



EUROPE



DIGITALEUROPE
Executive Council
for Health's
recommendations
for EU digital health
policy (2024-29)



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What is at stake?

Digital transformation could ensure that health systems in the EU become more resilient in the face of growing challenges: ageing population, chronic diseases and increasing demand for healthcare; shortages and uneven distribution of health professionals (medical deserts); health inequities; increasing costs; epidemics and environmental problems. As healthcare is a particularly knowledge-intensive sector, the rapidly growing volume of data relating to health and the extraction of valuable insights offer huge opportunities to improve patient care, manage health systems, develop public health policies, and facilitate health R&I.

The EU needs to adopt impactful measures to lead developments and widespread implementation of revolutionary solutions in digital health, and ensure that in doing so, it remains competitive for the benefit of patients and health systems. The use of AI and data science methods would be vital across the spectrum of healthcare: to enable new medical discoveries, connect patients with targeted treatments, optimise organisational processes and reduce expenditures. Virtual human twins and precision approaches tailored to the needs of individuals could offer significant hope for patients with cancer or rare medical conditions. Data linkages could help to identify commonalities in biological pathways at the population level to unlock efficiencies in preventive, diagnostic and therapeutic approaches. The broader uptake of telehealth and blended (clinical and remote) healthcare solutions, underpinned by the Internet of Health Things, would improve patients' accessibility to healthcare, support prevention measures and enable the generation of real-world evidence (RWE).

The 2024–29 term is make-or-break in the digital health sector, as it will determine whether:

- ▶ patients and health systems in the EU will have access to state-of-the-art digital health solutions at the same pace or faster than in other geographies;
- ▶ the EU can become a global leader in clinical trials, medical discoveries, and the development of medical devices and innovative digital health products and services;
- ▶ the investments made by the EU and Member States to improve the quality of health(care)-related data and develop eHealth infrastructure will yield a return for patients and health systems, and determine whether the EU can maintain this competitive advantage over other geographies;
- ▶ the EU can overcome legal barriers and facilitate the scalability of digital health solutions without causing disproportionate costs for the sector;
- ▶ leveraging data at large scale could make European health systems more effective, accessible, equitable, resilient and sustainable.

What are the priorities?

This strategic advisory paper by the digital health industry is a call for action for the EU to set the following policy goals in digital health in the 2024–29 term:

▶▶ **Prioritise digital transformation within the European Health Union and healthcare-related policy instruments** through:

- *ensuring that digital technologies and data-driven solutions are central to the formulation of all EU health policies;*
- *implementation of the European Health Data Space (EHDS) without fragmentation as well as safeguarding rights and legitimate interests in relation to the primary and secondary use of electronic health data.*

▶▶ **Enhance the use of data and new enabling technologies in health systems and health R&I** through:

- *development of EHDS infrastructure and accompanying health data governance arrangements (e.g. backbone infrastructure, federated data repositories, health data cooperatives, interoperable open ecosystems);*
- *advancing the adoption of data-driven and digital approaches in healthcare (e.g. personalised healthcare; telehealth and hybrid/blended healthcare; decentralised, pragmatic and registry-based clinical trials; real-world evidence; patient twinning; precision medicine; precision public health; population health management; value-based care) and strengthening resilience and security in health systems;*
- *including the use of AI and data science methods to better understand diseases and their impact on patients, diagnose difficult-to-detect diseases, develop targeted and more effective treatments, and use healthcare resources more efficiently;*
- *development of data-driven insights to improve resource efficiency in health systems, implement evidence-based practices, enable risk stratification, and facilitate better individual and population health outcomes (potentially, in combination with data from other future European data spaces).*

▶▶ **Improve skills and increase trust in digital health** through:

- *enhancing health workforce skills and digital health literacy through educational, training and citizen science programs, and improving the competence of the healthcare workforce and public sector procurers to deploy appropriate digital health solutions;*
- *incentivising multi-stakeholder collaborations and strengthening public–private partnerships to leverage the strengths and resources of each partner, and build trusted and sustainable digital health ecosystems.*

► **All funding and allocated resources should advance digital transformation in healthcare** including:

- *adequate resources for the impactful implementation of the EHDS;*
- *a dedicated EU digital health funding program* to develop skills and digital health literacy, strengthen cybersecurity capabilities in healthcare, and scale high-impact digital health solutions;
- *more efficient funding schemes for digital health*, such as funding requirements tied to value and outcomes, incentives to make upfront investments, and support the integration of secure and more effective cloud-based / scalable / software-driven ICT solutions;
- *harmonisation of value assessment frameworks, public procurement criteria and reimbursement pathways for digital health solutions* to facilitate their deployment and cross-border scaling.

► **Guarantee legal clarity and consistency in digital health policy within the EU** through:

- *clear, consistent and implementable rules* eliminating regulatory conflicts, duplications and uncertainties that are increasing complexity and innovation costs;
- *consistent and harmonised implementation of privacy, data protection and cybersecurity requirements* across Member States to address legal fragmentation, and *ensure the ubiquitous, cross-border and international data flow needs* of digital health ecosystems;
- *effective IP protection to incentivise R&I in digital health* in the EU;
- *recognition of globally-aligned harmonised standards and adoption of other soft law instruments* to improve interoperability and govern the proper deployment of digital health solutions and (re)use of data for health(care)-related purposes.

DIGITALEUROPE's Executive Council for Health (DECH)

[DIGITALEUROPE's Executive Council for Health](#) (DECH) aims to bridge the gap between industry and policy in the area of digital health. Launched in 2021, the DECH comprises of senior executives representing leading healthcare and technology companies (members of [DIGITALEUROPE](#)) in the digital health sector. The diverse profile of companies enables the DECH to share a wide range of industrial insights into how transformative digital solutions can address complex healthcare challenges. The DECH also reflects on the policy environment affecting the digital health industry and the broader health ecosystem in the EU. As part of this work, the DECH has previously delivered two reports defining [key pillars for strengthening trust and collaboration in the European health data ecosystem](#), and on the [EU's potential to drive innovation in healthcare](#).



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Background and purpose

DIGITALEUROPE's Executive Council for Health (DECH), comprising of senior executives representing leading healthcare and technology companies in the European digital health industry (all members of [DIGITALEUROPE](#)), has delivered previously two reports defining [key pillars for strengthening trust and collaboration in the European health data ecosystem](#) and on the [EU's potential to drive innovation in healthcare](#).

This strategic advisory paper is put forward at a critical time. European health systems face growing challenges (such as increasing demand for healthcare due to ageing populations; shortages and uneven distribution of health professionals; limited financial resources). At the same time, Europe is in the midst of a global race to develop and implement innovative solutions to enhance the use of data and new enabling technologies in healthcare.

Digital solutions can provide the means to support the transformation of European health systems and ensure that patients in the EU have access to the best healthcare in the world. New insights from linking and analysing health datasets by use of digital technologies offer immense potential to improve patient care, manage health systems, develop public health policies, and facilitate health R&I. Despite the considerable potential, the DECH is concerned that weak, underfunded policy measures will be insufficient to achieve complex and system-wide changes in European health systems, and to facilitate advancements relating to digital health in the global competition.

