A DIGITAL HEALTH DECADE: FROM AMBITION TO ACTION

4 pillars for a trusted and collaborative health data space
The right to health for all people means that everyone should have access to the health services they need.

There cannot be a Digital Decade for Europe without health innovation. In the next ten years, we must unlock health data to empower patients, beat cancer, find better treatments, support healthcare professionals, and establish more resilient healthcare systems.
Yet, we don’t have the luxury of time. The clock is ticking for an increasing number of patients. Lifespan in Europe is increasing, but so is the number of diseases. Over 4 million people in our continent are diagnosed with cancer every year and this number is expected to reach 5.2 million by 2040.¹

Tackling these issues will require a secure, trustworthy health data space, facilitating the collaboration between patients and their associations, health professionals, providers, and digital and health companies.

In our view, to reinforce trust, four elements are crucial: demonstrating how health data is used for better outcomes for all, how data infrastructure ensures privacy and security, building on existing successes, and rolling out patient-centric e-health services.

When we get that right, a digital health decade is within our reach. But we must make a concerted push to get it right from the start, sparing no effort in reaffirming Europe as a hub for life-saving innovations.

The good news is, we already have the best and brightest health innovators in Europe. For example, Corti AI, who won DIGITALEUROPE’s Future Unicorn Award in 2020, was recognised by President of the European Commission Ursula von der Leyen for their ground-breaking AI technology using voice recognition to predict heart attacks, developed with patients, healthcare practitioners, providers, and industry.

And, of course, technology and healthcare companies – both experts on data – have upped their game by collaborating, which enabled fast and safe vaccine development. When we ensure security, trust and awareness in these solutions, everyone benefits – patients, innovators, and the wider society. For instance, we are now dramatically increasing our understanding and detection of hereditary diseases, thanks to secure, trusted and larger-than-ever genetic datasets.²

But we still lack scale and streamlined processes for cross-border use of health data in Europe. This is stalling development of safer and more effective treatments, delivery of more personalised care using real-time data, advancement of trustworthy artificial intelligence in health, and response to public health crises.

This paper is the result of DIGITALEUROPE’s work with our Executive Council for Health and across the wide range of industries we represent to contribute to Europe’s goal to share and use health data for the benefit of all our citizens.

We look forward to helping shape a digital health decade for Europe with policymakers, patients, healthcare professionals and all those affected.

Together, we can achieve a truly transformative digital health ecosystem, where collaboration is the fuel for ground-breaking research, trusted health data spaces, and a healthier future for all.

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² A 2013-2021 pilot study in the UK, using the Genomics England platform, involved 4660 participants from 2183 families, among whom 161 disorders covering a broad spectrum of rare diseases were present. The disorders found had not been diagnosed with standard tests.
Digital technologies are increasingly crucial for achieving public health goals. This is one of the key lessons from the COVID-19 pandemic we should not forget. Like any other tool, digital technologies are only effective if they are accessible and useful for as many people as possible.
The European initiatives for the Health Union and the upcoming European Health Data Space (EHDS) are key milestones in Europe’s digital health roadmap, as they will shape the ways we collect, share and use health data in each European country and across borders.

We cannot shape a digital health decade without a safe, trusted, and collaborative digital health ecosystem. Driven by our Executive Council for Health, DIGITALEUROPE has brought together the digital and health industries to contribute to Europe’s goal. With this paper, we want to set out an inclusive discussion on trust, equity, and ethical implications of health data sharing and use, with patients at the centre.

To achieve the goal of a trusted health data space, we kick off by proposing success indicators. We encourage the European Union to agree on targets for digital health, similar to the approach in the proposed Digital Decade strategy. In these 2030 targets, the European Commission has set an EU-wide goal of 100% patients having access to interoperable Electronic Health Records (EHRs).

This is a step in the right direction. In 2021, only 64% of Member States have national rules for sharing EHR data cross-border, only 68% have earmarked budget for the digital health strategy, and only 43% use cloud services as part of their system infrastructure.

But there are further issues hindering a more digitalised Health Union. In Part 1, we identify four pillars needed to successfully encourage trust in, and uptake of, health data sharing and use in Europe:

- **Demonstrating benefits for all health communities** - including patients and healthcare professionals – and innovators, policymakers and healthcare systems;
- **Secure and interoperable infrastructure** allowing for the use of a broad array of health data types;
- **Leveraging existing health data sharing successes**, ensuring that health data can be accessed, shared and used for research and developing new approaches to prevention, diagnostics and treatment;
- **Digital health literacy** and awareness among patients and practitioners and e-health services designed with patients at their centre, in Member States and across the EU.

In Part 2, we present 15 case studies from our members to illustrate how concrete health technologies, projects from private companies, and partnerships among sectors, academia and patient associations, are building patient-centric e-health services. These are examples of projects that we should scale up in order to achieve a successful, harmonised, and inclusive EHDS.

Innovations drawing on both primary and secondary use of health data are essential to create long-lasting benefits for health communities

We speak of **primary use** of health data for healthcare delivery. This is needed, say, for patients to receive medical attention in another country or for remote care.

The **secondary use** of data (also re-use or further processing) is critical for researchers and to develop new approaches to prevention, diagnostics and treatment.

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1. The Lancet and Financial Times (2021) *Governing health futures 2030: growing up in a digital world*
TABLE OF CONTENTS
Foreword

Executive Summary

Part 1: 4 pillars for trust in the health data ecosystem

Measuring progress of the health data space project

How we will achieve trust and uptake

Pillar 1: Demonstrating benefits for health communities, innovators and society

Patients

Healthcare professionals

Digital health innovators

Policymakers and healthcare systems

Pillar 2: Data protection and security by design

Privacy by design

Security by design

Pillar 3: Leveraging existing health data sharing successes

Promote frameworks and profiles for research and healthcare delivery

Include existing industry-driven collaborations

Pillar 4: Rolling-out patient-centric services throughout Europe

Harmonised e-Health services across the EU

Boosting awareness of the different types of health data and their use

Investing in the transformation of healthcare organisations

DIGITALEUROPE’s Executive Council for Health

Our recommendations for key health data policies

Part 2: Digital health decade in action: case studies

Future digital health unicorns

Solutions in clinic

Remote solutions

Leveraging digital tools in health insurance

Collaborations between tech, health and academia

Building patient centric eHealths services
Increasing access to, and sharing of, health data must be built on trust to encourage all patients, healthcare workers, and other healthcare communities to participate and benefit from it. Trusted e-health systems will improve prevention, enhance patients’ quality of life, and increase access to diagnosis and treatments.

The European Health Data Space (EHDS) proposal has the potential to create a stronger trust framework in Europe. If we get this right, we can truly make a difference.
Measuring progress of the health data space

In our 2019 manifesto for a stronger digital Europe, and later in our Digital investment plan for Europe’s recovery, we set out a list of success indicators to measure Europe’s digital progress. This same approach has been taken up by the European Commission in its Digital Decade strategy, and should be mirrored for digital healthcare and the EHDS.

We present dual success indicators for all European Member States to achieve by 2030:

100%

of citizens should have secure access to their Electronic Health Records

and they should be able to manage their own data including across borders. In 2021, these services are not a reality for most and the level of structured and standardised health data is low. We need concrete action to enable mutual recognition of:

- Easy to use eID services.
  This service for identification and authentication is needed for enhanced cross-border access to health data and services for safer and continued care.

A simple common consent form.

In cases where aggregation and anonymisation of patient data is not feasible, and consent is the appropriate legal basis. The process is too complex now.

Researchers and innovators

should have a single access point for secondary use of data. This will require:

All EU countries to have a central health data authority. These national entities should provide controlled data services, like healthcare information sharing and analyses. Where things stand, such permitting is fragmented, and centralised governance bodies only exist in 13 Member States.

An EU-level entity for secondary use of health data. As a core tenet, the EU-level health data entity should promote the frictionless sharing of health data across Europe in a safe, controlled and privacy-preserving environment.

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6 Empirica and Open evidence on behalf of the European Commission (2021) MonitorEHR report.
7 Recital 10 of the eIDAS regulation (No 910/2014) refers to the requirement for the eHealth Network based on the cross-border healthcare directive to produce guidelines on cross-border access to electronic health data and services, including by supporting ‘common identification and authentication measures to facilitate transferability of data in cross-border healthcare’.
8 This is reported on page 98 of the European Commission’s Assessment of the EU Member States’ rules on health data in the light of GDPR. Member States use divergent governance models.
How we will achieve trust and uptake

The policy-framework and a European strategy for data are only part of the equation. We need to build on strong fundamentals to make sure we maintain the level of support needed throughout society to unlock the potential of health data.

