make recommendations for monitoring patient health status. One of most innovative features of Aida is the collaborative data set-up. Data collaboratives are new forms of co-operation where participants from different sectors including R&I, clinical partners, industry, and patients exchange their data under strict governance rules to create public value. Aida unites some of Europe's leading authorities in gastric inflammation and cancer, AI and machine learning, experts on data governance and privacy, public authority representatives and patient advocates.

Aida will last four years, and its results will be transferred to an independent foundation where all the consortium members and stakeholders are represented. The main goal of the Aida foundation is to exploit the potential of data exchanges in a collaborative way by creating a working example of a healthcare data space. In addition, the AI assistant will support preventative programmes. This research project proposes new frameworks for both data exchanges, through the data collaborative model, and creating public value from individual data, with the establishment of a foundation that will use the results to exploit further opportunities.

GENERATIVE AI-FOUNDATIONAL MODELS IN HEALTHCARE

The world of medicine is on the brink of transformation thanks to rapid advances in artificial intelligence (AI), especially Generative AI, through foundational models

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2.1 FOUNDATIONAL MODELS

The latest AI foundational models are trained on enormous and varied datasets, enabling them to tackle a broad range of tasks. Unlike previous AI models, which were built for specific tasks, foundational models can excel in a variety of areas, from understanding texts and describing images to playing video games.

The power of these models comes from their large size, the ever-growing datasets they are trained on, and improvements in their design. For instance, GPT-3 (and its more recent versions), a large language model developed by OpenAI three years ago, uses in-context learning to perform tasks it was never directly trained to do by simply learning from text examples.

Many recent foundational models can also handle and produce various types of data. For example, the Gato model can chat, caption images, play video games, and even control a robot arm.

Despite these advancements, the medical field has been slower in adopting foundation models. This is due to challenges in accessing large, diverse medical datasets, the complexity of medical tasks, and the fact that these models are relatively new.

Current medical AI models are mostly designed to perform specific tasks, like diagnosing pneumonia from a chest X-ray, and require extensive labelling of data. These models are limited in scope and cannot adapt to new tasks without being retrained on new datasets.

So far, of the hundreds of AI models approved by the Food and Drug Administration for clinical use, most are approved for just one or two specific tasks.

2.2 GENERALIST MEDICAL AI (GMAI)

Recent research has introduced a new concept called generalist medical AI (GMAI), which aims to broaden the application of AI in medicine.

GMAI models could perform a wide range of tasks using minimal or even no specific labelled data for each task. These models learn through self-supervision, using large and varied datasets, and can analyse different types of medical data. This data could come from imaging scans, electronic health records, lab results, genetic data, network graphs, or medical text.

There are several potential uses for GMAI that could have a significant impact on healthcare. To bring these applications to life, specific technical capabilities must be developed and the necessary training datasets must be assembled.

However, this GMAI approach will likely pose new challenges for regulating and validating AI in medicine. It may also influence how large medical datasets are collected in future. Despite these challenges, the potential benefits of GMAI are vast, offering the possibility of greatly enhancing healthcare delivery and outcomes. This becomes even more significant in today's fast-evolving landscape and the adoption of even further overlapping regulations such as the AI Act.

Unlike a human doctor, typical medical AI models start with no existing knowledge about medicine. Instead, they learn everything from data, looking for patterns and associations to help them make predictions. However, without any context or understanding of the underlying medical principles, these models may struggle, especially when there is not a lot of data available.

Generalist Medical AI (GMAI) models aim to address these issues by incorporating medical knowledge directly into the AI. They can use structures like knowledge graphs to understand medical concepts and their relationships. They can also pull in extra information from databases of articles, images or previous cases to help provide context.

> This means that a GMAI model can explain its predictions. For example, it might warn that a patient is likely to develop a serious lung condition because they've had a chest injury and their oxygen levels are dropping, despite receiving more oxygen.

If a GMAI model is asked to suggest treatments, its ability to understand and use causal relationships between medical concepts and observations will be crucial because observational data alone often does not give a clear picture of cause and effect.

Lastly, by drawing on a wide range of molecular and clinical knowledge, a GMAI model can tackle problems even with limited data, by applying knowledge from related problems. For example, AI has already been used to suggest new uses for existing drugs.

2.3 ACTUAL LLM IMPLEMENTATION AND PILOTS

There are many experiments been conducted on foundational AI models and sectorial knowledge to develop vertical GPT-like chatbots that can answer more specialised questions.

GLASS AI

Glass AI, still under development, combines a large language model (LLM) with a clinical knowledge database, created and maintained by clinicians, to create DDx and Clinical Plan outputs.

> The foundation LLM is combined with context, including evidence-based guidelines, schemas, and case studies, created by clinicians at Glass Health to achieve a high level of clinical excellence in its AI outputs.

Certainly, all AI outputs must be interpreted carefully and they should never replace or serve as a substitute for the independent professional judgment of a healthcare provider.

AIDA CHATBOT UNDER DEVELOPMENT

The AIDA chatbot provides medical information about gastric diseases like Helicobacter Pylori and gastric cancer. It is not itself an LLM but uses the API services of an existing LLM (OpenAI API services).

> The chatbot's primary behavior is defined by the system prompt, a series of instructions that guide the LLM on how to respond to users.

The AIDA chatbot is specifically designed to respond to questions about gastric disease and the AIDA project. It tailors its responses based on the audience. It leverages a long-term memory that provides comprehensive information about the AIDA project. Additionally, it has access to the AIDA website to stay updated on project news.

2.4 OPPORTUNITIES AND CHALLENGES OF FOUNDATIONAL MODELS

Controllability is a key feature of GMAI models. They can adjust their outputs to make complex medical information easier to understand. For example, these models could rephrase responses to be simpler, create tailored visualizations, or adjust the level of detail in their explanations based on user needs. They could also translate their outputs into multiple languages, ensuring they can communicate effectively with a diverse range of users.