EU decision-makers and national governments must make impactful (and bold) decisions to prioritise digital transformation in healthcare, accompanied by appropriate funding and resources. The Commission cannot drop its ambition to drive digital health forward. Member States must also recognise that it is in the best interest of society to work together on a common shift to patient-centric, data-driven and value-based healthcare. Policy measures should enhance the use of data and new enabling technologies in health systems and health R&I, improve skills and increase trust, ensure that all related funding and allocated resources advance digital transformation in healthcare, and guarantee legal clarity and consistency in digital health policy within the EU.

This paper outlines the digital health industry's views and guidance for the European Union's term (2024–29). It can be a useful reference point for the Commission, the European Parliament and the governments of Member States. To overcome common challenges affecting European health systems, the DECH shares its perspectives on how the digital health industry can contribute with solutions. The paper also provides recommendations on what EU policies are required to facilitate the necessary changes.



Opportunities for the EU to move faster in harnessing the benefits of digital health

Shift to patient-centric, data-driven and value-based healthcare

European health systems should adopt the following key principles (and accompanying policy measures) to drive structural reforms:

- ▶▶ ‘patient-centric’ healthcare: personalised, participative, precision, predictive and preventive healthcare;
- ▶▶ ‘data-driven’ healthcare: application of health science thinking and methods to digital solutions to deliver contextualised insights that support both standardised and personalised care;
- ▶▶ ‘value-based’ healthcare: holistically designed healthcare measurement, financing and procurement models that facilitate prevention, innovation (co-creation) and evidence-based decisions, and link payments/reimbursements to overall outcomes and value achieved for the benefits of patients, society and economy.

Hybrid healthcare and telehealth

The use of digital health solutions along the patient pathway and the integration of clinical (“in person”) and telehealth (“virtual”) services could refine and enhance hybrid healthcare delivery models. The pandemic demonstrated that telehealth can function as a “safety net” while mitigating the devastating impact of a public health crisis, and has become an essential tool in building resilient health systems that are able to adapt to changing circumstances. The use of digital health solutions in remote (non-clinical) environments can also become a force multiplier for health systems given their ability to scale healthcare services, expand healthcare providers’ reach to underserved areas, and improve the efficiency of workflows.

Telehealth solutions (e.g. teleconsultation, mobile apps, wearables) can support patients’ access to healthcare, patient empowerment and collaborative decision-making to improve patient outcomes, adherence and demonstrate the benefits of active participation in digital transition, increasing health equity and inclusivity. Remote and real-time monitoring of the physiological parameters of patients using connected devices, in combination with other data sources, can support prevention measures, enable more timely diagnoses and treatments, and generate real-world evidence (RWE). The growing social acceptance of these solutions is an opportunity to translate their capabilities into advancing the smart transformation of European health systems.

- ▶▶ For example, a mobile app can provide medication and refill reminders, appointment reminders, activity reminders, and measure and track lifestyle data that can be shared with a healthcare provider to support health-related decision-making (e.g. [J&J's Care4Today app](#)).

Digital twins in healthcare

Healthcare is the fastest growing segment of the digital twin field. Digital twins can provide virtual replicas of medical procedures, hospitals, human organs or even the entire human body (a ‘virtual human twin’ or ‘digital patient twin’). A virtual human twin is an integrated multiscale, multi-time and multi-discipline representation of quantitative human physiology and pathology. Its realisation through a collaborative distributed knowledge and resource platform is specifically designed to accelerate the development, integration and adoption of patient-specific predictive computer models, which can be used as clinical decision support systems, for personal health forecasting or as methodologies for the development and de-risking of personalised treatments (see also DIGITALEUROPE’s engagement in the [EDITH project](#)).

A virtual human twin can process data collected from a variety of sources without having to store the data in a single place, potentially for a patient’s lifetime. A virtual human twin can process data concerning a patient’s health in real-time and continually compare this with data from population studies, or with data on specific clinical pathologies, the course of specific diseases, or medications, diagnostics and therapies used for other affected individuals. Taking into account collected evidence, coupled with clinical guidelines, virtual human twins could enable the provision of more holistic and personalised treatments. Virtual human twins can be utilised in several ways (see e.g. [Siemens Healthineers’ digital patient twin applications](#)) to:

- ▶▶ coach patients based on their lifestyle patterns, vital signs and medical diagnostic data to stay healthy;
- ▶▶ recommend the best possible treatment based on the patient’s health profile to provide precise and personalised care;
- ▶▶ plan a surgical intervention to decrease risks and optimise outcomes;
- ▶▶ track patients recovery following therapy and detect any early signs of treatment failure or adverse effects.

Digital twins can also change the way clinical trials are run through the simulation of biological processes, which can help to obtain information or efficacy of treatments, investigate potential drug-drug interactions, create virtual trial arms, or refine dosing. Digital twins in vaccine discovery and development can minimise wet experiments, reduce manufacturing timelines and optimise product quality (see e.g. [GSK’s digital twin initiative](#)).

AI and other digital health applications supporting clinical developments and medical interventions

AI can support clinical development in several ways:

- ▶▶ AI in clinical research can improve the operational efficiency of clinical trials (including patient stratification) and minimise clinical development

costs. The application of AI to biology (for target discovery) and to chemistry (for drug design) has even enabled the [development of a drug from scratch using AI](#).

- ▶▶ AI can help to develop insights from evidence to support clinical development, as it enables the analysis of simultaneously collected, large, complex and often unstructured datasets, identifies intricate patterns and outputs, provides holistic clinical risk predictions, and helps to assess medicines' efficacy and safety outcomes (see e.g. [Bayer's collaboration with Microsoft on ALYCE, Advanced Analytics Platform for the Clinical Data Environment](#)).

Digital health applications can support medical interventions tailored to specific diseases:

- ▶▶ In cardiovascular health, cardiac implantable electronic devices (CIEDs) and mHealth solutions can play a role in the prevention (secondary prevention), screening and management of cardiovascular diseases (CVD).
- ▶▶ Immersive technologies and gamification, such as virtual reality and robotics, can enhance post-stroke rehabilitation and improve body movement.

Decentralised or hybrid clinical trials and integration of RWD/RWE

In addition to data from clinical trials, where data is collected in a controlled setting, data collected in the real patient environment, i.e. real world data (RWD) can provide insights about different risk characteristics, patient groups, interactions with other drugs, and the impact of new treatments and medical interventions. RWD complements clinical trial data and can have an impact on how clinical trials are designed and what type of data should be collected to assess their safety, efficacy and cost-effectiveness.

- ▶▶ The collection of eCOA (electronic clinical outcome assessment) / ePRO (electronic patient-reported outcomes) with the use of telehealth devices (e.g. mobile apps, wearables) in decentralised clinical trials help to save time, costs, improve data quality and patient experience ([Climedo, 2021](#), [2023](#)).

RWD can help to generate scientific insights, i.e. real-world evidence (RWE). This can support healthcare decision-makers faced with varied data needs from pre- to post-market, and address the challenge of utilising different forms of technologies and treatments in the context of finite healthcare budgets. RWE can also help prioritise the use of collective resources to have the best impact for specific high-risk citizen groups and scale across analogous communities.