Together with DIGITALEUROPE’s Executive Council for Health, we identified four pillars needed to successfully encourage trust in, and uptake of, health data sharing and use:

1. **Demonstrating benefits for all health communities, innovators and society:**
   We elaborate on patients, healthcare professionals, digital health innovators, policymakers and healthcare systems.

2. **Leveraging existing health data sharing successes:**
   As part of the EHDS, health data sharing infrastructure should include patients, healthcare providers, payers, researchers, and industry. Involving all healthcare communities and setting clear standards from the beginning will ensure the necessary quality, variety, and interoperability of health data. This way, we can leverage existing collaborations for data sharing and analysis.

3. **Data protection and security by design:**
   Much can be achieved by connecting a federated network of controlled data sources to enable research. But this will still require harmonisation of data protection rules, and approaches for de-identification methods through guidelines from the European Data Protection Board. Companies and governments should also collaborate to define or update their Member States’ healthcare data platforms strategies and to select common standards, protocols, and best practices.

4. **Patient-centric services throughout Europe:**
   There are already successful examples of high-quality, transparent and trusted services that are benefitting patients without placing additional burden on them. EU countries should build on what works: for instance, establishing an ‘opt-out’ model, allowing patients to decline secondary use of their health data (rather than actively having to opt in for every research project).

To bring all of this to life, we have gathered 15 projects that our members have been successfully implementing all over Europe, that you can find in Part 2.

The digital and healthcare industries can support this goal with insights drawn on decades’ worth of pioneering work in digital health, including the crucial aspect of managing health data in a secure and privacy-compliant way.

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10 Large-scale health data projects are far from reaching their full potential due to fragmented European health data rules and systems. There is still too much uncertainty around how health research can be conducted in accordance with data protection rules.

11 In Denmark, this widely supported opt-out system has been in place since 1977. The Danish system provides an example for enhanced data sharing for continuity of care and epidemiological research. Still, for some use cases, for instance at the international level, a trusted third party may prove appropriate and yet for others data collectives provide a solution.
Demonstrating benefits for health communities, innovators and society

The health data landscape in Europe is currently so fragmented that it’s not immediately clear in what ways the different healthcare communities – patients, workers, researchers – and innovators can use data to realise better health outcomes.

Healthcare providers and industry should collaborate in reaching out to each of these groups, tell the story, listen to feedback and, in doing so, increase mutual trust. This positive and collaborative cycle will ensure that, going forward, e-health infrastructure in the EU and in each Member State can truly meet everyone’s needs.

How will each of these communities benefit from a trusted health data ecosystem?
Patients

- **Reducing health inequalities.**

To identify and address health inequalities, we need insights. These can be obtained by combining data on clinical care indicators, health behaviour and health outcome measures from various sources, and then mapping this information against factors such as social health determinants.\(^2\)

This knowledge helps identify health disparities among communities that have traditionally been underserved and address them with more accurate interventions.

- **Finding solutions for patients with rare diseases.**

Digital health has the power to transform how healthcare is provided, not least for patients with rare diseases who are geographically spread out. Scale is key for a better understanding of their disease.\(^3\)

- **Improving remote healthcare everywhere in Europe.**

Europe’s 2030 goal for 100% access to Electronic Health Records\(^4\) will empower patients with new services to share their data across borders with healthcare professionals and for research.

Connected to a harmonised eID access tool, data sharing services will enable patients to be treated in their own homes or outside of hospitals – wherever it makes sense for them and their care teams.

For example, remote monitoring technologies also bring healthcare into the home and provide access for patients in rural and remote areas, helping to address the care disparity.

- **Using data-driven technologies to live longer and healthier lives.**

Data analytics and artificial intelligence (AI) solutions in healthcare can not only help detect a disease earlier but also support patients in their treatment, leading to longer and healthier lives.\(^5\)

This is especially important if we consider that, while globally the mortality rate has reduced, the time we spend living with illness or disability has increased. Conditions such as cardiovascular, metabolic, and respiratory diseases are more widespread, as are other severe illnesses such as cancer.

This means that there is growing need for innovative tools to facilitate prevention, earlier diagnosis, treatment decisions and therapy planning.\(^6\) However, data access is fragmented, and its utility is greatly reduced by lack of interoperability. Specific data needs should be defined to support the training, testing and validation of AI, for example to avoid unintended bias.

Data-driven technologies must ultimately meet patients’ needs. Therefore, innovators need large-scale, systematic and regular feedback from patients, including data generated by devices.

- **Helping patients make informed decisions about their own health.**

The Internet of Things (IoT) is connecting both patients and healthcare professionals. Patients are increasingly using wireless wearable devices such as fitness bands, monitoring cuffs and other connected medical devices for blood pressure and heart rate monitoring. Healthcare professionals are taking advantage of the IoT to monitor, treat and support their patients remotely.

Connectivity also helps care providers and their patients address health issues faster and more efficiently. For instance, data from trusted sources such as environmental agencies can be linked with patient data from a device. This can alert patients of situations which may negatively affect their well-being, such as high pollen count or weather conditions. In this way, patients are enabled to make informed decisions about managing their own health.

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\(^2\) The WHO provides a list of examples of social health determinants, including income and social protection, education, unemployment and job insecurity etc.
\(^3\) Courbier, C. Dimand, R. & Bros-Facer Virginie (2019) *Share and protect our health data: an evidence based approach to rare disease patients’ perspectives on data sharing and data protection.*
\(^5\) Nature (2021) *Artificial intelligence in longevity medicine*.
\(^6\) By 2030, UN Sustainable Development Goal #3.4 aims to reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promoting mental health and well-being.
Healthcare professionals

► More time for patient care.

Healthcare workers have been under tremendous strain, and this has become all the more clear during the pandemic.

Digital technologies can help healthcare professionals manage their workload, so that they can focus on caring for patients and improve their own quality of life, raising morale while improving quality of care. Digital platforms can also give healthcare professionals far greater and quicker insight into treatment patterns and trends.

While digital does not equal efficiency by default, there are many examples of new technologies meeting the needs of healthcare professionals: for instance, machine learning is already being used to reduce tedious data entry procedures.

► Supporting healthcare professionals in their work.

Digital health also supports healthcare professionals via (remote) access to screening, therapy, and device data. We see examples in artificial intelligence supporting patient health audits by nurses and the clinical introduction of digital pathology. The latter can help pathologists to streamline diagnostic processes, connect a team, even remotely, to enhance competencies and maximise use of resources, unify patient data for informed decision-making, and gain new insights by turning data into knowledge.

► Bridging the gap between data and health sciences.

Up to 70 per cent of health professionals report not using digital solutions due to gaps in knowledge and data analytics skills.

While digital health literacy is also crucial for patients, the importance of standards, medical terminologies and the sharing of technical knowledge in the healthcare sector urgently calls for highly trained data scientists (for example, in genome sequencing), data managers, developers and software engineers who can also understand and navigate this intricate landscape.

► Providing life-long learning in a rapidly developing environment.

Whether carried out at simulation centres or in practice, the education and training of healthcare professionals is an important activity taking place not only at large academic centres but also distributed across primary (day-to-day) and secondary (specialised) care facilities. The fast pace of innovations and the resulting recertification by a growing number of countries increases the need for educational activities, coming at a cost: time, space, funding, human resources and risk for patients.

Final examination is no longer the gatekeeper for healthcare professions: it is just the beginning of a life-long learning process which will need to be documented and evaluated. For that purpose, through data availability, healthcare education can be competitive in term of safety, efficiency, productivity and innovation.

Digital health innovators

▶ Accelerating the development of cures and treatments.

For smaller and larger companies working to improve healthcare and well-being, data-driven processes, automation and machine learning are a game-changer in developing and advancing medicines, medical devices, treatments, and software services.\(^\text{20}\)

Without increased access to and use of health data, we would not have seen COVID-19 vaccines being developed in record time. A good example is clinical trials or non-interventional studies – so-called “registry-based studies” – performed by pharmaceutical companies. For their research, they can now use data on patient population collected in one or several patient registries to generate higher quality evidence.\(^\text{21}\)

▶ Reaffirming Europe as a health innovation hub.

