



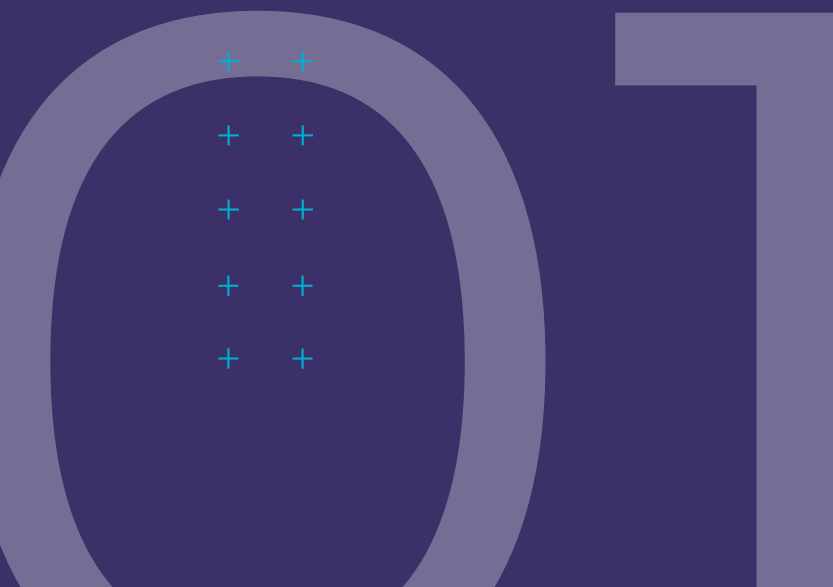


<b>01 EXECUTIVE SUMMARY</b>	<b>4</b>
1.1 Digital health acceleration	
1.2 Data Opportunity	
1.3 Challenges and complexities	
1.4 Emerging motions and projects	
1.5 Data and Big Data	
1.6 Transformation and needs	
1.7 Key Recommendations	
<b>02 UNDERSTANDING DIGITAL HEALTH</b>	<b>9</b>
2.1 Digital Health	
2.2 Data Driven Healthcare	
<b>03 HEALTHCARE TRANSFORMATION</b>	<b>12</b>
3.1 Triggering change in healthcare systems	
3.2 Payment systems push towards a value-based healthcare	
3.3 Challenges	
<b>04 HEALTHCARE DATA OPPORTUNITIES</b>	<b>15</b>
4.1 Value-based healthcare	
4.2 Personalised, predictive and preventive medicine	
4.3 Artificial Intelligence and Big Data analytics	
4.4 Emerging data	
<b>05 COMPLEXITY OF DATA GOVERNANCE</b>	<b>21</b>
5.1 A complex regulatory framework	
5.2 Standards and data interoperability	
5.3 Complexity in harmonisation	
5.4 Emerging approaches in Europe	
<b>06 EMERGING MOTIONS IN HEALTHCARE DATA</b>	<b>24</b>
6.1 TEHDAS	
6.2 Gaia-X	
6.3 Other initiatives	
6.4 Startups and MedTech	
<b>07 TRANSFORMATION AND NEEDS</b>	<b>27</b>
7.1 Sharing data can save lives	
7.2 Lessons learnt from Covid-19	
7.3 Cost of data ecosystems	
7.4 Privacy is not a trade-off for more data	
<b>08 CONCLUSIONS AND RECOMMENDATIONS</b>	<b>29</b>
8.1 Conclusions	
8.2 Key Recommendations	



# EXECUTIVE SUMMARY

Unlocking the power of data  
in healthcare: a European vision



### 1.1 DIGITAL HEALTH ACCELERATION

The global healthcare sector is still recovering from the COVID-19 pandemic, which continues to dominate attention and resources. Even before this historic, global event, the sector was facing critical challenges: from the aging population and cost constraints to the limited availability of healthcare workers, the search was on for an effective, sustainable and future proofed healthcare system. At the same time, digital technology was growing at exponential rates, with the World Economic Forum announcing the advent of the fourth industrial revolution (4IR), driven by smart technologies such as artificial intelligence (AI) and the internet of things (IoT), which have the potential to bring about powerful transformations.

The pandemic accelerated the need for change and has given a significant boost to the use of technology in all sectors, including healthcare, where digital health has become much more common. Consumers are becoming more and more digitally aware, with wearables, connected devices and mobile apps that offer direct or indirect health services, and generate huge amounts of data.

### 1.2 DATA OPPORTUNITY

Data is becoming central to the transformation of healthcare. It is one of the key elements in innovation in medical research, in improving patient care and optimizing population health, Data is just raw material that needs to be managed, curated, analysed and linked to other sources to create so-called “big data”, and then it can become a refined resource for advanced artificial intelligence algorithms.

Satya Nadella, CEO of Microsoft, recently said that “AI is perhaps the most transformational technology of our time, and healthcare is

perhaps AI’s most pressing application”. The opportunity AI presents is clear in areas from improving population health management, to support operations, to strengthening innovation, the global impact could be enormous. The global market was valued at \$8.23 billion in 2020 and is projected to reach \$194.4 billion by 2030, a CAGR of 38.1%<sup>1</sup>.

The transformations envisioned will create a new paradigm of the 4Ps (personalised, predictive, preventive, participatory), that will enable the emergence of a value-based healthcare strategy based on data.

The rapid development of IoT and analytical technologies has generated waves of high-quality data, a powerful tool that can extract value at a speed that was unthinkable just a few years ago.

### 1.3 CHALLENGES AND COMPLEXITIES

Sharing and using data is challenging, with various layers of complexity. One layer is the regulatory framework – many researchers or small start-ups cannot share data easily without the required legal skills. Moreover, there is fragmentation between member states and even regions, and new upcoming regulations like the Data Governance Act, Digital Services Act or the AI Act could generate barriers to future innovation.

A second layer of complexity is in data interoperability, where standards are emerging (e.g., FHIR, OpenEHR) and need to be validated and widely adopted. Other aspects include technical and semantic interoperability, which are relatively easier to solve, but consensus in legal and operational interoperability will be more difficult to reach. The Nordic interoperability project is a successful attempt to solve the various layers of interoperability.

<sup>1</sup> <https://www.alliedmarketresearch.com/artificial-intelligence-in-healthcare-market>

#### 1.4 EMERGING MOTIONS AND PROJECTS

This landscape of tremendous opportunity, but also hurdles and challenges, is generating different approaches to handling data: From the GAIA-X vision of decentralization and self-sovereignty with a federated, distributed approach to initiatives like TEHDAS, which has a vision and governance models for developing clarity on data-sharing and secondary use of data among European countries.

In a similar way, the MedTech and start-up ecosystem is growing rapidly, creating solutions that frequently target consumers rather than supporting organizations in providing care. And all these small, consumer-targeted solutions generate data without clear governance or an efficient model to share them, relinquishing all the additional value that can be generated to the society.

#### 1.5 DATA AND BIG DATA

Big data platforms can now correlate traditional and non-traditional data, extracting results in days that only a few years ago would have required decades.

It is important to understand that there are enormous differences between individual data and a big data platform. Analysing collectively very large datasets has a much higher value than analysing smaller datasets. To find new approaches to critical diseases as cancer, new vaccines, or protein development, data from many patients are required, and this requires effective data-sharing across countries and regions. This is the only option with rare, currently untreatable diseases.

Many ethics council and committee<sup>2</sup> are saying that biomedical research needs new paradigms for this new context. The advantages offered by the use of data, especially with big data and artificial intelligence, should lead to a vision based on the common good, not just individual interest.

#### 1.6 TRANSFORMATION AND NEEDS

Building consensus among stakeholders at various levels (technical, operational, legal) is hard and requires more of a cultural mind shift than technical or legal solutions. To promote the value of using data in healthcare, a cultural transformation is needed, at all levels of the industry and across systems, from understanding and promoting digital literacy, to the definition of effective privacy preservation techniques, to allow the consolidation of trust while not limiting the verification of results. Cultural transformation will allow better awareness that could bring increased investment: the cost to build a structured, high-quality data platform that could be offered to researchers is a fraction of the cost of building a new hospital, but it offers better value, at a global level.