Digitalisation of biology and the value of omics data

In specific cases, the use of omics data can drive the shift from a traditional 'one-size-fits-all' approach to tailored treatments for individual patients:

- ▶▶ For example, [genomic tumor testing](#) can identify possible genetic alterations and explore which treatment can be the most effective to fight cancer (precision oncology), while [circulating tumour DNA \(ctDNA\) technology](#) can help to detect cancer recurrence earlier.
- ▶▶ The study of [clinicogenomics](#) (i.e. a data set comprised of both genomic and phenotypic data) across large, diverse populations can help researchers better understand disease pathways, discover novel therapeutic targets, identify variation in disease onset and progression, evaluate drug safety and efficacy, and variability of patient outcomes.

Linkage of data from siloed health datasets and different data sources

The COVID-19 public health crisis demonstrated the importance of access to and sharing of data for health R&I, and shed light on the risks if data is disjointed on a national, cross-border or international level:

- ▶▶ To help paint a real-time picture of how the COVID-19 virus was moving around the world, the integration of several types of data from country, state/regional and lower level into an advanced analytical model helped to build a [global COVID-19 surveillance dashboard](#) to track and forecast epidemic hotspots, guide where to test investigational vaccine, and to predict health risks and how different treatment courses may affect patient outcomes.

The linkage of data from siloed health datasets and different data sources can help to make new discoveries and improve decision-making in medicine and the management of populations and health systems:

- ▶▶ The combination of data from EHRs (electronic health records) with genomic data and lifestyle data would be useful to understand individualised risk factors, and optimise diagnoses and treatments.
- ▶▶ The analysis of data from national health insurance reimbursement systems can provide insights about the benefits of diagnostic tools and therapy adherence on clinical outcomes for different cohorts of patients (see e.g. [ResMed's ALASKA project](#)).
- ▶▶ The population health management (PHM) approach links primary care, hospital, ambulatory, pharmacy, mental health and social data allowing to stratify population to identify the most vulnerable groups and develop targeted and preventative interventions (see e.g. [UHG/Optum cooperation with NHS England](#)).

Facilitate health data collaborations

The effective design of health data governance arrangements can enhance the (re)use of data for healthcare or health R&I purposes:

- ▶▶ Data sharing partnerships can drive health R&I and development of new treatments for vulnerable patient populations and rare diseases (see e.g. [International Neonatal Consortium](#)).
- ▶▶ As cross-organisational and cross-sectoral partnerships represent a new complementary way for tackling complex data-related challenges, the formation of [health data cooperatives](#) can enable access to high-quality data for partners within the ecosystem and provide whole person or whole system perspectives.
- ▶▶ Federated data repositories and responsible data governance arrangements can allow researchers to re-use existing data for novel research questions in privacy-preserving and cost-effective ways to make scientific findings more accessible and equitable (see e.g. [Haematology Outcomes Network in Europe](#)).
- ▶▶ A collaborative network of stakeholders can use a federated and standardised analytics platform and machine learning techniques to perform predictive analytics in oncology to allow access for partners to detect and validate new therapies, while preserving the privacy of patients (see e.g. [ATHENA](#), Augmenting Therapeutic Effectiveness through Novel Analytics).
- ▶▶ Open ecosystems can ensure interoperability and allow integration of innovative third-party solutions from trusted parties to deliver improved patient care (see e.g. [Roche's navify Marketplace](#); [SAP's Health Product Strategy](#)).

Population health management and integration of socio-environmental determinants of health

The population health management approach can improve population health through data-driven planning and delivery of proactive care. It includes:

- ▶▶ segmentation, stratification and impactability modelling to identify local 'at risk' cohorts;
- ▶▶ designing and targeting interventions to prevent ill-health and to improve care and support for people with ongoing health conditions;
- ▶▶ reducing unwarranted variations in outcomes and – where possible – applying new pathways to other similar populations to achieve scale of activity and investment;

- ▶▶ creating citizen/patient-focused intelligence to support the production of valuable insights for clinical, operational and strategic decision-making and pathway development at all levels;
- ▶▶ breaking down healthcare processes (e.g. treatment protocols, workflows or administrative duties) into components to eliminate systematic inefficiencies and find ways to improve outcomes;
- ▶▶ use of integrated data, analytics, combined with professional insights and the adoption of a learning health system culture to develop integrated care systems and guide the management of health systems.

The integration of data relating to socio-environmental determinants of health can be used to advance healthcare and policy-making:

- ▶▶ The linkage of health data with demographic and economic data could provide a more holistic perspective of the causes of specific health conditions. For example, by quantifying the present burdens, future trends and economic impact of brain health conditions, which accounts for more disability-adjusted life-years than any other widely-acknowledged health threat, the [Brain Health Atlas](#) aims to leverage data to guide policy change.
- ▶▶ The linkage of health(care)-related data from EHDS with data from other future European data spaces could enhance innovation, societal development, competitiveness and sustainable development. For example, population health and provision of healthcare services could be improved by leveraging the context-aware network and sensing infrastructure of smart cities.

Cloud services in healthcare and healthcare platforms

Considering that digital transformation in healthcare requires implementation of resource-intensive and complex technologies, infrastructures and systems, healthcare providers, researchers and companies are switching to cloud or scalable distributed (e.g. fog, edge) computing services:

- ▶▶ Cloud computing can enable (the development of) [elastic EHRs](#), [long-term storage of medical images](#), [scalable clinical genomics analysis pipelines](#), [vaccines](#), or [Internet of Health Things solutions at scale](#). Data collected by the use of Internet of Health Things (such as wearables) can be analysed more efficiently in [cloud-based health data lakes with the use of AI/ML solutions](#). This can support the development of [population health management dashboards](#).

Cloud computing can also support the development of platforms:

- ▶▶ [Digital health platforms](#), as information exchange infrastructures, can connect different user groups in a meaningful way (e.g. physicians and

patients, researchers and patients, or hospitals and payers) to serve specialised business models in both clinical and non-clinical contexts;

- ▶▶ An [integrated enterprise platform for healthcare organisations](#) can intelligently connect front-office point of care actions with back-office resource planning and health administration functions.

Generative AI and other NLP applications in healthcare

Generative AI and other natural language processing (NLP) systems can automatically create preliminary clinical documentation from patient–doctor conversations, ease the paperwork burden for healthcare professionals, and allow more time to focus on patients (see e.g. [AWS HealthScribe](#), [Optum’s oncology-focused NLP system](#)).

Measuring and improving healthcare outcomes and efficiency

Data-driven solutions can measure and make health outcomes transparent:

- ▶▶ A dedicated health data ecosystem and data governance framework can empower patients to measure their own health outcomes across the EU and integrate into care their experiences in a standardised way. This can support the development of new treatments reflecting what matters most to patients, and can facilitate the transition towards value-based healthcare (see e.g. [Health Outcomes Observatory](#)).
- ▶▶ Understanding what risk factors affect all populations equally would create an opportunity to improve the effectiveness of healthcare policies not only at national, but also at pan-EU level.

