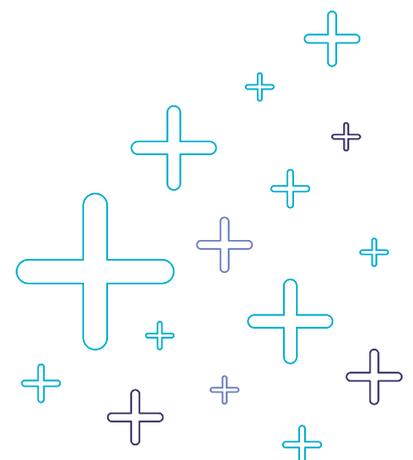




# EXECUTIVE SUMMARY

## UNLOCKING THE POWER OF DATA IN HEALTHCARE: A EUROPEAN VISION

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 futureproofed 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.



## DIGITAL HEALTH ACCELERATION

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.

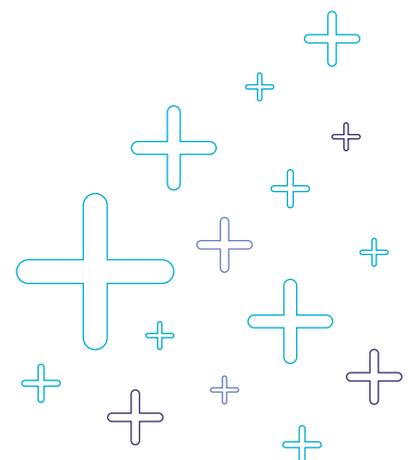
## DATA OPPORTUNITY

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.



## CHALLENGES AND COMPLEXITIES

Sharing and using data is challenging, with various layers of complexity.

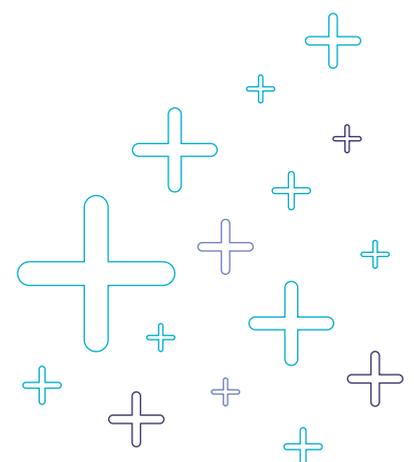
One layer is the regulatory framework – many researchers or small start-ups cannot share data easily without the required legal skills. Moreover, there is fragmentation between member states and even regions, and new upcoming regulations like the Data Governance Act, Digital Services Act or the AI Act 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.

## 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.



## 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 committees<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 interests.**

## TRANSFORMATION AND NEEDS

Building consensus among stakeholders at various levels (technical, operational, legal) is hard and requires more of a cultural mindshift 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**.



<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/>

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.

The time to accelerate on data usage is now.

## KEY RECOMMENDATIONS

### + Progress 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.

### + Support the creation of central data platforms that 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**



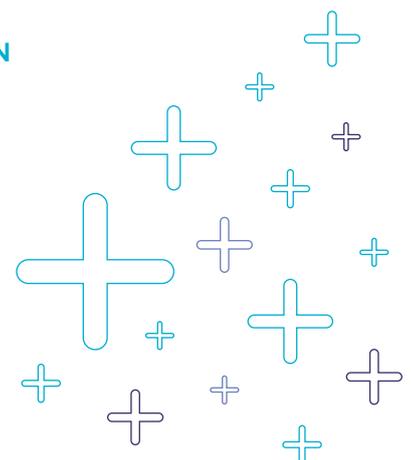
- + Facilitate interoperability to solve data flow challenges. Common data standards and open interfaces are necessary to achieve interoperable systems and true standardization.

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.**

- + Enable 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 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”.**



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

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

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.**