Central initiatives like H2O observatory<sup>3</sup> create data platforms and data-sharing processes that facilitate the transformation, accelerate innovation, and value regional data assets while accelerating cultural change.

Data ecosystems are already being created, but they must be promoted and supported effectively, and become a crucial part of national and regional strategies.

The UK government launched a new national strategy: “Data saves lives: reshaping health and social care with data” with the aim of promoting data usage and to “unlock the incredible power that data possesses” “[so that] we can bring the future forward and make us all healthier and safer”<sup>4</sup>.

On a more operational level there is often a culture of duplicative working behind closed doors, for national and local analytic teams, and a strong reliance on outdated and inefficient means of data management and analysis. Upskilling and modernising tools is part of the transformation needed.

<sup>2</sup> <https://pesquisa.bvsalud.org/global-literature-on-novel-coronavirus-2019-ncov/resource/pt/covidwho-1341983>

<sup>3</sup> <https://health-outcomes-observatory.eu/>

<sup>4</sup> <https://www.gov.uk/government/publications/data-saves-lives-reshaping-health-and-social-care-with-data/data-saves-lives-reshaping-health-and-social-care-with-data>

## THE TIME TO ACCELERATE ON DATA USAGE IS NOW.

### 1.7 KEY RECOMMENDATIONS

#### ADVANCING THE LEGAL FRAMEWORK ON DATA-SHARING AND BIG DATA USAGE

Data-sharing is essential to build significant big data platforms that will enhance value and unlock modern applied analytics. Current fragmentation and lack of clarity create hurdles that make data not fit for purpose in the world of big data, limiting innovation and research.

The acceleration of the technology must be embraced, and the industry must support progress through its expertise and best practices.

Regional differences must be reduced to allow better and wider data sharing and simplify cross-country collaboration to develop research based on data that will create global benefits.

#### SUPPORTING THE CREATION OF CENTRAL DATA PLATFORMS

Central data platforms will bring together research, clinical institutions, technology companies and the industry, collaborating in sharing and using data to make a difference to patients' lives.

This will create long-term improvements to health data that will create sustainable benefits generating high-quality datasets that will be made available, creating impact and sustainability.

The *Health Outcome Observatory* (H2O) brings together the public and private sectors to create a standardised data governance and infrastructure system to incorporate patients' experiences and

preferences across Europe.

With the H2O platform patients will be able to measure their outcomes. The observatory aims to foster innovation in healthcare in Europe and beyond.

#### FACILITATING INTEROPERABILITY TO SOLVE DATA FLOW CHALLENGES

Common data standards and open interfaces are necessary to achieve interoperable systems and true standardization.

Build interoperable showcases to enable solutions for the future as the Nordic Data Lake promoted the Nordic Interoperability project<sup>5</sup> for secondary use of patient data.

The **Nordic Interoperability Project (NIP)** is an initiative that aims to allow Nordic cross-border patient mobility by promoting interoperability across Nordic countries and supporting the development of future health (Nordics Health 2030) in the Nordics that will ensure robust, sustainable and resilient life conditions for future generations.

#### ENABLING CULTURAL TRANSFORMATION IN THE SECTOR

Facilitating the understanding of current regulations and concepts for researchers and healthcare providers will help to reduce complexity and create clarity and awareness. Regional and local data protection authorities should support this transformation in the sector. Aspects that are unclear, such as pseudonymisation or secondary use of data for research need specific clarification and dissemination to help reduce fears. A successful example of this comes from the Spanish Data Protection Authority and its work on creating awareness on anonymisation and pseudonymisation<sup>6</sup>.

On October 2021, the **AEPD (Spanish Data Protection Authority)** proposed a clarification on anonymisation and pseudonymisation, in its work on innovation

<sup>5</sup> <https://nordicinteroperability.com/>

<sup>6</sup> <https://www.aepd.es/en/prensa-y-comunicacion/blog/anonymisation-and-pseudonymisation>

and technology, where it defines clearly its goal to “promote and disseminate knowledge about risk management for the rights and freedoms of natural persons, the AEPD (Spanish Data Protection Authority) develops resources and tools to promote compliance with the RGPD (GDPR), focusing attention on supporting SMEs and entrepreneurs”.

### PROMOTING NATIONAL AND REGIONAL DATA STRATEGIES

All these recommendations could be captured and structured in specific national and regional strategies or action plans on data sharing and usage in healthcare.

Promoting a national strategy would guide action, and allocation of resources,

over a specified time period and towards the implementation of reforms and transformational initiatives.

In June 2021, the government of **Japan** release the draft of the **National Data Strategy** where it shared key principles regarding data as a source of knowledge, value, and growth for sustainability.

It recognized the paradigm shift in the use of technology in response to COVID-19 and promoted a digital society that must be global by design.

The strategy promotes the Data Free Flow with Trust (DFFT) initiative, a proposed guiding principle for international co-operation on data flows.





# UNDER- STANDING DIGITAL HEALTH

A range of different healthcare processes have been affected by digitalisation in recent years, with some areas being more affected than others.



## 2.1 DIGITAL HEALTH

We are seeing the progressive introduction of policies and strategies to encourage so-called eHealth, including the modernisation of drug development through digital means and the adoption of digital processes in clinical journeys and research. Even patients are increasingly using digital tools and solutions to monitor and inform themselves.

According to WHO, digital health is an umbrella term encompassing e-health and areas such as the use of advanced artificial intelligence and big data platforms. In the COVID-19 era, the digital delivery of healthcare has become more important than ever: from sharing the genome of the virus digitally to using digital solutions to trace infections, accelerate vaccines research and support the delivery of massive vaccination campaigns.

Since the pandemic, 58% of countries<sup>7</sup> have been using telemedicine to substitute in-person consultations. In France, the national insurance fund's reimbursements for teleconsultations rose from about 40,000 per month to more than 10 times that figure in a single week during the pandemic. Spending on big data and artificial intelligence in healthcare, whose use was already expanding in fields such as radiology and cancer screening, will reach an estimate of USD 8 Billion in 2022.

Start-ups using AI are growing in Europe, from Cardiologs<sup>8</sup>, which helps healthcare professionals to identify patients with heart disorders, to UK Healthily<sup>9</sup>, which empowers patients to help them check their symptoms before they decide whether to visit a doctor.

In parallel to the development of AI, the Internet of Things (IoT) is enabling the use of more and more connected devices to generate high-quality data for analysis and smart applications.

In Europe, healthcare is the fastest growing market for IoT<sup>10</sup>. With the vast majority of

patients now owning a smartphone, there is a similar proliferation of mobile health solutions, from apps to data collection forms. The EU Commission says there are more than 3.000 mobile health (m-health) apps available in the EU Market.

## 2.2 DATA DRIVEN HEALTHCARE

All these digital tools and processes generate an enormous amount of healthcare data, which is fuelling a debate on who owns the data - the patients, the healthcare providers or the companies that are collecting it?

An EU policy briefing from EPF on Big Data and AI<sup>11</sup> of April 2020 says that patients are increasingly comfortable and willing to share their health data, as they understand the vital importance of advancing health research, helping other patients, and ultimately benefiting society.

The growth of digital healthcare and other technologies offers the ability to process huge amounts of data and extract value that could benefit all parts of the healthcare system.

From fuelling innovation in medical research to improving patient care, data is becoming central to the modernisation of the industry.

The benefits include – faster and early diagnosis, deeper understanding of disease, increased effectiveness of treatment, and evidence of cost-effectiveness and outcomes that could enable a move to value-based payments.

The potential value of data in healthcare is accelerating as the ability to extract data from little-used areas, like decoding healthcare data from unstructured information, effectively processing genomic data or continuously gathering glucose levels from human saliva.

In these cases, AI serves not only as an analytical layer over high quality, curated data, but also as a powerful tool for extracting and understanding data from unstructured, non-

<sup>7</sup> <https://www.friendsofeurope.org/events/a-digital-health-revolution-the-european-health-data-space/>

<sup>8</sup> <https://cardiologs.com/>

<sup>9</sup> <https://www.healthily.co.uk/>

<sup>10</sup> [https://european-iot-pilots.eu/wp-content/uploads/2019/06/IoT-European-Large-Scale-Pilots-Programme\\_eBook\\_CREATE-IoT\\_V02.pdf](https://european-iot-pilots.eu/wp-content/uploads/2019/06/IoT-European-Large-Scale-Pilots-Programme_eBook_CREATE-IoT_V02.pdf)

traditional sources.