Digital solutions can improve healthcare efficiency in various ways:

- ▶▶ Remote health monitoring can reduce unnecessary appointments and enable patients to receive the care they need. In turn, this can help to free up staff and hospital capacity to deliver on clinical priorities.
- ▶▶ A [persona-centric approach](#) to the implementation of connected healthcare workforce solutions can enable the linkage of the right technical configurations to the appropriate staff personas.
- ▶▶ Due to increasing demand for medical imaging to aid early diagnosis, guide treatment decisions and support therapy planning, a cloud-hosted platform integrating AI can reduce radiologists’ increasing workload by helping to prioritise worklists, improve detection to reduce diagnoses errors and automate manual tasks (see e.g. [Bayer’s Calantic](#)).
- ▶▶ Medicine optimisation decision-making tools can support safe, cost-effective prescribing to provide personalised care for patients, identify non-adherent and at-risk patients, enable physicians and prescribers to spend more time with a patient, allocate workforce and deliver savings (see e.g. [Optum’s medicines optimisation solutions](#)).



Barriers undermining digital health in the EU

Inefficiencies in healthcare

Inefficiencies in healthcare are often the repercussions of siloed datasets, manual data processing operations and/or uncoordinated/ad-hoc processes:

- ▶▶ 30% of global data is generated in the healthcare and life sciences sector, but 97% of data generated in hospitals remain siloed, stored on-site and unused ([Deloitte, 2023](#)).
- ▶▶ Lack of interoperability and data integration along the patient pathway impedes clinical and regulatory decision-making, and impairs the capability to draw more accurate insights about individual and population health (see also [Harvard Business Review Analytic Services, 2023](#)).
- ▶▶ There is lack of consistency between the data processing practices and processes of similar healthcare providers.
- ▶▶ Healthcare providers do not take advantage of the benefits of cloud infrastructure, which would decrease maintenance and security costs.

Lack of awareness and skills hindering the uptake of digital health solutions

The uptake of new enabling technologies (such as cloud infrastructure, AI systems or IoT devices) and their applications in healthcare are set back by human-factor related barriers:

- ▶▶ There is a need to better explain to patients the health-related benefits of electronic access to and sharing of health data ([European Commission, 2018](#)).
- ▶▶ There is a general gap in training healthcare professionals in clinical informatics and deployment of digital health applications.
- ▶▶ Healthcare providers do not foster patient access and adherence to digital therapeutics ([Dahlhausen et al., 2022](#)).
- ▶▶ The lack of decision-makers' expertise, education and skills are the main barriers for the uptake of AI in evidence-based regulatory decision-making (e.g. health technology assessments) ([Zemplényi et al., 2023](#)).

Shortages and uneven distribution of health professionals, and inequalities and inequities in access to healthcare

Despite the fact that the number of doctors and nurses per population had increased over the past decade, the pandemic highlighted serious health workforce shortages in many EU countries ([OECD/European Union, 2022](#)).

Shortages of medical staff (particularly in remote and rural areas) have created ‘medical deserts’. The WHO has declared that ‘the health workforce crisis in Europe is no longer a looming threat – it is here and now’ ([WHO, 2023](#)).

At the same time, patients in the EU experience inequalities and inequities in access to healthcare ([European Commission, 2022](#)). In 2019, a quarter (25.5%) of the EU population aged 15 years or over who needed healthcare reported having unmet needs for reasons of finances, distance/transport, and/or waiting lists ([Eurostat, 2019](#)). Digital health solutions, in particular telehealth, could provide effective (supplementary) measures to address some of these needs. However, systematic changes to deploy these solutions have been hindered. For instance, regulations and healthcare delivery processes that enabled greater use of teleconsultations during the pandemic were temporary and have been revoked ([OECD, 2023](#)).

Inefficient public procurement and funding schemes for digital health

Experience during the pandemic has given a sense of urgency to find new approaches to public procurement within European health systems. The current system is hindered by shortages of specialised procurement skills, methodological weaknesses and lack of connection with broader policy objectives ([García-Altés et al., 2022](#)).

EU/national funds and tenders often favour hardware-based solutions (rather than leveraging software-driven solutions and existing infrastructure). This practice is expensive, slow and can be critically branded as a ‘90s approach’ to developing IT infrastructure for healthcare.

Different national value assessment frameworks and lack of reimbursement pathways for digital health applications undermine innovation due to uncertainties around payer environments and inability to scale ([EFPIA, 2023](#)). There are also a lack of measures to support sustainable commercialisation models in digital health. Funding projects often have a ‘market entry barrier’ attached, meaning that developers cannot go out and promote the product before the project is concluded. Overall, there is a risk that the EU will fall behind in health innovation due to unfavourable environment for investments.

Fragmented regulatory framework on data protection in healthcare

The interpretation and implementation of rules concerning the processing of personal data in the context of healthcare is inconsistent across the EU ([Commission, 2021](#), [TEHDAS, 2022](#)). This poses risks for all stakeholders. There are no adequate and recognised standards on the anonymisation of personal data (concerning health). Conditions on data processing for scientific research purposes are fragmented. Some Member States retain cross-border data transfer restrictions (often as part of the criteria for the public procurement and use of cloud services, or within local healthcare regulations).

Lack of legal clarity on the use of data and new technologies in digital health

The complexity and rapid expansion of the regulatory landscape is creating uncertainties for stakeholders, including researchers and innovators in the digital health ecosystem, which not only slows down health R&I as legal guidance is sought, but can also negatively affect investment decisions where more legal certainty is needed to give investors confidence. Legal uncertainty amplifies integrity risks, increases compliance costs and deters innovators (especially SMEs) from entering or investing in the European market. Ultimately, this legal trend may deprive patients in the EU from access to state-of-the-art digital health technologies.

- ▶▶ There is a lack of clear consistency between EU legal acts relevant to digital health, particularly regarding the proper interaction between the GDPR, EHDS, Data Governance Act, Data Act, AI Act, Medical Devices Regulation, *In Vitro* Diagnostic Medical Devices Regulation, Clinical Trials Regulation, Cyber Resilience Act, NIS2 Directive, Product Liability Directive, Database Directive and Trade Secrets Directive.
- ▶▶ Regulatory duplications (such as rules concerning the conformity assessment of specific products in digital health under the Medical Devices Regulation, *In Vitro* Diagnostic Medical Devices Regulation, AI Act, EHDS, Cyber Resilience Act) unnecessarily amplify administrative burdens and costs not only for manufacturers, but also for authorities.

It is important to point out that imposing data localisation requirements, or excessive conditions for international transfers of (personal) electronic health data or the deployment of key enabling technologies would generate problems in European health systems and health R&I:

- ▶▶ The discovery, development and manufacturing of certain types of personalised, potentially life-saving medicines (e.g. CAR-Ts / precision medicine) takes place outside the EU. As this process requires identifiers to ensure traceability throughout the manufacturing chain, by imposing data sovereignty requirements, the EU may destruct essential international health data flows, which in turn, may hinder research and be detrimental to continued care activities (see also [Frontier Economics, 2023](#)).
- ▶▶ Without a thorough impact assessment, an EU Cybersecurity Certification Scheme for Cloud Services (EUCS) may hinder the uptake of cloud services in European health systems by providing 'blanket data sovereignty' requirements (see also [DIGITALEUROPE, 2022](#)). The EU should seek alternative ways to defend European 'strategic autonomy' in healthcare without undermining the development and global competitiveness of the European digital health sector.