The EHDS can be a catalyst for entrepreneurs, companies and research centres to make Europe an attractive place to test and scale-up digital health innovations. Avoiding complex and burdensome processes is essential, especially for small and medium-sized enterprises (SMEs): a single access point to the EHDS for companies is the best solution.

Europe has a long tradition of innovation in health. Helping hundreds of thousands of companies – small and large – to scale and grow will not only bring a better and more diverse offer of healthcare services and products for patients. It will also secure Europe’s competitiveness globally and re-affirm its leadership in openness, fairness and transparency by fostering data sharing between healthcare companies.

▶ Faster time to market for innovative digital health.

By streamlining and harmonising processes for accessing health data for further processing, the EHDS can accelerate the roll-out of digital health tools while preparing regulators for future technologies. Many digital health solutions available today are not reaching all patients with unmet medical needs due to a lack of regulatory awareness, capacity and data availability in certain areas to enable market access.

▶ Unlocking real-world data for better evidence.

Data flows can support the analysis of real-world data\(^\text{22}\) to complement evidence from randomised clinical trials, optimise clinical trials recruitment, generate evidence to support new drug indications, and support surveillance of drug safety and efficacy post launch.\(^\text{23}\)

Such data would also give patients and providers access to near-real-time, post-market information that can better inform their decisions.\(^\text{24}\) We already see progress in the regulatory field but need more ambition and inclusion of innovators.\(^\text{25}\)

\(^\text{21}\) EMA (2021) Guidelines for generating high-quality evidence from registry-based studies.
\(^\text{22}\) Data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.
\(^\text{23}\) An EHDEN project suggest that RWD can already replicate clinical trials after systematically reviewing 20 years of research and multi-year clinical trials.
\(^\text{24}\) The HMA/EMA Big Data Steering Group is supporting this with a workplan. The Data Analysis and Real World Interrogation Network (DARWIN EU) is planned to incorporate real-world data into the regulatory framework.
Policymakers and healthcare systems

► Building resilience and preparing for an aging population.

Health spending will increase at a faster pace than economic growth. As chronic diseases are associated with age, the older you grow, the more likely you are to develop at least one chronic condition such as hypertension, diabetes mellitus or rheumatoid arthritis. Chronic diseases are costly to treat, taking up 80% of the €700 billion healthcare budget across Europe.

AI applied in health can support programmes that lead to dramatic reductions in the cost of research and state expenditures. With increased access to and sharing of data, policymakers have more real-time and robust evidence to support policy decisions, which will help ensure that the right resources are directed to the right policy issues at the right time.

► Increasing utilisation in healthcare systems.

According to a McKinsey study, increased data sharing has the potential to save up to €120 billion in the EU’s health sector annually.\(^{29}\) Data-driven automation has the potential to reduce costly back-office inefficiencies and support clinicians on the front lines, contributing to optimal use of talent.\(^{30}\)

Digital care is more time-efficient and beneficial to clinic capacity and to reduce pressure on healthcare resources. Digital health can support both complex, at-risk patients receiving tailored care in a clinical setting, as well as serving other patients who may benefit more from high-quality remote care. Waiting times for appointments decline, clinic capacity for assessments increases.

Using digital health tools for disease management can also improve the quality of care while reducing costs through patient rehabilitation outside of hospitals. Greater focus on patient care outside of hospitals and on behavioural health means that we are moving away from centralised clinical models towards delivering care in alternative settings.\(^{31}\)

► Optimising use of resources and talent.

By 2030, Europe’s demand for healthcare workers is projected at 18.2 million, while today we only have 8.6 million physicians, nurses and midwives.\(^{32}\) We need to ensure their time is used where it adds most value. We need to ensure their time is used where it adds most value. AI-based technologies will be crucial to ensure that healthcare systems can keep up with demand.

One such area is imaging power. Radiology professionals are severely stretched due to dramatic growth in demand and increasing complexity of workflows.\(^{33}\) New AI-based solutions can provide the means to turn the ever-increasing amount of data collected into valuable insights, thus enabling radiology experts to provide more accurate and timely diagnosis for their patients.

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\(^{26}\) Eurostat (2020), Ageing Europe - statistics on population developments
\(^{27}\) Eurostat (2021), Health care expenditure by financing scheme
\(^{28}\) Statista (2021), Growth of the real gross domestic product in the European Union and the Euro area from 2016 to 2026
\(^{30}\) Harvard Business Review (2019). AI can save up to $150 billion in annual savings for U.S. health care by 2026. (study by Accenture)
\(^{31}\) Lumeon (2021). The future of digital transformation in healthcare
\(^{32}\) EIT Health & McKinsey (2020) Transforming healthcare with AI: The impact on the workforce and organizations
Data protection and security by design

Building a transparent and trustworthy network for health data and creating legal certainty are key steps for assuring patients and other healthcare communities that data remains protected, secure, and is handled in an ethical way.

Although multiple health data sharing initiatives exist across Europe, there is a lack of standardisation and scale.

All the technology needed to achieve this is there. Now, the next goal is adopting a common approach and compatible governance models with standardised analytical tools and methods. A well-defined data infrastructure, distributed across Europe, is fundamental to facilitate consistent and secure use and re-use of health data.

There are examples of progress, such as focused funding through the Digital Europe Programme and industry led initiatives (i.e. Gaia-X), that aim to create the foundation for a federated, open data infrastructure based on European values. Europe should tap into the intensifying collaboration between technology and healthcare industries for guidance.
Privacy by design

The General Data Protection Regulation (GDPR) provides a solid framework for data protection that needs to be further harmonised to enable health data sharing as intended. To this end, technology and healthcare companies can provide expertise on technical safeguards for data protection practices and support common agreements for use (and re-use) of health data. For the European Health Data Space (EHDS) to prudently unlock re-use of personal data the connected digital infrastructure must follow the GDPR’s “privacy-by-design” principle – that is, embedding data protection features from its very design.

The EHDS aims to create a data governance model, if supported by the Member States, to solve many privacy-related challenges by advancing federated networks (linking together distributed datasets). This enables a federated research model, allowing the processing of personal data to remain local. Only aggregated information leaves the hospital or institution. This is one of several efficient methods of reducing risks related to data protection.

In short, such a model facilitates connectivity and the use of advanced IT tools while respecting GDPR and intellectual property requirements. However, two major considerations must be taken into account:

- **Scale is key for machine learning in a federated space:** Federated learning models can gain insights through machine learning without moving patient data. Reduced ability to fully verify the correctness of the scientific results is linked to reduction in robustness, but we can resolve this by gaining access to significantly larger cohorts in real-world settings, which could result in even more robust algorithms with less bias on certain populations.

- **Cloud technology can deliver more with seamless integration:** While we support federated networks of data sources, we will achieve even greater levels of insight and benefit for EU citizens when data can be shared and accessed by researchers between Member States. Sharing a federated cloud – combining a community of clouds and services – would enable smaller EU countries to have access to data services that are not available locally. It can be used to securely transfer data seamlessly between data centres in different geographies.

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34 These accommodate analysis of real-world data standardised to common data models. Such models facilitate interoperability and connectivity while respecting GDPR requirements and commercial IP. A key example of federated data model projects is the Innovative Medicines Initiative (IMI) initiative EHDEN.


36 Robustness in terms of being able to fully verify the correctness of the scientific results, largely due to the limited possibilities to perform source data and quality verification, and quality.
During the pandemic, we have seen a dramatic increase in cyberattacks directed at hospitals and healthcare facilities, already overwhelmed with dealing with the virus.\(^{37}\)

Cyber risks, threats, and vulnerabilities are multifaceted. It will be difficult to encourage trust in health data sharing and use when large and small breaches take place regularly. They often start locally, say in a regional hospital.

Common standards and protocols are vital for better risk management and cyber resilience in an interconnected health data ecosystem. Establishing such frameworks requires adopting effective cryptography techniques such as encryption, building on stronger cooperation between governments and industry, and supporting initiatives improving cyber hygiene and resilience.\(^{38}\) There should be collaboration opportunities for security leaders within the same sector to focus on developing effective frameworks and codes.

Another crucial step is for all Member States to define or update their healthcare data platforms strategies, which could be measured through the adoption of data management standards.