The AICube story<sup>12</sup> is a perfect example of what's happening outside of traditional innovation pipelines, the usage of modern artificial intelligence techniques, together with the power of Internet of Things allow the creation of a device which have the potential to reduce greatly the cost of gathering glucose measurements for diabetes patients, offering them a more simple, effective and non-invasive measurement, bringing an immediate improvement in the effectiveness of the measurement and a cost reduction for the system.

**AI CUBE** - By 2040, there are expected to be 642 million diabetics, increasing the cost of care for the condition to US\$1 trillion by 2045. Diabetes is one of the most widespread chronic conditions, but an early diagnosis can reduce the complications related to the disease as well as the economic burden on healthcare systems. AICube developed an "augmented" smart toothbrush that collects a saliva sample and monitors the glucose level in the saliva. The handset also hosts an accelerometer to determine tremor severity for Parkinson's patients. The outcomes are wirelessly processed through a machine learning algorithm and the data from each user are evaluated against the parameters already

in the database, which is continuously updated. AICube aims to support early diagnosis of disorders to introduce early and effective treatments, and reduce associated complications. Start-ups like AICube are fuelling innovation in MedTech, which is expected to reach a market value of about US\$660 billion by 2028.

The same measurement could happen for healthy individuals, offering early diagnostics or preventive medicine recommendations (identifying nutritional patterns or stress level for example), and creating a data platform for research, or for clinical improvements.

The data provided will be standardised and harmonised and could create a registry of glucose measurement that could be complemented by specific EMR or behavioural data from those monitored. But who will own the data? How can it be managed and made available to researchers and other stakeholders to effectively realise its potential value?

And, finally, is the regulatory landscape favourable for small start-ups that are investing heavily in product development and commercialisation, as they bring, they will land their products to market?

We will address these questions in the next chapters.

<sup>11</sup> <https://www.eu-patient.eu/globalassets/policy/epf--big-data-and-artificial-intelligence--eu-policy-briefing-for-patient-organisations-april-2020.pdf>

<sup>12</sup> <https://www.theaicube.com/>



# HEALTHCARE TRANS- FORMATION

The rapid acceleration of digital technology is transforming healthcare systems worldwide, creating a wave of opportunities and challenges.



### 3.1 TRIGGERING CHANGE IN HEALTHCARE SYSTEMS

In recent years, a huge wave of digital transformations has changed how individuals and organisations behave, and created new business models and impacts.

This has accelerated the rate of investment hugely, creating the notion of 'exponential technology', with innovations progressing at a pace with or exceeding Moore's Law, according to the Deloitte definition, leading to "a renaissance of innovation, invention and discovery that has the potential to positively affect billions of lives".

At the same time, the healthcare sector has faced several challenges, including an aging population, increasing costs due to the increase in chronic diseases and the shortage of doctors and nurses. Improvements in life expectancy have stalled and health inequalities are widening.

In this complex scenario, a more holistic approach is emerging, based on the WHO's definition of health as "*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity*".

The pandemic accelerated the adoption of digital health solutions, and this has created

an increased opportunity to guide the industry to a more sustainable and effective approach.

The digital world is creating digital citizens, while new approaches to research and care are generating new data streams which creates opportunities for a more sustainable and effective system.

Data is arguably the most valuable resource for improving outcomes, increasing efficiency and helping to create a more personal, preventive, and predictive system. The use of data, together with artificial intelligence and analytics techniques, will also encourage the emergence of a value-based healthcare system, where proactive initiatives to improve global population health could be planned and delivered.

Figure 1, in the next page, provides a schematic of this healthcare transformation. The factors that drive the need for change on the top left of the figure (e.g., aging population, chronic diseases, increasing costs and the Covid-19 pandemic) together with the enablers for change on the bottom left (e.g., data and AI, MedTech, safeguards) create the conditions for a healthcare transformation from which a value-based healthcare that is personal, preventive, predictive and participative, can emerge.

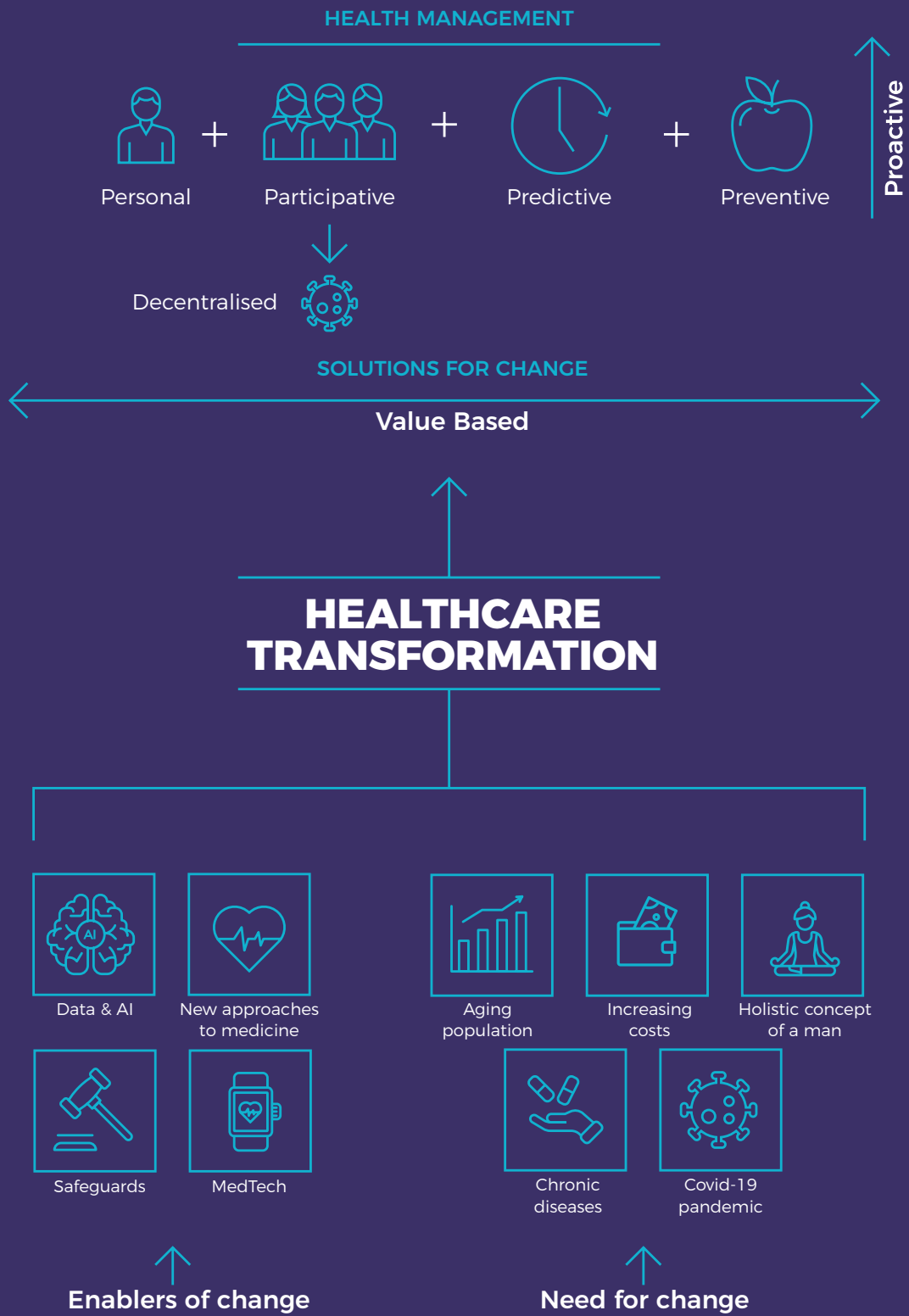
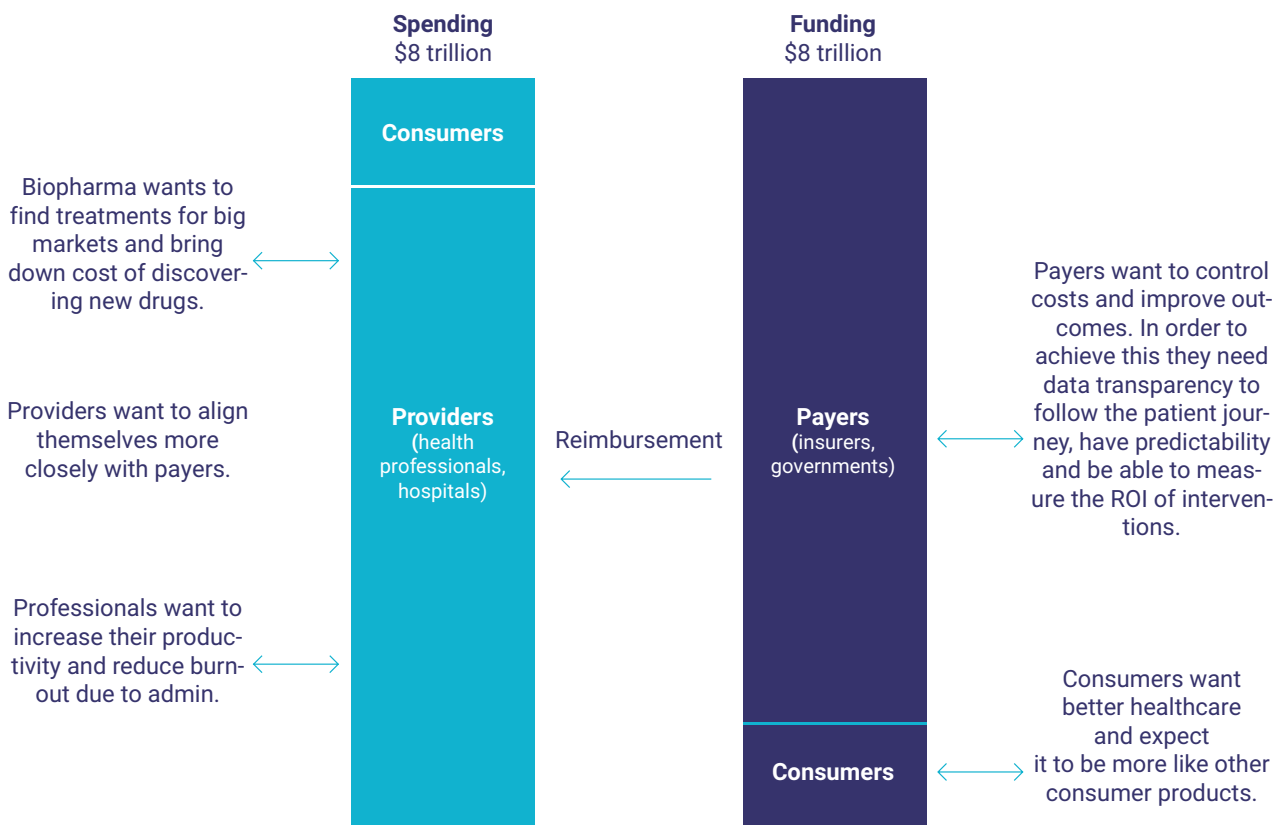