Lack of interoperability in digital health

Divergent approaches to health data management undermine data quality, data transmissions, data analytics and overall operational efficiency in healthcare. Lack of interoperability and data integration means that there is no end-to-end view of the patient pathway, which hinders healthcare delivery and innovation. Effective interoperability implementation would improve resource management. Otherwise, healthcare providers have to spend time repeating the same manual processes in handling data, which could be substituted with properly implemented software and protocols. This would free human resources from administrative tasks to enable improved patient support.

Rules undermining the functioning of the digital single market in digital health

Outdated EU legislation and national prohibitions and discriminatory rules undermine the provision of both national and cross-border digital health services (such as teleconsultations or online pharmaceutical services). These restrictions curtail the convenience and value that patients could obtain out of access to such services, and in some cases, prevent timely access to diagnosis and treatments, putting at risk health outcomes.

As it stands, patients in 18 Member States cannot access prescription medicines online, whereas patients in 9 Member States benefit from this, many for over 15 years. This is not only a regulatory, but also a market failure ([Copenhagen Economics, 2024](#)). In essence, this has created tier 1 and tier 2 pharmacy systems in Europe. In the latter, both the supply side (customer-oriented pharmacies) and demand side (patients) miss out on improved access, which could be achievable via regulated online services for prescription medicines, including their secure and reliable delivery at home. Existing regulatory barriers make it unattractive for pharmacies to scale digitally. Repealing prohibitions and regulating online pharmaceutical services would be essential to advance equitable access to healthcare, better treatment outcomes, crisis preparedness, and fight against falsified medicines.

Lack of safeguards for IP rights protection in digital health

While the number of patented medical technologies is increasing in both the US and China, the corresponding number of patents in the EU has stagnated in the past decade ([OECD Science, Technology and Innovation Scoreboard](#)). Despite the importance of patents and other IP rights in incentivising R&I in digital health (including compensation of researchers and innovators for their trial-and-error efforts), the emerging EU legal landscape does not provide adequate and effective safeguards for the protection of IP rights, including trade secrets and regulatory data. While constructing a (health) data economy, the EU must ensure respect for obligations deriving from IP-related international treaties. Lack of IP protection in the healthcare and life sciences sector may expose stakeholders (patients, researchers, innovators) to significant risks.



Recommendations for EU digital health policy (2024-29)

Prioritise digital transformation within the European Health Union and healthcare-related policy instruments

Ensuring that digital technologies and data-driven solutions are central to the formulation of all EU health policies

The EU must prioritise digital transformation within the European Health Union and healthcare-related policy instruments. It is important to ensure that digital technologies and data-driven solutions are central to the formulation of all EU health policies. In addition to this:

- ▶▶ It would be useful if the Commission adopted a communication to set a common vision for a new era in digital health, building on the existing regulatory framework. This should outline the EU's plan to successfully implement the EHDS, enhance the use of data and new enabling technologies in health systems and health R&I, improve skills, reform funding schemes, and review regulatory shortcomings in the field.
- ▶▶ Due to the complexities of digital health, it would be essential to increase multi-stakeholder exchanges to understand the practical implications of (existing or planned) EU policy instruments in health, and how digital solutions can effectively support their implementation. Stakeholder inclusivity is a prerequisite for developing fit-for-purpose and impactful policies that can address patients', health professionals', health researchers' and other stakeholders' needs, while supporting the global competitiveness of the European health sector.

Implementation of the European Health Data Space (EHDS) without fragmentation

Once a fit-for-purpose regulation establishing the EHDS is adopted, the Commission needs to monitor its legal and technical implementation to avoid fragmentation. The active engagement of a broad range of stakeholders would facilitate responsible, trustworthy and impactful implementation of the EHDS. The co-legislative procedure has highlighted the complexity of regulating the EHDS, therefore, it would be useful to leverage the expertise of stakeholders from across the healthcare ecosystem, including those of the digital health industry, in the implementation of the EHDS at both EU and national level.

The Commission, together with Member States, should support and incentivise the implementation of the EHDS by:

- ▶▶ accompanying the EHDS with a roadmap for digitalisation of healthcare establishing uniform health data access and management across

Member States, including a common standard for data exchange and a unified approach to issuing data access permits;

- ▶▶ improving interoperability between healthcare systems and health IT infrastructures through harmonised international standards and public procurement criteria;
- ▶▶ providing uniform e-templates to facilitate the exercise of the rights of natural persons (through electronic health data access services), the registration of EHR systems and wellness applications, and filing of data permit applications;
- ▶▶ implementing a cross-border identification and authentication mechanism that enables the effective use of electronic health data access services and health professional access services;
- ▶▶ establishing a website for the EU Datasets Catalogue;
- ▶▶ encouraging effective and secure use of cloud services in healthcare;
- ▶▶ adopting a broader set of indicators to monitor the development of Member States in digital health.

Enhance the use of data and new enabling technologies in health systems and health R&I

Development of EHDS infrastructure and accompanying health data governance arrangements

The EU must consider how to make the EHDS fit-for-purpose, interoperable on all levels, and ensure its responsible and consistent implementation (with a view to connecting to other common European data spaces in the future). It should ensure that insights and evidence of best practices can be generated to inform targeted interventions in order to improve the health and wellbeing of populations across the EU.

The Commission, together with Member States, should build the necessary infrastructure for the EHDS to enable the development and interconnection of new health data governance arrangements (e.g. federated data repositories, health data cooperatives, interoperable open ecosystems). In the long-run, the infrastructure for the EHDS should enable the creation of an 'EU digital backbone' that can catalyse the further development of software-driven digital health solutions. This would bring significant efficiency gains, as it would ensure that the development of similar hardware infrastructure does not have to be replicated in each local environment.

Advancing the adoption of data-driven and digital approaches in healthcare

To overcome the digital divide, public investments in healthcare must ensure that no patient is left behind. Member States should create action plans to support the digital health literacy of vulnerable groups and individuals based on their health risks (e.g. patients living with chronic diseases or multi-morbidity conditions). The EU should encourage the uptake of digital health solutions while recognising ‘digital patient journeys’, involving innovative technologies along the whole patient journey from diagnosis to care. In addition to this, the utilisation of the EHDS must ensure inclusiveness and representativeness in data pools and approaches to address structural discrimination.

The EU should coordinate efforts to advance the adoption of data-driven and digital approaches in healthcare (e.g. personalised healthcare; telehealth and hybrid/blended healthcare; decentralised, pragmatic and registry-based clinical trials; real-world evidence; patient twinning; precision medicine; precision public health; population health management; value-based care).

Strengthening resilience and security in health systems

It is essential to reconsider the resilience of healthcare organisations in protecting data and ICT systems. Cybersecurity solutions should provide intrinsic security features and a holistic presence across the ecosystem. All healthcare organisations need to have a complete and mature cyber resilience program to ensure a “ready state” for withstanding cyber attacks. This should be a combined result of planning, technology and discipline, so that security teams know exactly how they are going to act when a breach is discovered.