This would help identify legacy systems – not fit anymore for the current cyber landscape – and opportunities to modernise them. It would also foster healthy competition and bring to the forefront the best possible cybersecurity systems available for data processing in the healthcare setting.

Industry leaders in IT security operate in both the EU and the US. We can achieve the most secure systems by intensifying efforts to solve EU–US challenges for collaboration on health data security.

The European approach to updating healthcare data platform security can take inspiration from success stories where companies and governments have been collaborating.\(^{39}\) These can be industry collaborations for a common streamlined security framework\(^ {40}\) and by learning from existing efforts to establish national secure health data platforms.

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\(^{37}\) ENISA (2020), *Cybersecurity in the healthcare sector during COVID-19 pandemic*

\(^{38}\) Read more in DIGITALEUROPE’s resources on cybersecurity.

\(^{39}\) Such as ZVEI, a member of DIGITALEUROPE, who collaborated with the German Federal Office for Information Security to produce *guidance to increase cybersecurity in hospitals*, among other things.

\(^{40}\) For example, such frameworks offer services that comply with the ISO/IEC 27000-series.
These are the key elements for maintaining a secure data management system:

- **Cloud-based enterprise services:** These systems answer to cross-sectional IT needs, such as between hospitals, healthcare providers and researchers. They provide secure environments for large-scale data operations aligned to widely used clinical data standards. Interconnected clouds, certified for personalised data, offer greater robustness than individual clusters. Already available cloud services can protect against near all different points of infrastructure vulnerability, including privilege escalation, misconfigurations, weak security posture, unpatched systems, unencrypted data, human error, vulnerable web applications, and malicious insider abuse.

- **Building cyber resilience through management and training:** Companies share best-practices in developing a proactive information security strategy to properly manage information assets and protect against deliberate as well as inadvertent threats, necessary to safeguard any business and its stakeholders. This involves robust systems and processes, but also regular training and internal guidance, and systematically identifying and tracking risks.

- **Identifying evolving cyber risks and developing methods:** The cyber risk landscape is dynamic and continually evolving. A security control framework that identifies risks to the EHDS and provides policies and standards as well as a framework to measure, monitor and report on adherence by all participants will foster the transparency and trust needed by Member States, patients and providers. The system should be risk-based and provide for control baselines appropriate to the sensitivity of private information. To this end, IT security providers develop repeatable and vetted technology patterns that implement and monitor cybersecurity principles and operational frameworks to ensure those capabilities are sustaining for all participants in the EHDS and the system.

- **Cyber assurance:** Assessment and reporting processes for the EHDS and participants will allow for measurement of security effectiveness among participants in the system and control inheritance by participants required to achieve shared levels of security.
Leveraging existing health data sharing successes

To promote trust across borders, we should build on existing frameworks and profiles for research and healthcare delivery, for example, for ensuring ethical and secure conduct.
Promote frameworks and profiles for research and healthcare delivery

In addition to ethical concerns, we need to keep in mind that health data, in order to be shared and used, needs to be of sufficiently high quality for its intended purpose. There are industry standards available that have been developed for those needs.

For instance, robust and ethically sound AI in a health context relies on access to fit-for-purpose quality, high-volume, accurate, sufficiently representative, and properly annotated datasets. These must meet the required standards to demonstrate that, for instance, medical devices or pharmaceutical products are safe and effective to fulfil their intended purpose.

Industry has taken proactive measures that can be expanded and built upon, including:

- **Industry good practice:** Public and private-led codes of conduct, international frameworks, compliance requirements, and guidelines for ethics and transparency in (clinical) data practices. An example can be found in the Global Alliance for Genomics & Health, producing standards and guidance for data security, ethical concerns and more.

- **Improving sound and proven statistical methods:** Scientifically and statistically sound methods to help reveal patterns of association or disease causation can be used with unprecedented accuracy, sophistication, scale and speed.

Industry has the capacity and know-how to combine datasets, using statistical methods, for new insights at the population, cohort, or personal level.

- **Fit-for-purpose standards for health data:** Companies with significant experience and expertise with privacy preserving, Findable, Accessible, Interoperable and Reusable (FAIR) and high-quality data provide insights needed to develop common standards, ethical, technical and quality requirements. In the box below you can find examples of data quality characteristics. Industry provides technological solutions to facilitate data processing and reduce delays from data collection to data (re-)use.

- **Widely adopted standards and models:** While we applaud the progress made with the EU Electronic Health Record Exchange Format (EEHRxF) and x-eHealth exchange format, we should put more focus on reducing data siloes through agreeing on a set of existing standards. Industry is pioneering the roll-out of interoperability standards to normalise cross-sectoral and cross-border data exchange using internationally supported standards. Examples are Fast Healthcare Interoperability Resources (FHIR) developed by Health Level Seven International (HL7), Integrating the Healthcare Enterprise (IHE), and the OMOP Common data Model.

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41 Such as the widely supported Declaration of Helsinki.
42 GA4GH workstreams can be found here.
44 For instance based on the industry supported ethics guidelines for trustworthy AI developed by the European Commission AI High-Level Group.
46 x-eHealth assembles a shared commitment of 47 health actors, the underlying idea of this project is to develop the basis for a workable, interoperable, secure and cross border Electronic Health Record Exchange Format.
47 Fast Healthcare Interoperability Resources.
48 Integrating the Healthcare Enterprise International.
49 We see an increase in the use of Fast Healthcare Interoperability Resources (HL7), Integrating the Healthcare Enterprise International (IHE) and the Observational Medical Outcomes Partnership Model (OMOP).
These are examples of data quality characteristics used by researchers today:

- **Accuracy**: data reflects an event as it actually happened.
- **Consistency**: data is consistent across datasets, and over time.
- **Completeness**: data required for a given purpose is present; for example, a health record should contain all pertinent documents with appropriate documentation.
- **Timeliness**: data is updated as an event occurs, such as when a treatment is performed, or results noted.
- **Accessibility**: data is available to authorised persons when and where needed.
- **Interpretability**: patients or users can properly understand the data.
- **Transparency**: data retention and expiration policies are defined and agreed upon.
- **Portability**: data has attributes that enable it to be installed, replaced or moved from one system to another preserving the existing quality in a specific context of use.

**SCALING-UP A DYNAMIC AND INCLUSIVE HEALTH DATA SPACE:**

Industry is a key partner to complete the health data ecosystem, providing state-of-the-art infrastructure, technologies and services, and clinical trial and research data.
Include existing industry-driven collaborations

Both international and European companies are deeply intertwined with the research and SME communities in Europe. Through their cooperation, these communities have the resources (funding, expertise, partnerships with public research and people), the capabilities and the global reach to maximise the societal and individual benefit of increased data access and use.

DIGITALEUROPE’s Executive Council for Health serves as a prime example of the global spread of the digital health ecosystem, covering continents and a network of hundreds of thousands of researchers devoted to finding cures and treatments, working in cutting-edge R&D departments.

The EHDS can provide talents in smaller and larger businesses with a European data resource that can help their businesses scale up and demonstrate the value of their innovations. These are areas where the EHDS can take advantage of these communities:

► Providing clinical trial data: The healthcare industry has a long history of being trusted stewards of data delivering clinical trial results on time (or early) to high quality standards. Many organisations share clinical trial data for researchers because it helps physicians, patients and healthcare providers to make informed treatment decisions. Examples of such initiatives are YODA, Project Data Sphere, TransCelerate, and many more. These projects make sure that when volunteers participate, their data doesn’t go to waste and can be re-used for future research.

► Collaborations between health, tech and academia: There is no need for the EHDS to start from scratch. Data sharing infrastructures are already being built across Europe, such as the raft of IMI BD4BO projects. Many of these projects already receive substantial European Commission investment and are already well down the road to achieving results for EU citizens and patients. More importantly, the EHDS can make use of the European and international multi-stakeholder communities which have been created and the efforts which have brought together patients, clinicians, researchers and healthcare professionals with data scientists. Building from such projects ensures proper use of Commission funds, avoiding unnecessary duplication and re-invention.

► A broad array of data sources: Health data from both public and private sources can be used, in compliance with data protection rules, in projects aimed at unlocking unique insights for patients, healthcare workers, policymakers, researchers and developers. For example, this could be (in some cases in real-time) data from a medical device or fitness band, patient generated reports, registries and repositories, electronic medical records, insurance claims data, genomic data or even environmental data. Take for instance genomic data; Genomics England has already engaged with industry partners to develop technological solutions for its platform, such as a purpose-built patient choice tool called e-consent.