Figure 1 - Healthcare transformation  
Source: 2022, Stratejai

### 3.2 PAYMENT SYSTEMS PUSH TOWARDS A VALUE-BASED HEALTHCARE

Those who pay for healthcare (mostly insurer and governments) want to control costs, improve outcomes and get value for money. To achieve this, they need data transparency throughout the patient journey, predictability and the ability to measure the return on

investment (ROI) of interventions. Consumers just want better healthcare. This moves the payment system towards a value-based care. Providers (health, professionals, hospitals) want to align themselves more closely with payers and increase their productivity. At the same time biopharma wants to find treatments to address large markets and bring down costs of discovering new drugs.



**Figure 2 - Spending and funding of healthcare system**  
 Source: Dealroom analysis of data from OECD, Eurostat, CMS, WHO

From 1970 to 2019, before the pandemic, the cost of healthcare grew from 5% of GDP to 10% in Europe, and from 6% to 17% in the US<sup>13</sup>. This spending, which is now around US\$ 8 trillion worldwide, is projected to grow by 5% per year, faster than the overall economy.

Prevention is key to lower healthcare spending, with Deloitte envisioning healthcare systems shifting from being dominated by care and treatments to being dominated by health and well-being.

### 3.3 CHALLENGES

There are many challenges in effectively exploiting this wave of opportunities, from digital literacy to skill shortages, to the urgency of creating accessible high-quality data ecosystems.

Digital literacy is a fundamental competency in the workforce, in research, and even at policymaking level. The ability to use sophisticated dashboards, understand data and effectively adopt privacy in the digital sphere are just some of the skills needed to

use data effectively. All data analytics, usage and research requires multi-disciplinary teams.

Data-sharing regulations are fragmented, difficult to interpret and frequently created from ethical principles that are meant for other industries or scenarios, limiting the consistent development of health data projects.

New emerging regulations like the Data Governance Act (DGA) or the Artificial Intelligence Act (AI Act) proposals could simplify the sector or could add another level of complexity that will limit the advance of the use of data for innovation in healthcare.

We need a cultural and technical transformation to facilitate research, disseminate best practices and practical solutions, and support data sharing and usage. Effective technical infrastructure for data storage, usage and analysis is also needed. Ineffective or inadequate tools to manage data-driven processes in healthcare can lead to critical failures that have held back progress and, in some cases, created negative backlashes.

---

<sup>13</sup> Data by American Century Investments, based on study on US, Australia, Canada, Germany, Netherlands, Japan, Switzerland, UK





# HEALTHCARE DATA OPPORTUNITIES

From value-based healthcare to personalised and preventive medicine, data are fundamental for the future of care.



#### 4.1 VALUE-BASED HEALTHCARE

Value-based healthcare is an emerging strategy in which providers, including hospitals and physicians, are paid based on patient health outcome. It was developed by the economist Michael Porter<sup>14</sup> and is gaining traction thanks to the promise of maximising value for patients and achieving the best outcomes at the lowest cost. It could benefit the entire system, from patients to providers to payers, as well as wider society.

Value-based models have seen new types of data emerge such as patient-reported outcomes (PRO), which are directly reported by the patient. Measuring the outcomes creates data of the progression of patient health during treatment, showing how effective a therapy is for specific patients.

Storing and analysing these data, and correlating with other data sources from patients (behaviour, nutrition, Electronic Healthcare Records), open the possibility of creating new research or generating predictions and effectiveness models that could be applied globally.

**The H2O project<sup>15</sup>** (Health Outcomes Observatory) is part of Europe's Innovative Medicine Initiative, which brings together public and private sector to offer a powerful platform for measuring and gathering patient outcomes.

It offers the infrastructure and the data governance to manage those data effectively, with the aim of standardising measurements and allowing patients to keep control of their data.

This could allow their healthcare provider to handle therapies more effectively, especially in patients with Non-Communicable Diseases. Like water, data is an essential resource, and in healthcare it can empower and serve patients, whilst safeguarding their privacy. Health data can facilitate a richer dialogue between patients and their

healthcare providers and also improve self-management, leading to better care for individuals and more efficient and sustainable health care for the entire community.

#### 4.2 PERSONALISED, PREDICTIVE AND PREVENTIVE MEDICINE

The P4 approach (personalised, predictive, preventive and participatory) to medicine is a new paradigm in healthcare that could lead to radical change.

In recent years, there has been a gradual growth in the role of prevention. More effort has been put into screening, public health policies, and health awareness campaigns. Despite this, lifestyle changes are difficult to adopt and the take-up of public health services like screening and vaccinations is not as good as it should be.

P4 medicine is a new healthcare model that use multidimensional data and machine-learning algorithms to develop public health interventions and monitor the health of the population, with a focus on wellbeing and healthy ageing.

Below, we highlight how different data approaches and opportunities could impact these aspects.

#### PERSONALISED MEDICINE

The Human Genome Project led to fundamental changes in the practice of biology and medicine.

Biology became "an informational science" and revolutionary changes started to emerge in how to think about diagnosis, therapy and even prevention.