At a higher level, the EU needs to reaffirm its commitment to European and global health security. The EU should continue to deliver on its plans to build a strong European Health Union that is capable of responding to public health crises, while also strengthening its international cooperation on global health security. The COVID-19 pandemic demonstrated the challenges posed by cross-border health threats as well as the solutions. It is important to acknowledge the potential value that multi-party international health R&I collaborations can bring to make health systems more resilient. This includes the need to securely allow data flows required for these collaborations.

Development of data-driven insights in healthcare

The use of data and new enabling technologies in health systems and health R&I should facilitate the development of data-driven insights to improve resource efficiency in health systems, implement evidence-based practices, enable risk stratification, and facilitate better individual and population health outcomes (potentially, in combination with data from other future European data spaces). As part of these efforts:

- ▶▶ The EU needs to coordinate to incorporate outcomes measurement in European health systems focusing on clinical outcomes as well as patient-reported outcomes (including RWE).
- ▶▶ As the combination of health datasets of a group of individuals can generate new insights into population health, the EU should leverage results from the use of electronic health data for secondary use (courtesy of the legal avenues offered by the EHDS) for the purpose of analysing population health in the EU.
- ▶▶ The Commission should collect and develop best practices for Member States on healthcare measurement, financing and procurement models that facilitate prevention, innovation (co-creation) and evidence-based decisions, and link payments/reimbursements to overall outcomes and value achieved for the benefits of patients and society/economy.

The EU should further the understanding of what constitutes high-quality RWD and reliable RWE, and counter a fragmented interpretation of these concepts:

- ▶▶ The Commission and the EMA should enhance cooperation with regulatory agencies across the globe to address current gaps posed by the lack of standardisation of RWD/RWE terminology and formats, and the heterogeneity of data quality across RWD sources;
- ▶▶ Policy measures should foster the quality, integrity and aggregation of RWD (e.g. responsiveness to treatment, diet, exercise, co-morbidities, and co-treatments) joined, categorised and used in the context of RWE, sharing back with healthcare providers and individuals the potential links between disparate data sets, in order to provide a holistic, insights-based bio-psycho-social approach to understanding populations' needs and challenges.
- ▶▶ There is a need to provide guidance on acceptance of evidence generated via computer models to support the implementation of digital twins in healthcare.
- ▶▶ RWE should be used to understand the value of healthcare solutions, to review and regulate products throughout their life cycle, including assessing their safety and efficacy.

Including the use of AI and data science methods in healthcare

The EU and Member States should facilitate the safe and responsible use of AI and data science methods across the spectrum of healthcare to enable the better understanding of diseases and their impact on patients, diagnose difficult-to-detect diseases, develop targeted and more effective treatments, and use healthcare resources more efficiently. When developing related policy instruments, it is important to bear in mind that an AI system is often used as a component of a larger ICT system, connected with Internet of Health Things. To address the risks and challenges of using AI in healthcare, robust (globally-

aligned) standards, best practices and guardrails are needed that protect patients, while nurturing innovation and recognising that AI evolves over time.

Improve skills and increase trust in digital health

Enhancing health workforce skills and digital health literacy

The EU should enhance health workforce skills through the development of a comprehensive health workforce strategy with specified goals, measurable targets, highlighting best practices and implementing a monitoring mechanism. The strategy should include policy measures to support the digital education and training of health professionals and other workforce in healthcare. It is crucial to ensure that the health workforce has the necessary knowledge and skills to deploy cutting-edge technologies, and process electronic health data in ways that it maximises its potential value while mitigating risks.

The EU should facilitate the development of general and professional training modules (as part of secondary and tertiary educational curricula). The current curricula of health professionals do not reflect the skills required to navigate modern healthcare delivery. Digital skills and interdisciplinary patient care are missing. As technologies are evolving (for example, by moving toward minimally invasive techniques and procedures), educational and training schemes need to keep up. The EU should also support (cross-border) educational programs (e.g. joint actions) to nurture a new generation of health data professionals (including health data protection officers, health data scientists, health data security specialists). Digital skills could be included in the EU requirements on mutual recognition of professional qualifications.

It is also important for Member States to facilitate organisational changes. For example, every hospital has a Chief Medical Officer, but it is time they also have a Chief Algorithmic Officer or CTO. The EU should encourage a shift from ‘treating an organ to treating the person’, for example, by creating an EU award to recognise the most patient-friendly facilities in Member States.

Public procurement professionals in healthcare should receive training and expert support to facilitate the procurement of appropriate digital solutions for health systems and institutions. There has been growing recognition that public procurement professionals in healthcare must possess specialised competence. This requires detailed understanding of the organisation of health services, including the complex interrelationships between different groups of health workers, changing technologies, and advances in models of care.

For the EHDS and digitalisation in healthcare to succeed, the EU must make significant efforts to raise public awareness about the potential value of interconnecting data and using digital technologies in healthcare. Public health campaigns, education and citizen science programs (such as co-creation in health R&I) could improve digital health literacy. They could increase trust and facilitate the exercise of the rights of natural persons (patients) with regard to

the processing of personal electronic health data concerning them. As part of these efforts, the EU should also develop citizen cybersecurity learning schemes, including an additional dimension for healthcare-related issues.

Incentivising multi-stakeholder collaborations and strengthening public–private partnerships in digital health

The EU should continue to incentivise multi-stakeholder collaborations and strengthen public–private partnerships to leverage the strengths and resources of each partner, and build trusted and sustainable digital health ecosystems. For instance, by forging alliances between governmental bodies, trade associations, private companies and educational institutions, stakeholders could collectively invest in skills development initiatives.

Strong collaborations between industry, academia and other research institutes are also crucial in advancing health R&I. These partnerships should seek to promote knowledge transfer, joint research projects and the exchange of expertise to bridge the gap between academia and industry. It is important to also include SMEs and start-ups to foster a dynamic and innovative ecosystem. Dedicated EU frameworks for public–private partnerships, such as the Innovative Health Initiative, are important for the ecosystem to thrive.

All funding and allocated resources should advance digital transformation in healthcare

Adequate resources for the impactful implementation of the EHDS, a dedicated EU digital health funding program and more efficient funding schemes for digital health

The EU needs to adopt effective instruments and incentives to support digital transformation in European health systems. This should include a dedicated EU funding programme to support digitalisation of health systems and impactful implementation of the EHDS, as well as to fund high-impact digital health pilots and large-scale deployments. Building on the Recovery and Resilience Facility (RRF), the EU should set up this program along targets and milestones aligned with the European semester, with built-in mechanisms to exchange best practices between Member States, and add incentives for outcomes-based care:

- ▶▶ EU funds should be allocated to create infrastructure for access to and seamless exchange/sharing of health data, as demonstrated by the example of the Cancer Imaging Initiative. Funding should also support cloud-based SaaS/PaaS/IaaS solutions, as well as data migration to existing services.
- ▶▶ A roadmap for implementation of the EHDS should identify data gaps and allocate funding for federated data infrastructures, as well as a European network of centres of excellence to promote R&I in the health

sector through the collection and use of RWD, on the model of the European Reference Networks.

- ▶▶ Funding is also required to enhance health workforce skills and digital health literacy, as outlined above.
- ▶▶ Healthcare operational programmes and projects should be tied to digitalisation and measurable outcomes.
- ▶▶ EU-level possibilities for innovation procurement should be expanded, following the example of the US Biomedical Advanced Research and Development Authority.