> GMAI models can adjust their outputs to make complex medical information easier to understand

Additionally, GMAI models can be adapted to fit local customs and policies, making them suitable for use in different regions or hospitals. To use these models most effectively, users may need training on how to ask the questions and understand the model responses.

Adaptability is another characteristic of the models. Unlike existing medical AI models, which can struggle when data changes due to shifts in technologies, procedures, settings, or populations GMAI models can adjust through in-context learning.

> For instance, a hospital could quickly teach a GMAI model to interpret X-rays from a new scanner by providing a few examples.

This means GMAI models can adapt to new data in real-time, whereas conventional models would need to be completely retrained with a new dataset.

Currently, in-context learning is mostly seen in LLM. For GMAI models to adapt to different contexts, they must be trained on a very diverse range of data from various sources and types. For example, to adjust to new variants of COVID-19, a GMAI model could use knowledge of past variants and update this understanding when presented with new information. So, a doctor might ask the model to check X-rays for signs of pneumonia caused by a new variant, giving it new factors to consider based on the latest knowledge about the disease.

2.5 CHALLENGES

There are significant challenges that could limit the applicability of those models and make them impossible to use in practice.

> Both developers and regulators will need to clearly explain how GMAI models have been tested and what they are approved to do

Validating GMAI models will be challenging due to their wide range of capabilities. Current AI models are designed for specific tasks, like diagnosing a certain type of cancer from a brain scan, so they only need to be validated for those specific uses. But GMAI models can handle new tasks that they have not been explicitly trained for, making it harder to predict all possible problems.

If a GMAI model is asked to do something it has not been tested for, it should be able to warn users that it is entering uncharted territory, rather than providing potentially incorrect information. The broad capabilities of GMAI models will require forward-thinking regulations, changes to institutional and governmental policies, and could also affect issues around insurance and liability.

> Social biases in AI models can harm marginalized populations by perpetuating existing biases.

These biases can be picked up during training if the datasets used under-represent certain groups or contain harmful correlations. These risks could be more pronounced with GMAI models due to the large and complex datasets required for training.

To mitigate these risks, it is important to thoroughly validate GMAI models to ensure they perform equally well for all populations, including minority groups. Also, regular checks and regulations are needed even after the models are deployed because new issues can arise as the models are used in new ways or settings. Offering rewards for identifying issues, such as harmful content or biases in the model, could encourage the AI community to help scrutinize GMAI models. Identifying and addressing biases quickly should be a top priority for everyone involved in developing and regulating these models.

> The creation and use of GMAI models pose potential risks to patient privacy.

These models may have access to a vast array of patient information, from clinical data and molecular signatures to demographic details. Larger AI models can unintentionally memorize and reveal training data, which could expose sensitive patient information.

To minimize this risk, it is important to de-identify data and limit the amount of information collected for individual patients.

However, the risk does not stop at the training data. Once a GMAI model is in use, it could also expose current patient data. There are ways to trick models into ignoring their programming rules, which could allow unauthorized users to extract sensitive data. For instance, even if a GMAI model has been programmed not to share patient information with unapproved users, a malicious user could potentially manipulate the model to bypass this rule.

Sustainability is also key concern with the use of GMAI models. Recent models have grown significantly in size, leading to increased costs for data collection and training. These models need vast training datasets, which are costly to assemble. Also, the computational power required to train these large models is expensive and has a significant environmental impact, generating large amounts of CO2 emissions.

Given these costs, it is important to consider the optimal size for datasets and models. A recent study suggested having 20 times more data than model parameters for the best performance. However, current models have been successful with a smaller ratio. Determining the necessary size for models and datasets in GMAI is challenging, as it heavily depends on the specific medical use case.

2.6 3.6. LOOKING FORWARD

Foundation models, particularly GMAI models, have the potential to greatly transform healthcare. These models can interpret different types of data, learn new tasks quickly, and ue medical knowledge, making them useful for a wide range of medical tasks. Their adaptability means they can adjust to new situations, diseases, and technologies without constant retraining. They can be used in traditional medical settings and on mobile devices, helping both healthcare professionals and patients.

However, GMAI models also present unique challenges. Their broad capabilities make them hard to fully validate, and their size can increase computational costs. Also, creating and managing the large, diverse datasets needed to train these models while ensuring patient privacy, is a significant challenge. It is essential that the AI community and healthcare stakeholders to consider these challenges from the start, to ensure GMAI models deliver real value. GMAI models offer great potential to improve healthcare, support doctors in a range of tasks, improve communication, make high-quality care more accessible, and reduce administrative tasks so doctors can spend more time with patients.

+ ANDREA COSTAGLIOLI	+ INPECO
+ ANDREA PESCINO	+ StratejAI
+ ANDREA PULIGHEDDU	+ SLP
+ ELISA FICARRA	+ UNIMORE
+ FEDERICO DE MONTALVO JAASKELAINEN	+ Spanish Bioethics Committee
+ FRANCIS D'SILVA	+ CGI Norge
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+ JESPER GRØNBÆK	+ Danish HealthTechHub
+ JOE PATON	+ Champalimaud Foundation
+ JULIAN ISLA	+ Foundation 29
+ LUCY SETIAN	+ Novartis Foundation
+ MARCIS LEJA	+ Riga East University Hospital
+ MARIO RIBEIRO	+ IPO Porto
+ MENI STYLIADOU	+ Takeda
+ MITCHELL SILVA	+ CEO Esperity and Patient Centrics / Chairman of EUPATI Belgium
+ OLGA P NYSSEN	+ H.Pylori registry
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