► Global ecosystems for research: The EHDS creates the potential for Europe to exchange data with other centres of excellence for research internationally. Industry should be seen as a partner to promote cooperation on international data transfers and global data flows for advancing research to combat pandemics and diseases.

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50 In the US, a reported after a large-scale study shows that that industry is indispensable and handles data responsibly.
51 Yale University Open Data Access (YODA) Project.
52 Project Data Sphere aims to break down barriers to cancer clinical trial data sharing, including data provided by industry.
53 TransCelerate BioPharma covers 20+ biopharmaceutical organisations. There are over 1,000 people from TransCelerate Member Companies, spanning more than 30 countries, who contribute to the thoughtful execution of our Initiatives.
54 The Big Data for Better Outcomes (BD4BO) programme is generating knowledge, data and methodologies needed to support the transition towards more outcomes-focused, sustainable healthcare systems.
55 Genomics England aims to sequence 100,000 whole genomes from NHS patients with rare diseases, and their families, as well as patients with common cancers. A 2013-2021 pilot study in the UK, using the platform, involved 4660 participants from 2183 families, among whom 161 disorders covering a broad spectrum of rare diseases were present. The disorders found had not been diagnosed with standard tests.
56 Read our Ten priorities for the EU-US Trade and Technology Council.
Rolling-out patient-centric services throughout Europe

Innovation is only as impactful as the number of people using it. Promoting trust and uptake will trigger a positive cycle, because increased data use will lead to better outcomes. Patient-centric e-health services will empower patients to communicate more easily with their physicians and healthcare providers, and to share feedback with innovators and policymakers.
Harmonised e-Health services across the EU

When Member States develop their health strategies, they must be ambitious, but also in sync with EU frameworks. We need to promote, coordinate and support Europe-wide initiatives to accelerate the level of uptake and to realise interconnected European data spaces. Achieving scale relies on Member States and their respective healthcare ecosystems.

FEW AND FAR BETWEEN:

Action is needed to support Member States in rolling out interoperable Electronic Health Records

% of Member States with key rules and systems in place[^1]

<table>
<thead>
<tr>
<th>Service</th>
<th>% of Member States</th>
</tr>
</thead>
<tbody>
<tr>
<td>National rules allow citizens to choose to whom to provide access</td>
<td>57%</td>
</tr>
<tr>
<td>National rules for sharing of EHR data cross-border</td>
<td>64%</td>
</tr>
<tr>
<td>Earmarked budget for the digital health strategy</td>
<td>68%</td>
</tr>
<tr>
<td>Interoperability models (HL7FHIR)</td>
<td>43%</td>
</tr>
<tr>
<td>System infrastructure using cloud services</td>
<td>43%</td>
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</tbody>
</table>

Digital technologies provide solutions for governments that are investing in patient-centric healthcare systems. But in the interconnected digital age, we cannot build digital health infrastructure in 27 different national siloes. The proposed EHDS requires well-defined services that should be fast and reliable.

Broad support and uptake from patients and healthcare workers is vital to ensure they can truly benefit from health data sharing and use. To this end, we must empower everyone with higher level of digital health literacy, whether it’s by helping patients better understand the different types of health data and their use, or by supporting healthcare workers with trainings, digital health skills and shifting to new ways of working.

[^1]: Empirica and Open evidence on behalf of the European Commission (2021) MonitorEHR report. These percentages were calculated with the available graphical data in the report.
Boosting awareness of the different types of health data and their use

It will be important to distinguish between fact and fable. We can foster knowledge and trust by maintaining public transparency on data access conditions and rules. This requires efforts in raising awareness, publishing approved uses of data, and promoting success stories and concrete benefits to society.

Most importantly, patients need to understand for what purposes their data is being used, whether it is for improving care, population health, or scientific research.

For instance, gleaning off insights from large, aggregated datasets has significantly different implications than using and combining datasets for personalised treatments, but both are crucial to the development of better healthcare. We support initiatives like the Data Saves Lives or Understanding Patient Data.

A framework of trust starts with the groundwork, but it should be clear from the start what needs and uses will arise in the future. We should clearly define and spread awareness on which health data uses have particular requirements and which have a high impact and should be prioritised. You can find a helpful overview below.

DIFFERENT TYPES AND USES OF HEALTH DATA:

While we speak of “health data” it is important to define which types of data are used for which purpose. Industry is also a key source of health data.

<table>
<thead>
<tr>
<th>Individual level health data</th>
<th>Used for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examples: EHR systems, apps, sensors, devices, genomics, Clinical Decision Support</td>
<td>- Health status monitoring</td>
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<tr>
<td>- Continuity of care</td>
<td></td>
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<tr>
<td>- Care pathway tracking, clinical workflow management</td>
<td></td>
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<tr>
<td>- Real-time feedback and guidance to patients and clinicians</td>
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<tr>
<td>- Personalised medicine</td>
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<tr>
<td>- Disease interception, prevention and wellness</td>
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<tr>
<td>- Healthcare provider reimbursement</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Population level health data</th>
<th>Re-used for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examples: EHR systems, regional and national eHealth infrastructure</td>
<td>- Healthcare provider performance and planning</td>
</tr>
<tr>
<td>- Quality and safety, care pathway optimisation</td>
<td></td>
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<tr>
<td>- Medical device and algorithm refinement</td>
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<tr>
<td>- Pharmacovigilance</td>
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<td>- Public health surveillance</td>
<td></td>
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<tr>
<td>- Public health strategy</td>
<td></td>
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<tr>
<td>- Health services and resource planning</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Large-scale health data</th>
<th>Re-used for:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examples: national and international research infrastructures, federated query research, cross-sectoral infrastructures</td>
<td>- Epidemiology</td>
</tr>
<tr>
<td>- Digital innovation: devices, sensors, apps</td>
<td></td>
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<tr>
<td>- AI development</td>
<td></td>
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<tr>
<td>- Personalised medicine and bio-marker research</td>
<td></td>
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<tr>
<td>- Diagnosis and treatment options development</td>
<td></td>
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<tr>
<td>- Disease understanding and stratification</td>
<td></td>
</tr>
</tbody>
</table>

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56 Data Saves Lives is a multi-stakeholder initiative with the aim of raising wider patient and public awareness about the importance of health data.  
59 Understanding Patient Data: Putting people at the centre of decisions about patient data.
At the organisational level, effective change management and much more funding from all levels of government are needed throughout healthcare systems to ensure the momentum towards digital, initiated by the COVID-19 pandemic, is not lost. For instance, there are indications that telehealth adoption, after an initial increase during lockdowns, has slowed down.\textsuperscript{60}

This will require enhancing digital skills and literacy for healthcare practitioners and patients. One successful example is Portugal’s Cascais hospital, that created new roles to act as champions in introducing technology to staff and building digital skills internally, such as Chief Medical Information Officer, Chief Nurse Information Officer, and Chief Pharmacy Information Officer.

One the other hand, we must not forget about educating data scientists and developers on the needs of patients, regulators, and healthcare practitioners.\textsuperscript{61} This is also relevant for the application of AI to clinical practice. Key challenges include those intrinsic to the science of machine learning, logistical difficulties in implementation, a lack of scale, but also consideration of the barriers to adoption as well as of the necessary sociocultural or pathway changes.\textsuperscript{62}

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\textsuperscript{61} DIGITALEUROPE is actively taking part in projects to improve e-accessibility, upskilling, women in IT, blockchain skills, the software skills alliance, and the jobs and skills platform. We look forward to ambitious European digital health projects.
\textsuperscript{62} Read in depth on AI in health applications, including ethical and cultural concerns in DIGITALEUROPE’s paper on harnessing the power of AI in health applications.
In July 2021, DIGITALEUROPE launched its Executive Council for Health to bridge the gap between business and policy expertise, and to advance the digital transformation of the health industry. The Council – comprising 19 senior executives from leading health and technology companies – encompasses Future Unicorn Award winning small and medium-sized companies (SMEs) and leading firms with many decades of experience in digital health.

The Council members collaborate to provide unique insights to policymakers on how digital can address urgent healthcare challenges. Unequivocally, trust and the roadmap for the European Health Data Space (EHDS) are the first concern, as they are foundational to the EU’s ambitions.