Now ever more -omics are being considered, from human genomics, epigenomics and microbiomics, more detailed data is being gathered, from foodomics to transcriptomics, and more data is being collected, analysed and researched. This creates the potential for

<sup>14</sup> <https://hbr.org/2013/10/the-strategy-that-will-fix-health-care>

<sup>15</sup> <https://health-outcomes-observatory.eu/>

“individualised (Personalised) medicine from pre-womb to tomb” <sup>16</sup>.

Those data are relatively new, and create a huge and valuable database, but it must be consolidated and harmonised to support significant research projects. There is little commercial use for genome data on its own, but it becomes powerful when wedded to clinical outcomes. However, sharing these data is complicated for infrastructural and governance reasons, and the use of modern analytical technologies is still limited.

**Decider project**<sup>17</sup> - Ovarian cancer is a “silent killer”, killing more than 40,000 women a year in Europe alone. The treatment options include surgery and platinum-based chemotherapy. However, the effectiveness of the latter tends to decrease during the treatment cycles as patients develop chemotherapy resistance. The Clinical Decision via Integrating Multiple Data Levels to Overcome Chemotherapy Resistance in High-Grade Serous Ovarian Cancer, also called the DECIDER project, is an EU-funded international, interdisciplinary research project studying chemotherapy resistance in ovarian cancer patients. The research aims to use data to develop tools to identify resistant patients and effective treatment combinations. To tackle interoperability challenges, the team will develop an open-source software platform where all relevant patient data will be integrated and visualised to support clinical decision-making. Although the data used in the research come from patients in Finland, the consortium includes 14 participants across Europe. The project will promote data sharing in health research by implementing data pseudonymisation and anonymisation techniques to manage sensitive patient data.

## PREVENTIVE MEDICINE

Identifying risks at population and personal level could allow the development of preventive strategies that could be targeted at

individuals at higher risk of a specific disease. Defining precisely the impact of behaviours like nutrition and other social determinants of health on risks and impacts could allow the creation of effective initiatives to improve population health and reduce health expenditures.

Sharing effectively different sources of data from different systems, some outside of the healthcare context, or sharing data across countries and region will be key to defining these risks.

**Carecol** - Gastric cancer affects 1% of European citizens, but it is still the fourth most lethal form of cancer, killing 75,000 Europeans per year. Gastric cancer is usually triggered by an infection of the gastric mucosa by *Helicobacter pylori* (H.pylori) and progresses through a number of steps to a carcinoma. Given that half the global population is infected with H.pylori and only 1% develops gastric cancer, the aims to identify specific risk factors and create risk scores for the development of a gastric carcinoma in patients with H.pylori. This information could enable the development of targeted eradication strategies that will reduce mortality and secondary conditions while limiting cost and usage of antibiotics.

The data collaborative started in Latvia, a small country that has a significant incidence of gastric cancer. Latvian experts built a consortium with experts and prominent research centres from all across Europe to enrich the data collaborative and increase the effectiveness of the data platform.

## 4.3 ARTIFICIAL INTELLIGENCE AND BIG DATA ANALYTICS

Satya Nadella, CEO of Microsoft, said recently that “AI is perhaps the most transformational technology of our time, and healthcare is perhaps AI’s most pressing application” <sup>18</sup>.

<sup>16</sup> [https://www.cell.com/fulltext/S0092-8674\(14\)00204-9](https://www.cell.com/fulltext/S0092-8674(14)00204-9)

<sup>17</sup> <https://www.deciderproject.eu/>

<sup>18</sup> Announcement of strategic collaboration with Novartis. YouTube 2019 - [www.youtube.com/watch?v=wMfsQE-D2q4](http://www.youtube.com/watch?v=wMfsQE-D2q4)



**Improving population-health management**

**Improving operations**

**Strengthening innovation**

**Figure 3 - AI Impact and data analytics impact areas in healthcare**  
Source: EIT McKinsey Report, 2020

In research, AI can search scientific literature for relevant studies and combine different kinds of data. Recently it has been used to develop new antibiotics that are effective against antibiotic-resistant bacteria <sup>19</sup>. In clinical care, AI is becoming widely used to interpret medical imaging and support

accurate diagnosis.

By comparing the thousands of images collected every day, AI can be trained to perform an initial comparison and spot problems, which may reduce the time that health professional must spend analysing images.

+++

**AI is perhaps the most transformational technology of our time, and healthcare is perhaps AI's most pressing application.**

SATYA NADELLA  
**MICROSOFT**

<sup>19</sup> <https://news.mit.edu/2020/artificial-intelligence-identifies-new-antibiotic-0220>

Algorithms can help dermatologists make better diagnoses, for example, detecting 95% of skin cancers by learning from large sets of medical images <sup>20</sup>.

Speech recognition can assist in diagnosis if the patient talks or writes to an artificial doctor to give their medical information and history.

In the early days of the COVID-19 pandemic, a mobile phone app and AI algorithms was used to detect if a patient was positive by simply hearing his cough through the smartphone <sup>21</sup>.

In this case, data were donated spontaneously from people who wanted to contribute, to create a high-quality algorithm, but such a tool could have been a more powerful tool to fight the pandemic if a better approach to data sharing and governance had been in place.

**AI4Leprosy Project-** Tackling the world's oldest disease with the latest technology. Leprosy is an infectious disease that mostly affects populations underserved by healthcare. Although it has been largely eliminated, still about 200,000 new patients are diagnosed annually. In the absence of a diagnostic test, clinical diagnosis is often delayed, potentially leading to irreversible neurological damage and its resulting stigma, as well as continued transmission.

The AI4Leprosy project focused on creating an AI-powered diagnostic tool to detect leprosy using image analysis.

Novartis Foundation, Microsoft AI4Health and the Oswaldo Cruz Foundation collaborated to collect, examine, and process anonymised skin lesion images and symptoms from leprosy patients in Brazil. The main goal of the project was to make more accessible an accurate method of classifying leprosy to assist clinicians, especially in remote communities.

The data were used to train an open-source AI-powered model to assess the probability of a patient having leprosy. The AI models implemented had a satisfactory accuracy of over 90% using images and symptoms data. The model has the potential to be integrated in simple mobile apps which can be rolled out in remote rural and urban environments in Asia and Africa, with the aim to remediate any selection bias that would have been introduced in the piloting phase.

#### 4.4 EMERGING DATA

The development of digital health, the acceleration of ownership of personal connected devices, the usage of data that tracks collateral elements to determine health,



The AI models implemented had a satisfactory accuracy of over 90% using images and symptoms data. The model has the potential to be integrated in simple mobile apps which can be rolled out in remote rural and urban environments in Asia and Africa, with the aim to remediate any selection bias that would have been introduced in the piloting phase.

Dr ANN AERTS

**HEAD OF NOVARTIS FOUNDATION**

<sup>20</sup> <https://www.karger.com/Article/FullText/504785>

<sup>21</sup> <https://arxiv.org/pdf/2004.01275.pdf>

and the emergence of the MedTech industry, are all contributing to the generation of many types of data that create opportunities for analysis, research innovation in healthcare.

We already covered the -omics, one of the bigger sources of new data. But many other types of data add value to the landscape - new biomarkers like volatile organic compounds (VOCs) in breath or electrolytes in sweat or urine; precise continuous measurement from wearables and fitness trackers, which are already being used to measure heart rates or blood oxygen and the amount and quality of sleep. All these biomarkers need to be integrated and harmonised with data coming from electronic medical records or biobanks to create new insights and bring innovation.

Who owns these data, who can access them and how to preserve the privacy of individuals without sacrificing the opportunity of generating innovation are key reflections that are needed to improve the innovation pipeline.

**The VOGAS Project** - Breath analysis is becoming an important field of research, because some volatile organic compounds (VOCs) present in human breath are potential biomarkers for several diseases. The analysis of breath can therefore be used to diagnose or monitor therapy progress, which is convenient, non-invasive and pain-free for the patient. Early-stage diagnosis of gastric cancer is associated with a high probability of cure. However, the lack of

reliable non-invasive screening tools is hindering progress, especially in Eastern Europe and Latin America. The EU-funded VOGAS project is developing a non-invasive gastric cancer screening tool to detect characteristic patterns of volatile organic compounds (VOCs). The VOCs' origin and composition in gastric cancer patients will be analysed, and the identified VOCs will be compared to the compounds in human breath, employing gas chromatography, mass spectrometry and a gold nanoparticle micro-array reaction pattern. A new type of breath analyser will be developed and validated in clinical studies in countries with a high disease burden.