Harmonisation of value assessment frameworks, public procurement criteria and reimbursement pathways for digital health solutions

The EU should support cooperation between Member States to create harmonised value assessment frameworks and reimbursement pathways for digital health applications taking into account the specific features of certain solutions. The Commission should collect and develop best practices for Member States on healthcare measurement, financing and procurement models that facilitate evidence-based decisions, and link payments/reimbursements to overall outcomes and value achieved for the benefits of patients and society/economy.

Guarantee legal clarity and consistency in digital health policy within the EU

Clear, consistent and implementable rules

The digital health sector does not need another ‘tsunami of legislation’ in the coming years. Sectoral and horizontal legislation already provide a comprehensive regulatory framework. What EU stakeholders in digital health need are legal clarity, consistency and certainty. Ensuring these requirements would also help researchers and innovators in the EU to compete at a global level. These considerations are particularly important in the digital health sector where a sufficient degree of legal stability is necessary to assure confidence and predictability in making long-term investment decisions. This could be achieved by:

- ▶▶ ensuring harmonised rules concerning the processing of personal electronic health data for primary and secondary use purposes;
- ▶▶ ensuring that new EU legislations are with respect to the governance and safeguards of existing (international) IP rules in order to incentivise and protect health R&I in the EU;

- ▶ clarifying delineations and interaction between EU legal acts regulating safety, performance, quality and interoperability requirements for digital health products (cf. MDR/IVDR, AI Act, EHDS, CRA);
- ▶ harmonising rules on conformity assessment procedures across the EU, eliminating regulatory duplications and ensuring effective exchange of information between notified bodies with respect to the market authorisation of the same product intended for use in digital health.

Consistent and harmonised implementation of privacy, data protection and cybersecurity requirements

The upcoming review of the GDPR should tackle the problem that the implementation of data protection rules in the context of healthcare and scientific research is fragmented across the EU. This should be in support of the rules set forth under the EHDS. In addition to this, it would be important to clarify data protection (as well as privacy and security) rules when data processing takes place in IoT or big data environments.

EU regulatory framework on anonymisation and pseudonymisation needs further harmonisation. Anonymised data sets that are stripped from critical characteristics may not allow researchers to combine information and derive conclusions crucial for the development of better devices, therapies or treatments, and to draw insights about the entire patient pathway and long-term impact of treatments (RWE). This is also a relevant consideration for the training, testing and validation of AI systems in healthcare. For these reasons, the EDPB and EDPS should clarify the concepts, rules and best practices of anonymisation and pseudonymisation (taking into account state-of-the-art advancements in this respect), and provide guidance concerning their legitimate application to the processing of (personal) electronic health data.

Ensure ubiquitous, cross-border and international data flow needs

The EU should update legislation to ensure cross-border delivery of healthcare and related services (e.g. ubiquitous telehealth solutions, online pharmaceutical services), such as the Cross-Border Healthcare Directive [2011], the Regulation on the coordination of social security systems [2004], and the Community Code relating to medicinal products for human use [2001].

It is also essential to avoid excessive requirements for international transfers of (personal) electronic health data (in addition to the rules set forth by the GDPR). It would be important to ensure that data transfer requirements do not leave a leeway for inconsistent and fragmented approach between Member States, which could lead to different degrees of protection of data subjects.

Effective IP protection to incentivise R&I in digital health

‘IP underpins digital health. It provides coverage to protect the innovation of scientists and entrepreneurs while also facilitating easier access for users to

benefit from these advancements. Whether it is an innovative software algorithm for remote patient monitoring or a mobile application that offers personalized fitness plans and health tracking features, IP assures that unique and game-changing digital health solutions can be created and made widely available to improve healthcare outcomes of people across the world.’ [direct quote from [WIPO website](#)].

It would be important to ensure that regulatory rules aimed at establishing a (health) data economy in the EU remain consistent with international IP law (e.g. Agreement on Trade-Related Aspects of Intellectual Property; Paris Convention for the Protection of Industrial Property; WIPO Copyright Treaty) and existing protection of IP under EU and national legislations. While pursuing European policy objectives, the regulatory environment in the EU must remain competitive with the rivalling US and China, otherwise it will result in a competitive disadvantage and reduced access to state-of-the-art medical innovation for patients and health professionals in the EU.

Recognition of globally-aligned harmonised standards

Achieving technical and semantic interoperability and seamless exchange of data and information are critical to the success of the EHDS and improvements to clinical operations, patient outcomes and cost of healthcare. The interoperability of EHRs (electronic health records), in line with the European Electronic Health Record Exchange Format and internationally recognised standards (e.g. HL7 FHIR, DICOM, DICOM Web, and IHE profiles), as well as semantic and technical interoperability needs to be strengthened.

Globally-aligned standardisation, harmonisation and interoperability are essential to:

- ▶ ensure accuracy, consistency and availability of data across healthcare product lines in documentation and exchange of product information;
- ▶ provide access to EHRs and care plans for multi-agency teams to monitor performance, assess care pathways, and allow care in the home and support with limited staff and resources;
- ▶ accurately monitor the impact of digitally-enabled care and understand future projections for demand for digital pathways;
- ▶ eliminate barriers hindering crucial international health data flows;
- ▶ support the global competitiveness (e.g. export opportunities) of the European digital health sector.

Harmonised and interoperable machine-readable datasets are also a prerequisite to scale up the capabilities of new technologies (such as AI) in healthcare. To this end, the EU should set forth that datasets made available for dedicated purposes (e.g. scientific research) should be in line with [FAIR](#) principles (findable, accessible, interoperable and reusable).



Annex: digital health industry use cases

Avery Dennison: digital identification in healthcare	
Use case	
<p>Digital identification solutions, such as 2D barcodes, RFID (radio frequency identification) and NFC (near-field communication) have been disrupting industries and transforming supply chains. By assigning a digital identity to healthcare products, digital identification can help addressing problems related to patient safety, inventory accuracy, product waste, medication adherence or drug counterfeiting. Avery Dennison offers a suite of digital ID technologies that authenticate product history, provide tracking and inventory solutions, and conjure up richer consumer encounters.</p>	
Functionalities, stakeholders, scope of data and enabling technologies	
<p><i>Benefits of digital IDs</i></p> <p>A digital ID holds information about a physical item, such as a medical device or a laboratory sample. It spans the entire lifecycle of a product from manufacturing until it reaches the caregiver or the patient. Using real-time data, digital IDs can be leveraged for multiple purposes, such as track and trace, inventory accuracy, product authentication and patient safety by tracking medications from manufacturer to patient, ensuring correct dosages and timing. Digital IDs can also help to analyse inventory levels, supplier and sales data, KPIs and demand. This information can drive proactive decision-making and optimisation of workflows, leading to improved efficiency in the healthcare ecosystem.</p> <p><i>Applications examples in healthcare</i></p> <p>For pharmaceutical manufacturers, RFID technology enables end-to-end digitalisation, improves control over the quality of the product, and helps with recalls without modification to existing production lines. For supply chain operators, it offers end-to-end visibility, reduces supply chain disruptions, and helps manage inventory, recalls, and temperature monitoring. At the point of care, it offers increased visibility, tracking, automation and security capabilities for healthcare facilities and patients.</p> <p>NFC technology can be used for product authentication by enabling item-level authentication and traceability for the caregiver and patient. It can support remote patient treatment by enabling a digital connection with the product for feedback, insights and education. For example, the incorporation of atma.io can enable vaccine vials to establish direct communication channels with healthcare providers by turning them into digital platforms.</p>	