We support the European Commission’s ambition to enable sharing of data for healthcare, create a genuine single market for digital health products and services, increase access to health data for research, innovation, and policymaking, and foster the use of artificial intelligence in health.

To this end, we are aware of our role. Industries can do much to support the integrated network of academia, SMEs and public-private partnerships in healthcare, and therefore we understand our responsibility in fostering trust and support for the EHDS. We invite representatives of patient, clinicians, healthcare providers, regulators, and other groups to engage with us.

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63 DIGITALEUROPE’s Future Unicorn Award aims at celebrating scale-ups from across Europe that have the potential to become the future European tech giants.

64 The European Commission’s strategy under “Protecting our European way of life”, dubbed the European Health Union encompasses crisis preparedness and response, a pharmaceutical strategy and a beating cancer plan.
Building trust with EU citizens on data sharing initiatives involves structurally demonstrating results on issues that are meaningful to people’s everyday health and life. It needs to be possible for anyone in Europe to see real world outcomes of care and treatment, whilst supporting research for innovations in healthcare.

The EHDS should align with current and developing legal frameworks. Read our positions on:
- **How to make the most of the GDPR for research**: There is still too much uncertainty around how health research can be conducted in accordance with data protection rules, and Guidelines from the European Data Protection Board should aim to remove as much of this uncertainty as possible. Resolving these issues is necessary to make the future EHDS possible and successful. Codes of Conduct for health research could be helpful.
- **Initial findings on the proposed AI Act**: Ensuring consistency and synergies with the EU framework is key. The EHDS should enable trustworthy AI with representative and fit for purpose data.
- **Recommendations for the Data Governance Act**: The European data economy will be a key driver of the EU’s growth this decade. Our key recommendations are to:
  - Prudently unlock re-use of sensitive data.
  - Safeguard existing data sharing initiatives.
  - Leverage data altruism.
  - Keep the framework simple.

In our response to the consultation on the EHDS we called for the coordinated promotion of system-wide interoperability for both primary and secondary use of data.\(^6\) This should build on a system of incentivisation to boost mainstream health systems’ adoption of Europe-wide interoperability standards. For further processing of health data, we should co-create ethically acceptable incentives, governance models and establish multi-country data sharing collaborations.

Clarify and harmonise conditions for the secondary use of health data.

Member States should cooperate more in using interoperable standards and eID, delivering faster on initiatives.

The EHDS framework should include mechanisms for broad participation and data use, including through altruism schemes, for both bigger and smaller companies. Scientific research is not only conducted by academia or public research institutes but also by private sector-stakeholders who, by developing innovative products and services, are an integral part of the healthcare ecosystem.

The EHDS framework should safeguard European industry’s competitiveness in the international field.

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\(^6\) Such as FHIR developed by HL7, a not-for-profit, ANSI-accredited standards developing organisation dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.
PART 2
Digital technologies developed by companies in Europe are ready to scale up, providing solutions in a clinical setting, remote solutions, health insurance, collaborations between tech, health and academia, but also in building patient-centric eHealth services.
Early detection, more accurate diagnosis and efficient workflows are all key to better primary and secondary care. Digital health solutions working towards that objective have gone through a research and development phase, an authorisation phase, are subject to post-market surveillance reporting requirements, and receive optimalisation support long after they are delivered to their respective users.

We provide examples of data-driven digital health innovations, how they improve healthcare, how they work, which actors are partnering, and with what technologies and data practices they operate.
Future digital health unicorns

DIGITALEUROPE’s Future Unicorn Award aims at celebrating scale-ups from across Europe that have the potential to become the future European tech giants. The award is compiled by asking all the national trade associations affiliated with DIGITALEUROPE to select a single scale-up from their country. In 2020 and 2021, the winners turned out to be health companies.

Driving small innovators to new insights and scale

**Oncompass – Hungary (IVSZ)**

**Oncompass Medicine** is a start-up that developed an artificial intelligence-based medical software for targeted cancer therapy. Thanks to artificial intelligence, the software can compute more than 20,000 potential associations between cancer genes and targeted therapies in 20 milliseconds to predict each patient’s response to targeted therapies. It increases cancer patients’ chance to receive the right effective treatment, lowers unnecessary costs, and helps pharmaceutical companies develop therapies faster and safer.

**Corti AI – Denmark (IT-Branchen)**

**Corti** is a scaling-up company that uses voice recognition and artificial intelligence and to help medical professionals make life-saving decisions in split seconds. By analysing millions of patient interviews they identify patterns in conversations and use them to predict potentially fatal incidents like cardiac arrest.
Solutions in clinic
Smarter insights to treat complex arrhythmias

**Improving healthcare:**
Helping to improve procedure efficiency, lab efficiency and patient outcomes via collaboration between physicians, electrophysiologists and electrophysiology lab administrators, using multicentre studies and AI-based data analysis for analysing treatment approach.

**How does it work?**
The CARTONET™ digital platform stores all CARTO® 3 System cases, analyses them using AI-based algorithms and stores the analysis on the cloud. This enables the physician to review the analysis of each case and to perform modifications of the algorithm analysis in a simple way. The system can then generate statistics based on hundreds of cases' analysis data, and aggregate this information on cases that were identified to be in multicentre studies to present the global statistics which can lead to research in analysing the treatment approach.

**Partners:**
This solution was developed by Biosense Webster, a Johnson & Johnson medical device company, with collaboration Siemens Healthineers’ teamplay platform on top of Microsoft Azure cloud.

**Main technologies:**
“WEB PACS”, Database, AI – deep learning.

Read more about this here.

**Member:** Johnson & Johnson

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Enabling personalised care along cancer care pathways

**Improving healthcare:**
Improved patient outcome, for instance for lung and prostate cancer patients with an AI-Pathway Companion that supports physicians in providing better care with complex diagnosis and therapeutic decisions along care continuum.

**How does it work?**
- The AI-Pathway Companion focuses on domain expertise in the field of oncology. The infrastructure layer shows the patient’s relevant clinical history, current patient status, diagnostic images and results from the pathological reports, eliminating the need to access information from multiple databases or files.
- Through ongoing development and refinement of data interfaces, this Companion aims to increase the number of disease parameters captured throughout the clinical pathway, thereby expanding the relevant data points with the goal of advancing personalised cancer care.
- Leveraging AI technologies to provide further insights, the AI-Pathway Companion compares the patient’s clinical status against the current guidelines and through a decision diagram supports physicians in their daily decision-making for next Repsteps in terms of diagnosis and therapy.

Read more here.

**Member:** Siemens Healthineers
Remote solutions

Novel AI-Powered Solution for Cardiovascular Disease Prevention

Improving healthcare:
➤ The digital-first approach to Cardiovascular Disease (CVD) prevention provides a holistic set of digital tools and coaching placing participants on a healthier path by personalizing care, gathering data, and providing actionable insights, all in a user-friendly mobile app.

➤ The program seeks to reduce the broader burden of disease for those at risk while lowering costs for employers and health plans. According to the World Health Organization, at least 80% of heart disease, stroke, and type 2 diabetes are preventable.

How does it work?
➤ Medical devices capture blood pressure and weight automatically tracked in the app alongside food, medications, physical activity, glucose, and A1C from thousands of other integrations. The program combines behavioral science principles, data science, and customized educational content to guide members towards positive habits in weight management, physical activity, and diet for a heart-healthy life.

➤ It uses machine learning algorithms and more than 30 billion health data points from millions of members worldwide. Blood pressure insights help members at risk for CVD understand how their blood pressure is trending and offer tactical recommendations and support in real-time.

Partners:
Bayer worked together with One Drop to develop this solution.

Main technologies and data:
Data Science (including Machine Learning, Artificial Intelligence) across clinical, behavioural, and self-reported data sets, integration of diagnostics data (blood pressure, weight, glucose), self-reported data (food intake, manually and via barcode scanning, physical activity, medication intake, etc.)

Read more here.

Member: Bayer
Remote patient monitoring for respiratory conditions

Improving healthcare:
▶ Connected positive airway pressure (PAP) and ventilation devices can support treatment delivery to patients by monitoring the patient’s treatment remotely and transmitting the data in a secure manner to the HCPs.