Consider the following future scenario. Cheap breath analysers measure individuals' breath in the morning, then their glucose level as they brush their teeth. Those data are complemented by measurements of electrolyte levels in urine, sleep patterns and heart parameters through a cheap wearable device. All these continuous measurements create a solid pattern to predict diseases, suggest preventive actions and better understand patient-reported outcomes.

Critical conditions will be avoided in most cases and even when they do happen, healthcare operators will have details of what has led to the incident, enabling them to maximise their response as cheaply as possible in terms of cost and effort. All those data need to be correlated, which will require study and innovation.



# COMPLEXITY OF DATA GOVERNANCE

Different regulatory frameworks, multiple standardisation approaches and various layers of interoperability create a fragmented, layered landscape that is complex to manage. While it offers safeguards, it also increases costs and resistance to research and innovation.



## 5.1 A COMPLEX REGULATORY FRAMEWORK

The existing regulatory framework is very stringent. The processing of health data is subject to the EU's General Data Protection Regulation (GDPR). Appropriate legal bases for their use are covered by the Regulation, and there is a general ban on transfer and disclosure. Secondary use (if compatible) is very limited, particularly for research and statistical purposes, with respect to which a data protection impact assessment (DPIA) is necessary in any case. The Digital Governance Act will define a common approach to data sharing within the EU. The AI Regulation is meant to make the internal market work better by laying down a uniform legal framework in particular for the development of AI, its commercialisation and its use in conformity with EU values.

Lack of clarity on how data will be used creates perceptions that are difficult to overcome. For example, data for research, application of GDPR, approaches such as pseudonymisation could help but are not clearly defined.

Both regulations can help to create a safer landscape for data usage, data sharing and AI applications in healthcare. On the other hand, they may be perceived as an additional layer of complexity.

It is not only about data, it is also about liability across different AI technologies, which is crucial to securing the workforce's confidence in using AI technologies. Currently, there is uncertainty as to who will be held to account if AI products are used to make clinical decisions that harm patients. Responsibility could fall to the clinician who uses the technology, the deploying organisation, the industry innovator that developed the technology or those who validated and approved the technology for clinical use. Various legal frameworks may be applicable including negligence, product

liability and manufacturer responsibility.

In order to introduce a proportionate and effective set of binding rules for AI systems, the upcoming AI Act suggests a clearly defined risk-based approach. That approach should tailor the rules to the intensity and scope of the risks that AI systems can generate. It is therefore necessary to prohibit certain unacceptable artificial intelligence practices and to lay down requirements for high-risk AI systems and obligations for the relevant operators.

## 5.2 STANDARDS AND DATA INTEROPERABILITY

Data present complexities in their interoperability, and while standards are emerging (e.g., FHIR, OpenEHR) they need to be validated, harmonised and widely adopted. Today more than 40 organisations specialised in health and IT are developing standards around the world.

In Europe, the **EU EHR Exchange Format** developed the EU's eHealth Network to support the digital transformation of health and care in the region by seeking to unlock the flow of health data across borders, and support implementation of the Cross-Border Health Care Directive. Fast Healthcare Interoperability Resources (FHIR) is a standard for exchanging electronic health records (EHR). The standard was created by the US-based Health Level Seven International (HL7) health-care standards organisation.

Standards can be considered the "DNA" of interoperability. The health interoperability ecosystem comprises individuals, systems and processes that want to share, exchange and access all forms of health information. Each is involved in creating, exchanging and using health information and/or data.

It is essential to promote common approaches for data sharing in health research



by implementing data pseudonymisation and anonymisation techniques to manage sensitive patient data.

**NIP<sup>22</sup>** -The Nordic Interoperability Project is an initiative that aims to allow Nordic cross-border patient mobility by promoting interoperability across Nordic countries and supporting the development of future health (Nordics Health 2030) in the Nordics that will ensure robust, sustainable and resilient life conditions for future generations.

An efficient interoperability ecosystem provides an information infrastructure that uses technical standards, policies and protocols to enable seamless and secure capture, discovery, exchange and utilisation of health information. And this requires different types of network architectures (centralised, federated, hybrid), but also a strong governance structure (e.g. a council of health ministers as in the case of NIP)

### 5.3 COMPLEXITY IN HARMONISATION

It is complex to harmonise standards connected with the various levels of healthcare systems, devices and applications that can access, exchange, integrate and co-operatively use data in a co-ordinated manner. This happens across organisational, regional and national boundaries to provide timely and seamless portability of information and to optimise the health of individuals and populations globally.

Interoperability is layered in four dimensions:

- + **Foundational:** Establishes the inter-connectivity requirements needed for one system or application to securely communicate data to and receive data from another.
- + **Structural:** Defines the format, syntax and organisation of data exchange for interpretation, including at the data field level.

- + **Semantic:** Provides common underlying models and categorisation of the data. This includes the use of data elements with standardised definitions from publicly available value sets and coding vocabularies, providing shared understanding and meaning to the user.

- + **Organisational:** Includes governance, policy, social, legal and organisational measures that can help data to be communicated and used within and between organisations, entities and individuals, securely, seamlessly and in a timely manner. These components enable shared consent, trust and integrated end user processes and workflows.

### 5.4 EMERGING APPROACHES IN EUROPE

Several approaches to interoperability have emerged, which has actually increased complexity.

The European Commission's priorities for the 2019-2024 EU Digital Strategy included the creation of a European Health Data Space (EHDS) to foster the exchange of different kinds of health data (electronic health records, genomics, registries, etc.) in Europe. It aims to support data exchange not only to help deliver primary care, but also for the development of new treatments, medicines, medical devices and services. However, some existing regulatory gaps in member states' implementation of the GDPR for the secondary use of data must be addressed before the EHDS could be implemented.

The European Interoperability Framework (EIF) gives specific guidance on how to set up interoperable digital public services. It offers public administrations 47 concrete recommendations on how to improve the governance of interoperability activities, establish cross-organisational relationships, streamline processes supporting digital services, and ensure that both existing and new legislation do not compromise efforts.

<sup>22</sup> NIP - <https://nordicinteroperability.com>

To ensure secure access to genomic data, the European 1+ Million Genomes Initiative aims to create a technical infrastructure to improve disease prevention, allow for more personalised treatments and provide sufficient scale for new clinical research to have a meaningful impact.

Beyond these broader European initiatives, many countries are also leading specific regional and national efforts to expand exchange abilities.

It is essential that efforts to ensure AI is trustworthy are harmonised. The Assessment List for Trustworthy Artificial Intelligence (ALTAI) is a tool that helps business and organisations to self-assess the trustworthiness of AI systems under development in areas such as Human Agency and Oversight; Technical Robustness and Safety; Privacy and Data Governance; Transparency; Diversity, Non-discrimination and Fairness; Environmental and Societal well-being; and Accountability.



# EMERGING MOTIONS IN HEALTHCARE DATA

Emerging motions such as TEHDAS and GAIA X are growing fast. Other motions are contributing to the debate (e.g., Digital Health Society and the Health Data working group) or providing data sets (e.g., BigMedilytics). Startups and MedTech companies are pushing for innovation and adoption of new technologies



## 6.1 TEHDAS

Towards European Health Data Space<sup>23</sup> is a project that aims to overcome data barriers by developing clear principles for the secondary use of data among European countries. It develops options for governance models for the exchange and secondary use of health data between European countries, based on transparency, trust, citizen empowerment and a vision for common good. It aims to provide recommendations for European countries on planning national legislation to enable cross-border exchange and secondary use of health data.

The challenge when discussing governance mechanisms is to consider what we want to share, for what purpose and with whom. For medical research, for example, suitable governance will be dependent on study design.

## IS THERE A SUITABLE GOVERNANCE MODEL FOR DATA SHARING AND DATA USAGE?

A recent study conducted across Europe conclude that citizens' views on suitable governance depends on the actors involved, their purpose, and how identifiable the data is.