▶ Remote monitoring enables HCPs to manage and coordinate care for their patients with chronic diseases, understand how a treatment protocol works, and decide on customised interventions if needed, even possibly remotely, aiming at limiting the burden of transportation to the hospital and risks associated with hospital stays.

▶ Such tools can help an estimated 936 million individuals aged 30–69 years worldwide with their sleep apnoea and an estimated 380 million people worldwide with COPD.66

▶ Remote monitoring services drive patient engagement, adherence, and better outcomes in treating sleep apnoea and other chronic conditions.67

How does it work?
▶ Connected devices – for chronic respiratory disorders and diseases such as sleep apnoea and chronic obstructive pulmonary disease (COPD) – collect data on how the treatment is being delivered and how the device is being used by the patient. Treatment device data can be transferred remotely and analysed to provide valuable insights to healthcare providers on treatment protocol.

▶ For example, analysis can identify operational issues such as air leakage resulting in disturbance for the patient’s partner or non-effective therapy. Data can also be used to identify patient compliance problems and enables HCPs to make better decisions in order to balance treatment intensity with outcomes.

Partners:
This solution enables data to flow between the device, the platform, third-party cloud providers, and care teams.

Main technologies and data:
Machine therapy data is recorded on the device; the data is encrypted and transmitted over the internet to a platform where it is dynamically processed often with advanced algorithms. The data is accessed by the healthcare provider to monitor the patient’s use and treatment.

Read more here.

Member: ResMed

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Smart Watches in the early identification of cardiac arrhythmia

Improving healthcare:
- It contributes to reducing stroke and other atrial fibrillation (AF)-related complications though a smart device (wristband and wristwatch) running an AF screening app to collect photoplethysmography (PPG) signals.
- Technology incorporated in smart watch and associated App run on any smartphone provides early warning of potential cardiac irregularities that warrant further investigation, potentially enabling the early identification of cardiac problems.

How does it work?
- Monitoring is via a wearable device that when worn provides continuous home monitoring with smart device–based PPG technology for AF screening. This enables AF detection leading to early interventions that may reduce the likelihood of stroke and other AF-related complications. The use of a wearable Smart Watch addresses the problem of low detection and adherence rates that characterise current management approaches for patients with suspected AF.
- Patients with "possible AF" episodes using the PPG algorithm were further confirmed by health providers among the MAFA (mobile AF app) Telecare center and network hospitals, with clinical evaluation, ECG, or 24-h Holter monitoring.
- 246,541 individuals downloaded the PPG screening app, with 187,912 individuals using the smart watches to monitor their pulse rhythm. Among those with PPG monitoring, 424 (0.23%) received a "suspected AF" notification. Of those, 227 individuals (87%) were confirmed as having AF.
- During algorithm development phase and beta phase, data was collected from both people with and without AF problem, with even distribution on gender, and wide coverage of different aging groups (18 to 80).

Partners:
Hospital, University.

Main technologies and data:
An App using an algorithm to screen for photoplethysmography signals from smart watch and wrist band.

Read more here.

Member: Huawei
Leveraging digital tools in health insurance

By integrating digital tools in health insurance, companies are using data and technology to help achieve the Quadruple Aim to enhance patient experience, improve health outcomes, reduce health care costs, and improve experience of healthcare providers. We highlight one example for care management, but there are many more possibilities, such as for:

- Wearable device well-being programmes, enhanced models of care for affordability, coordinated by aligning incentives for patients, care providers and hospitals.
- Online and mobile resources that help enable people to better manage their health, navigate the health system and more easily manage their payments and benefits.
- Integrated care models that leverage various data sources to provide personalised, preventive care resources and programs.

Virtual care management for patients living with chronic conditions

Health insurers can provide eligible beneficiaries with remote patient monitoring through Vivify Health platform which pairs them with nurse-led care teams and connected devices, such as a weight scale, blood pressure cuff, glucose monitor, or pulse oximeter, to monitor their daily vitals and inform interventions. This offers a continuous health care experience, keeping individuals connected to their care team and empowering them to manage their health from the convenience of their homes.

**Improving healthcare:**
The program serves more than 30,000 members and has reduced in-patient admissions by 5 percent and readmissions by 65 per cent, reduced mortality by 3.4 percent this year and resulted in 97 per cent patient satisfaction.

**How does it work?**

- Eligible members can be connected with a Registered Nurse for care management and offered devices that sync to a Vivify app which helps them track their clinical and biometric information, such as glucose levels, blood pressure pulse and weight. This info is reviewed by the nurse on a daily basis and if changes occur the care provider may engage. The set-up enables monitoring at home or on the go.

- The solution increases digital engagement and supports more frequent interaction for patients with chronic conditions to help drive positive behaviour and help enable access to timely clinical intervention. It allows users to recognise and better manage their symptoms and comorbidities, transforming episodic care into proactive, ongoing care management.

**Partners:**
health insurance company with its own or outsourced remote care team; digital care management capability provider that enables individuals to communicate and share information with their care management staff.

**Main technologies and data:**
platform of connected devices with smart paths to enable patient management, including in-app video chat, messaging and telephonic capabilities. Patients can either use their own device, or a tablet is provided by the insurer, together with other peripheral devices specific to their chronic condition(s) to help track their biometric data and symptoms. The tablets provide a simplified interface, tailored to the physiology of older users – screen brightness, larger icons, and electro-sensitivity optimized for thinner skin.

Find out more about this [here](#).

**Member:** United Health Group
Collaborations between tech, health and academia

Europe cannot have a digital decade without digital health innovations. The COVID-19 pandemic prompted the need for unseen levels of collaboration, not just for track-and-tracing, but also for instance to build a molecular compound library. They resulted in a fundamentally different kind of partnership that will be increasingly important in the future.

Fortunately, there are many examples that can lead the way through a clear framework for health data sharing and use – we must not start from scratch. Europe should embrace the already existing collaboration between health, tech and academia.

Improving outcomes with a haematology network

**Improving healthcare:**

- Improving outcomes for haematological cancers patients by increasing the knowledge and understanding of this disease through a collaborative platform that allows for the analysis of data on multiple data sets with methodological and statistical possibilities.

- It increases the value of the data by enabling their re-use across a wide range of research studies and encourages publishing results so that insights can contribute towards improving patient outcomes. Datasets on haematological malignancies from 23,000 patients have already been transformed so they can be used for analysis.

**How does it work?**

- The Haematology Outcomes Network in Europe (HONEUR) is a secure, collaborative platform run as a federated model, where the data stay at the respective sites and the analysis is executed at the local data sources. It uses the common data model called OMOP (Observational Medical Outcomes Partnership), ensuring participating sites maintain local governance and can initiate their own research questions. No patient-level data are stored on the HONEUR portal – only aggregated results of a research question can be shared securely through firewalls.

- Data partners not only benefit from participating in a network that is pioneering data management and analysis, but their efforts are also compensated at Fair Market Value, and contributors can even increase the value of their data via expanded authorship in publications and potential sponsored studies.

**Partners:**

Janssen collaborated with a consortium with partners from 9 countries, including cancer centres, university institutes and hospitals and other local data projects.

**Main technologies and data:**

Federated data model, patient-level data, disease characteristics, patient baseline characteristics, medications, outcomes.

Read more [here](#).

**Consortium:** HONEUR

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68 Take for instance the CARE consortium (under the IMI umbrella) consisting of 40 members, and the COVID-19 Therapeutic Accelerator Initiative, that worked together with DIGITALEUROPE member Bayer.
Identifying and studying new COVID-19 variants using cloud technology

Improving healthcare:
▶ The Global Pathogen Analysis System (GPAS) facilitates better tracking and management of diseases and pathogens worldwide to ensure a fast and effective response. This includes an early warning system to track the spread of variants in real time.

▶ GPAS is run by a not-for-profit entity, offering a global turnkey solution that standardises how genomic sequence data is processed. This is a new type of partnership with academia, non-profit, and industry working together. GPAS is part of the Public Health England New Variant Assessment Platform.

How does it work?
▶ GPAS’ services are cloud-based and secure which alleviates any current issues with worldwide genomic sequencing improving equal distribution of infrastructure and operational support. Unlocking genomic insight requires expertise and access to high-performance computing and sharing data across borders needs a highly secure digital environment (and patience, and trust).