The study<sup>24</sup> concludes that data governance policy should reflect the perspectives of all stakeholders on an ongoing basis, to inform and change health data-sharing practices in accord with stakeholder views. The findings showed that

1. data should be used for ethical purposes even when there is commercial interest
2. data subjects and/or public institutions that provide and share data should also benefit from the sharing of data
3. third party use of data requires greater transparency and accountability than currently exists

4. there should be greater information provided to empower data subjects.

## 6.2 GAIA-X

Gaia-X is a project that aim is to develop common standard and architecture requirements for European data infrastructure in several sectors. While TEHDAS looks at governance as a centralised mechanism for sharing and using healthcare data, Gaia-X is a decentralised multisector federated architecture for data exchange (including for the healthcare sector).

Within GAIA-X, the foundations for a federated, open data infrastructure based on European values are being developed. GAIA-X connects centralised and decentralised infrastructures to turn them into a homogeneous, user-friendly system. The resulting federated form of data infrastructure strengthens the ability to access and share data securely and confidently.

The principles relate to distribution of data and computing capacity, in a federated environment where data monetisation could occur. There are already several use cases for health.

**A GAIA X use case – CARECOL** (see page 15 for more details) Data collaboratives can be used for predictive risk scoring and risk stratification, identification of behavioural risks and research on diagnosis development. CARECOL has developed an MVP healthcare solution that registers applications developed in the data collaborative as trusted data spaces for Gaia-X Federation Service so that they can be extended and used by the GAIA-X ecosystem.

## 6.3 OTHER INITIATIVES

Other initiatives that will contribute to finding a

<sup>23</sup> <https://tehdas.eu/>

<sup>24</sup> Governing health data across changing contexts: A focus group study of citizen's views in England, Iceland, and Sweden

common approach both for data sharing and innovation in the healthcare space include:

**BigMedilytics**- An initiative that aims to transform the healthcare sector through intensive usage of Big Data approaches.

**Digital Health Society and Health Data working group** published a report proposing a common basis for health data access across Europe<sup>25</sup>. They examine what society needs to have trust in the use of health data and propose a recipe for trustworthy digital health: standards, architecture and value. The group's calls for action include: raising the digital, literacy and skills of all stakeholders; accelerating interoperability across Europe and globally; adopting a risk stratification approach; and building a trustworthy framework for data access and use.

Regulatory frameworks are seen as an unalterable reality by public opinion and legislators are often swayed by that public opinion. It is time to work together to generate a positive discourse that enables a push for legislative change that transforms the approach to health data.

## 6.4 STARTUPS AND MEDTECH

The pace of innovation offered by technological growth and investments is creating a vibrant healthcare technology or MedTech sector, which is developing rapidly and needs to be integrated with both clinical practice and research.

**Babyl** aims to transform healthcare delivery, making healthcare universally available. Almost 70% of healthcare money goes into predictable, preventable diseases. Identifying a problem early could mean a \$10 solution rather than a \$4,000 one if it is seen too late. Accessibility and affordability are important concerns for healthcare services. Using a phone app, individuals can access their clinical records, consult with clinical experts and doctors, monitor and diagnose their conditions, book appointments and have their prescriptions delivered. Babyl created a highly personalised health service combining computing power and medical expertise. The service is integrated into the Rwanda National Health Insurance Scheme and is the largest provider of digital health in the country.

<sup>25</sup> <https://echalliance.com/proposing-a-common-basis-for-health-data-access-across-europe/>



# TRANS- FORMATION AND NEEDS

Sharing and using healthcare data could save lives and lead to improved sustainability and lower costs but it requires more clarity.



### 7.1 SHARING DATA CAN SAVE LIVES

Data-sharing in healthcare is a common good that could save lives and lead the system to an improve in sustainability, reducing costs.

More scientific data has been generated in the past five years than in the entire history of mankind<sup>26</sup> previously and the healthcare system needs to understand and embrace this revolution to create a real impact.

Technology improvements allow us to process huge amount of data in a much shorter timeframe than before. What needed decades to be analysed can now be processed in days and at a very affordable cost. Algorithms can evaluate and extract information from many healthcare processes to generate a positive impact.

But this must be accompanied by a new ethical approach – the advantages that are offered by massive data processing should lead to a vision more centred on common good than on individual interest.

### 7.2 LESSONS LEARNT FROM COVID-19

Covid-19 taught the world how important it can be to share and use data effectively. The virus had a global impact whose consequences have still not yet been fully mapped. But because of the need to cross-reference as much information as possible in the shortest possible time worldwide, the way data was collected and shared changed drastically, particularly the health data of individuals affected by the virus. The pandemic demonstrated, emphatically, how close the link between health (including public health), privacy and digital can be.

When the virus became a pandemic, the healthcare sector implemented exceptional measures to accelerate the research process through data sharing. This required extra safeguards to prevent data breaches.

A disruptive example of this can be found in Italy's **art. 9 of leg. Decree 139 del 2021** "DL Capienze": the rule expands the uses of data processing classified as necessary for the exercise of public powers or in the public interest. Public administrations may independently define the legal basis and uses of personal data processing if they relate to the exercise of the public powers vested in them.

### 7.3 COST OF DATA ECOSYSTEMS

Data ecosystems are an emerging concept. The recent Goldacre Review <sup>27</sup>, noted that currently, data management systems and projects are fragmented and siloed, increasing costs, fostering monopolies over data, and relying on inadequate security and slow, risk-averse governance systems. It concludes that "for less than the cost of digitising one hospital, the system can have the secure data platforms and workforce needed to realise the full value of NHS data, driving research, health service improvement, and innovation"

A coherent, connected system could reduce fragmentation in many areas, from data accessibility to governance processes. Investments could be focused on these platforms, and these could become centres of gravity to attract more data sources, both raw and refined.

Increased investments and governance resources could foster modern approaches, such as using and integrating non-traditional data sources like real-world data (RWD) or real-world evidence (RWE). Data ecosystems will be easier to disseminate and could produce better results.

### 7.4 PRIVACY IS NOT A TRADE-OFF FOR MORE DATA

More data means less privacy but in healthcare this trade-off is not possible.

<sup>26</sup> <https://datasaveslives.eu/toolkit>

<sup>27</sup> <https://www.goldacrereview.org/>

Preserving privacy is a fundamental principle in healthcare. However, the fragmentation of local regulation, and the lack of detail in general regulations (i.e., GDPR) on big data usage in healthcare, creates the need for clarity.

The role of data protection boards is to validate or block data sharing processes, frequently limiting the effectiveness and the scopes of projects. A cultural transformation is needed to promote and standardise solutions that could reduce complexity.

The **Spanish Agency of Data Protection** (AEPD<sup>28</sup>) created specific “Action Areas” where they promote and disseminate knowledge about risk management. One of these was on “Innovation and technology”<sup>29</sup> where it offers clarifications, tools, guidelines and surveys on a range of emerging topics. It promotes clarity and sets out guidelines on advanced techniques as pseudonymisation or Differential Privacy<sup>30</sup>, and creates the foundation for a more active role in contributing to the necessary cultural transformation.

---

<sup>28</sup> <https://www.aepd.es/es>

<sup>29</sup> <https://www.aepd.es/en/areas/innovation-and-technology>

<sup>30</sup> <https://www.aepd.es/en/prensa-y-comunicacion/blog/anonymisation-and-pseudonymisation-ii-differential-privacy>





# CONCLUSIONS AND RECOMMEN- DATIONS

This chapter includes key recommendations such as: advancing the legal framework on data-sharing and big data usage; supporting the creation of central data platforms; facilitating interoperability to help data flow more effectively; enabling cultural transformation in the sector; promoting national and regional data strategies.



1

ADVANCING THE LEGAL FRAMEWORK ON DATA-SHARING AND BIG DATA USAGE.

2

SUPPORTING THE CREATION OF CENTRAL DATA PLATFORMS.

3

FACILITATING INTEROPERABILITY TO SOLVE DATA FLOW CHALLENGES.

4

ENABLING CULTURAL TRANSFORMATION IN THE SECTOR.

5

PROMOTING NATIONAL AND REGIONAL DATA STRATEGIES.

## 8.1 CONCLUSIONS

Data and its usage are, in many ways, the key to innovation in the healthcare sector. Artificial intelligence has significant potential to add value, and data usage and sharing will be fundamental to making the whole system more sustainable and effective. There are many inspirational stories and success cases that highlight the potential of modern technologies that are not yet widely adopted. There is a significant movement towards using data more, such as European Health Data Spaces and Gaia-X.

Despite the opportunities, many challenges remain. The regulatory framework is complex, unclear, and not keeping pace with new technology. Fragmentation at local level also creates uncertainties when cross-border data sharing is required to create big data projects. Upcoming regulations can mitigate these challenges or introduce additional complexity for researchers and industry in using data. Interoperability is still limited with a lack of proper standardisation and harmonisation. All of these issues slow down the cultural transformation that is needed to increase the use of data in healthcare.



The pace of technology development allows us to process huge amount of data in minutes, extracting exceptional knowledge and insights, where only a few years ago it would have required decades.

PROF. FEDERICO MONTALVO JASKAALAINEN

To provide guidance to the council, we make some key recommendations:

## 8.2 KEY RECOMMENDATIONS

### ADVANCING THE LEGAL FRAMEWORK ON DATA-SHARING AND BIG DATA USAGE.

Data-sharing is essential to build significant big data platforms that will add value and unlock modern applied analytics. The current fragmentation and lack of clarity creates hurdles that make data not fit for purpose in the world of big data, which limits innovation and research.

GDPR has not adequately addressed the necessary conditions for research using health data, especially as technological development accelerates. *“National legislations are not homogeneous; each data protection authority defines its own criteria, and it is practically impossible to share pseudonymised data or personal data. Especially when it comes to the analysis of large volumes of data.” – Prof. Ricard Martinez - University of Valencia.*

Regional differences must be reduced to allow wider data-sharing and simplify cross-country collaboration that can develop data-based research that will create global benefits.

### SUPPORTING THE CREATION OF CENTRAL DATA PLATFORMS.

Support the creation of central data platforms that will bring together research, clinical institutions, technology companies and industry to collaborate in sharing and using data to improve patients' lives.

Central data platforms will improve health data and generate high-quality datasets. Additionally, as the NHS Goldacre report says, creating and supporting such platforms costs a fraction of building a new hospital, with much more impact.

## HEALTH DATA COLLECTED BY INSTITUTIONS TEND TO REMAIN SILOED WITHIN THOSE INSTITUTIONS LIMITING ACCESS BY OTHER SERVICES, INDIVIDUALS OR RESEARCHERS.

The Health Outcome Observatory (H2O) brings together the public and private sectors to create a standardised data governance and infrastructure system to incorporate patients' experiences and preferences across Europe. The platform will enable patients to measure their outcomes. The observatory aims to foster innovation in healthcare in Europe and beyond.

### FACILITATING INTEROPERABILITY TO SOLVE DATA FLOW CHALLENGES.

Common data standards and open interfaces are necessary to achieve interoperable systems and true standardisation. Build interoperable showcases to enable solutions for the future as the Nordic Data Lake promoted the Nordic Interoperability Project<sup>31</sup> for secondary use of patient data.

The European EHR Exchange Format aims to create the ability to exchange health records across European borders for citizens seeking treatment while abroad in the EU, be that specialist advice, because they fall ill while travelling, or for citizens who have moved to another Member State and would like joined up medical records. Cross-border exchange of health records must be promoted more consistently.

**The Nordic Interoperability Project (N!P)** aims to allow Nordic cross-border patient mobility by promoting interoperability across the Nordic countries and supporting the development of future health (Nordics Health 2030) in the region, ensuring robust,

<sup>31</sup> <https://nordicinteroperability.com/>

sustainable and resilient life conditions for future generations.

### ENABLING CULTURAL TRANSFORMATION IN THE SECTOR.

Enable cultural transformation in the sector. Helping researchers and healthcare providers to understand current regulations and concepts will help to reduce complexity and create clarity and awareness. Regional and local data protection authorities should support this transformation. Aspects that are unclear, such as pseudonymisation or secondary use of data for research need specific clarification and dissemination to help reduce fears.

A successful example of this comes from the Spanish Data Protection Authority and its work on creating awareness on anonymisation and pseudonymisation<sup>32</sup>.

On October 2021, the **AEPD (Spanish Data Protection Authority)** proposed a clarification on anonymisation and pseudonymisation, in its work on innovation and technology, where it defines clearly its goal to “promote and disseminate knowledge about risk management for the rights and freedoms of natural persons, the AEPD (Spanish Data Protection Authority) develops resources and tools to promote compliance with the RGPD (GDPR), focusing attention on supporting SMEs and entrepreneurs”.

### PROMOTING NATIONAL AND REGIONAL DATA STRATEGIES.

All these recommendations could be captured and structured in specific national

and regional strategies or action plans on data sharing and usage in healthcare. Promoting a national strategy would guide action, allocation of resources and implementation of reforms and transformational initiatives.

In June 2021, the government of Japan release the draft of the National Data Strategy, which shared key principles regarding data as a source of knowledge, value, and growth for sustainability.

It recognised the paradigm shift in the use of technology caused in response to COVID-19 and promoted a digital society that must be global by design. The strategy promotes the Data Free Flow with Trust (DFFT) initiative, a proposed guiding principle for international co-operation on data flows.

On June 15th 2022, the **UK Ministry of Health** released the strategy “**Data Saves Lives**”<sup>33</sup>. In the Ministerial foreword the Secretary of State for Health and Social Care claimed: “We cannot deliver the change that we need to see – and our 10-year plans for cancer, dementia and mental health – unless we embrace the digital revolution and the opportunities that data-driven technologies provide.”

The strategy aims to improve the usage of data in several areas of the healthcare system, from empowering health and care professionals to researchers to better policymaking around health issues.

<sup>32</sup> <https://www.aepd.es/en/prensa-y-comunicacion/blog/anonymisation-and-pseudonymisation>

<sup>33</sup> <https://www.gov.uk/government/publications/data-saves-lives-reshaping-health-and-social-care-with-data/data-saves-lives-reshaping-health-and-social-care-with-data>



# HEALTHCARE DATA INNOVATION COUNCIL

Council members



---

+ BARRO SENEN	+ University of Santiago de Compostela, Spain
+ BEATE BENTZEN HEIDI	+ University of Oslo, Norway
+ BENANTI PAOLO	+ Pontificia Università Gregoriana, Italy
+ BONFIGLIOLI ELENA	+ Microsoft, Belgium
+ COSTAGLIOLI ANDREA	+ INPECO, Switzerland
+ CUCCHIARA RITA	+ UNIMORE, Italy
+ D'SILVA FRANCIS	+ CGI Norge, Norway
+ DE MONTALVO JAASKELAINEN FEDERICO	+ Spanish Bioethics Committee, Spain
+ DUPONT VINCENT	+ HH Ventures, Belgium
+ FICARRA ELISA	+ UNIMORE, Italy
+ ISLA JULIAN	+ Foundation 29, Spain
+ LAITINEN TOMI	+ BC Platforms, Switzerland
+ LANSDORP-VOGELAAR IRIS	+ Erasmus MC, Netherlands
+ LAPPUKE ROLANDS	+ Advisor to the President, Latvia
+ LEJA MARCIS	+ Riga East University Hospital, Latvia
+ MATYSIAK-BUDNIK TAMARA	+ CHU de Nantes, France
+ PARINI PAOLO	+ Karolinska University Hospital, Sweden
+ PATON JOE	+ Champalimaud Foundation, France
+ PESCINO ANDREA	+ Stratejai, Italy
+ PULIGHEDDU ANDREZ	+ SLP, Italy
+ RIBEIRO MARIO	+ IPO Porto, Portugal
+ SEDOLA STEFANO	+ Stratejai, Belgium
+ SERRANO GABRIEL LOPEZ	+ Microsoft, Spain
+ SETIAN LUCY	+ Novartis Foundation, Switzerland
+ STYLIADOU MENI	+ Takeda, Switzerland
+ VAN HOOLANDV TINEKE	+ Epic 10, Belgium

Council members are selected in their individual capacity as people who can contribute a variety of experience and specialised knowledge to the work of the Council.