▶ The secure, cloud-based system can analyse and translate data to give users an instant global perspective on their findings whilst maintaining full ownership and control by protecting personal identifiable information (PII). It can also integrate with sequencing infrastructures and data repositories that already exist for seamless tracking.

Partners:
The Global Health Security Consortium, the Lawrence J. Ellison Institute for Transformative Medicine and the Tony Blair Institute for Global Change have worked in coordination with Oxford University and Oracle to support the development of the platform and to get it in the hands of global researchers.

Main technologies and data:
In-built computational infrastructure for rapid – same-day – data analysis, supporting epidemiological research, therapeutics, and diagnostics.

Read more on this here.

Member: Oracle
Breakthroughs in pancreatic cancer

**Improving healthcare:**
Developing better treatment for pancreatic cancer patients by increasing understanding of the pancreatic ductal adenocarcinoma (PDAC) biology and patient stratification through combining genomics and imaging phenomics.

**How does it work?**
- The PancAIM platform integrates the entire range of genomics with radiomics and pathomics and applies a data-efficient two-staged AI method relying on four central concepts of AI in healthcare: data providers, clinical expertise, AI developers, and medtech companies to connect to data and introduce AI into healthcare.
- Among the main steps of the project, are:
  - Develop digital platform integrating genomics and clinical PDAC data.
  - Develop and use unimodal AI biomarkers for integrative research.
  - Develop and select most promising AI-assisted clinical products integrating omics and medical imaging data.
  - Implement and validate clinical products.
  - Sustain the platform for further research and clinical applications.

**Partners:**
A consortium of industry and research universities from 9 countries.

**Main technologies and data:**
Combines genomics and imaging phenomics, enable development of clinical use AI applications.

Read more on this [here](#).

**Consortium:** PancAIM
Boosting trust and uptake of AI in precision oncology

Improving healthcare:
► Increased clinical trust and adoption of enhanced AI in oncology.

► The research findings are available to the public free of charge which supports advancements in care and treatment development.

How does it work?
► EuCanImage is building a highly secure, federated and large-scale cancer imaging platform integrating advanced capabilities and new standards to develop and validate integrative decision support systems for precision oncology.

► It will determine the optimal facets of ethical data collection, including legal and ethical framework for oncological imaging to ensure a privacy-by-design approach to the platform’s development.

► It will offer a user friendly catalogue for cancer imaging and non-imaging data, for which a comprehensive suite of opensource tools and procedures for data anonymisation.

► The goal is to build and demonstrate a FAIR and GDPR-compliant and scalable platform for leveraging large-scale, high-quality and interoperable cancer imaging datasets adequately linked to biological and health cancer data.

Partners: It is a multidisciplinary consortium combines the expertise of 20 partners from 11 countries. It includes major universities, research institutes, and industry partners.

Main technologies and data: Tools will be designed for standardising image data cross sites and scanners enabling the large-scale data and machine learning to provide semi-automated capabilities for data curation and annotation, which can be executed in a distributed privacy-preserving manner, utilising also synthetic image generation.

Read more here.

Consortium: EuCanImage
Using big data to for safer pregnancies with diabetes patients

Improving healthcare:
A state-of-the-art analysis provided relevant insights about the use of Remote Patient Monitoring systems for Gestational diabetes Mellitus (GDM) care provision. Gestational diabetes (GDM) develops in women during pregnancy because the mother is not being able to produce enough insulin.

How does it work?

The BigMedilytics pilot group has created an AI solution for GDM care, including an app, that facilitates self-management and remote-monitoring of GDM through the use of a mobile application linked to a secure medical portal.

The primary data source is the collection of daily blood sugar levels (BSLs), at least four times a day (‘Fasting’ and ‘Post meal’) using glucometers equipped with Bluetooth, thereby obtaining a lengthy review of glycaemic control, which ensures a prompt recognition of high sugar levels. Other relevant information and clinical data were collected for the development of a prognostic model.

Real- time data and historical data were collected to gain improved understanding of patterns of BSL in the population of patients with GDM.

All necessary documentation has been produced to ensure full compliance with both EU and National Irish regulation in terms of data privacy and ethical aspects, with a particular emphasis on the GDPR requirements and security measures to avoid any ethical issue or data breach.

Partners:
The study performed with industry partners was initiated by collecting and analysing data records from two different hospitals based within the RCSI Hospital group in Ireland – the Rotunda Hospital in Dublin and Our Lady of Lourdes Hospital in Drogheda. In total 131 records were analysed.

Main technologies and data: Use of RPM solutions in combination with AI models for GDM care

Read more here.

Consortium: BigMedilytics
Better therapeutic effectiveness for cancers

Improving healthcare:
Improving cancer care insights for bladder cancer and multiple myeloma by using privacy-preserving machine learning to analyse patient-level data.

How does it work?
◆ The Augmenting Therapeutic Effectiveness through Novel Analytics (ATHENA) data science innovation project, launched in 2020, facilitates the re-use of clinical data for secondary research by using a federated data network model for data analytics. Data remain local, under governance of the data custodian (in this case, the hospital), and the analysis is brought to the data. Only query results will go back to a central location and no patient-level data leave the hospital.

◆ In partnership with the Universities of Leuven and Ghent, IMEC, Robovision, Inovigate and several other hospital partners and small & medium sized companies, ATHENA uses an AI system and supports research organisations and biomedical companies to analyse the data. It was conceived with the aim to advance medical science, for the development of new treatments and to accelerate clinical research. Hospitals around Europe can join the initiative, potentially increasing the volume of data as well as the robustness of the insights.

Partners:

Main technologies and data:
Advanced machine learning methods, federated networks.

Read more here.

Consortium: ATHENA
Building patient centric eHealths services

In Estonia, where now 99% of citizens have a secure country wide digital record using an eID-card, the first step in 2001 was to build robust digital infrastructure, which engendered trust and support. In Finland, the Act on Secondary Use of Health and Social Data enabled FinData to grant authority for secondary use of data and Kanta provides nation-wide data-services for healthcare delivery.

Many bigger Member States are already taking action, like France and Germany. For inspiration, Europe may even look to Australia, where a federal-level Health Service Library has been established covering health and social care, including public, private and non-profit organisations.

Healthcare and technology companies are providing electronic health records solutions

Austria: Electronic health records for faster and more precise physicians

In Austria, the roll out for the nationwide Electronic Health Record (ELGA) started five years ago, in 2015. Today, work is already underway on the implementation of valuable extensions, such as the eVaccination pass or care networks as part of ELGA. As a modern and secure infrastructure, ELGA is available to all citizens and all those who receive care in the Austrian health care system. It facilitates access to health data for patients and authorized ELGA health service providers – attending physicians, hospitals, nursing homes or pharmacies. ELGA is working with different models of opt-out, leading to a general coverage of 97 per cent of the insured population as enrolled ELGA users.

The Netherlands: A secure portal for exchanging COVID-19 patient data

Since its launch in 2020, 95% of Dutch hospitals have already been connected to the portal. It optimises the use of healthcare resources by allowing hospitals to seamlessly share COVID-19 patient information with one another. The COVID-19 portal running on XDS cloud services, available to all Dutch hospitals, is not linked directly to an individual hospital’s EPD (Electronic Patient Dossier), PACS (Picture Archiving and Communication System) or pathology department systems. Instead, specific information, such as a patient’s radiology images, reports and patient summary is shared via the portal.

Australia: A federal level opt-out approach to Electronic Health Records

By the end of 2018, a My Health Record was created for every Australian, unless an individual chosen not to have one. It is now a nation-wide EHR platform, overcoming challenges of multilevel government structures. This is one of the largest National Health Record Platforms worldwide, allowing authorized health professionals access to some 3 billion clinical documents belonging to 23 million citizens. Australia also is an active contributor to the Global Digital Health Partnership (GDHP), a platform for governments to exchange experiences in digitisation of their own health system.

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69 e-Estonia: healthcare gives an overview of Estonian eHealth progress. This has been realised with the support of European funding.
60 Finnish Social and Health Data Permit Authority FinData promotes secondary use of Finnish social and health care data, facilitates data permit processing and improves data protection for individuals.
61 KANTA is the Finish service that ensures secure and reliable processing of patient information.
62 France recently launched their Système National des Données de Santé (National Health Data Space).
63 Australian Digital Health Agency (2021), My Health Record.
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We wish Europe to develop, attract and sustain the world’s best digital talents and technology companies.

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