Bayer: digital twins in clinical trials
Use case
<p>The use case demonstrates the value of digital twin technology in innovating clinical trials and how Bayer leverages such technology in critical steps of clinical trials. It further exemplifies the existing barriers to implementing digital twins in clinical trials, as well as showcases how Bayer shares relevant knowledge of the digital twin technology on an open source platform – Open Systems Pharmacology.</p>
Functionalities, stakeholders, scope of data and enabling technologies
<p>Bayer has used digital twin technology to:</p> <ul style="list-style-type: none"> ➔ <i>Run simulations to inform dose selection for an anticoagulant medication</i> <p>Bayer has also developed virtual diabetes twins to predict the level of blood glucose that successfully informed insulin dosing. This technology has been instrumental in developing treatments to slow the progression of chronic kidney disease (CKD) and lowers the risk of cardiovascular complications in adults with CKD in type 2 diabetes.</p> <ul style="list-style-type: none"> ➔ <i>Predict the level of blood glucose to inform insulin dosing</i> <p>Bayer has also used digital twins to create virtual trial arms or ‘external control arms’, which can replace control/placebo arms in some clinical trials. This can help fill evidence gaps e.g. where an RCT (randomised control trial) is not feasible or ethically sound, in addition to reducing costs, overall development time and/or trial recruitment time.</p> <ul style="list-style-type: none"> ➔ <i>Accelerate and scale quantum chemistry calculations</i> <p>Bayer is further accelerating research by applying high-performance computing power. Therefore, Bayer is collaborating with Google Cloud to use their high-speed processors to run cutting-edge machine learning models and computationally intensive workloads so as to help accelerate and scale Bayer’s quantum chemistry calculations.</p> <p>Bayer - Digital twins in clinical trials</p>

CyberArk: identity security in healthcare

Use case

The drive to digitalisation in healthcare is built upon a suite of IT capabilities from the storing of electronic health records to the use of collaborative applications. These are run on IT systems, which are built and maintained by system administrators. To ensure adequate protection of personal data, protection is also needed around the activity of system administrators, so that they do not accidentally or maliciously exploit their privileges to view electronic health records, or they do not become fall victims of cyber attacks. [CyberArk](#) focusses on protecting the highest-risk users in organisations, in particular within the healthcare sector, to protect against external and internal exploitation of privileged and sensitive access, helping to address NIS2 and other country-specific security and privacy requirements.

Functionalities, stakeholders, scope of data and enabling technologies

The CyberArk Identity Security Platform provides intelligent privilege controls around all sensitive and high-risk access that can occur within a highly-digitised IT environment. These controls extend to both human and non-human access. In the latter case, an example would be the automated processes that need access to systems and data, which can be sensitive in nature. CyberArk protects the highly privileged access that machines often require, as these too can be an attack vector.

Furthermore, the solution suite provides protection to workstations from ransomware attacks to ensure health professionals can continue to work even whilst their organisation is being targeted by cyber attacks. Endpoint Privileges Manager provides proactive controls preventing ransomware from being able to execute its objectives and restricting its ability to spread.

CyberArk solutions include the following (non-exhaustive list of) capabilities:

- The discovery, secure storage and automated management of privileged credentials, helping to prevent these accounts from compromise by malicious actors.
- Tamper-proof session monitoring of system administrator access, delivering full accountability around all activity.
- Just-in-Time access delivered through controlled processes to ensure all access to critical systems is for legitimate purposes.
- AI-driven detection of risky activity with automated responses, including the ability to terminate sessions.
- Comprehensive secrets management to secure access required by automated processes to critical systems and data within healthcare.
- Endpoint privileges protection with in-built ransomware protection to prevent malware from being able to disrupt operations.

Johnson&Johnson: collaborative health research platform

Use case

[HONEUR](#) (Haematology Outcomes Network in Europe) is a collaborative research platform to improve the understanding of haematological cancers, by interconnecting clinicians and researchers from various institutions to create synergies in pursuing their research questions. The goal is to make studies quicker and more efficient, sourcing existing knowledge already generated elsewhere at a larger scale than possible by an individual institute. All this to create new treatments and improve outcomes for patients in Europe.

Functionalities, stakeholders, scope of data and enabling technologies

How data creates a solution:

HONEUR allows for data re-use from across observational studies. It is designed as a federated network in which patient data is stored locally at the participating institutes. This setup allows to run studies, respecting the local governance rules of each institute as well as achieving the capability to reach large scale data while always protecting privacy. It is a collaborative effort to conduct haematological cancer research and develop insights that would otherwise remain unattainable in isolation. No patient-level data are stored on the HONEUR portal – only aggregated results of a research question.

The outcomes:

- Sharing research insights with the wider research community.
- Rather than creating a central data repository, the HONEUR federated data network enables partners to keep full control over their data and the analysis.
- Greater patient empowerment and autonomy allows patients to take charge of their health journey and take proactive action.

Kelyon: digital health platform
Use case
<p>Kelyon helps to shape the future of healthcare with disruptive digital health solutions that combine innovation with experience to deliver and empower patient-centred care worldwide. Kelyon provides digital health and digital medicine solutions (including SaMD) for the prevention, diagnosis, treatment, recovery, monitoring and health promotion of patients suffering from chronic and complex diseases.</p>
Functionalities, stakeholders, scope of data and enabling technologies
<p>Kelyon digital solutions are based on three modular structured platforms customisable and configurable according to customer-specific needs:</p> <ul style="list-style-type: none"> ▪ kHealthNet is a smart, web-based digital platform enabling timely coordination and support of collaboration in Hub-Spoke networks involving healthcare professionals and clinicians belonging to different healthcare structures. Kelyon leverages new networks to break down barriers and create more value through a process-oriented approach. The coordination of the network's components guarantees the efficiency and effectiveness of the information flow that can be grafted into one of the specific phases of the disease cycle (prevention, diagnosis and treatment). ▪ kDiseaseManagement is a web/mobile patient management platform that supports healthcare professionals in treating and managing patients with chronic or complex diseases and empowers patients by enhancing their engagement in the disease management process. ▪ kPatientRegistry is a web-based clinical registry platform that supports health professionals through an interactive database to improve patient care by collecting and analysing health data, and facilitating research to identify the best care pathways for rare and complex conditions. <p>These solutions are driven by AI, machine learning and deep learning. With these functionalities, health professionals and researchers can evaluate available treatments, procedures and therapies:</p> <ul style="list-style-type: none"> - to better understand expected outcomes and make evidence-based decisions to share best practices; - to understand how patients with different characteristics respond to various treatments. <p>Kelyon serves a wide range of clients in digital health, including pharmaceutical companies, medical-scientific societies, and other healthcare and research organisations.</p>

mementor by ResMed: somnio app as a digital therapeutic

Use case

[mementor](#) is a digital health subsidiary of [ResMed](#) that develops and distributes digital medical products in sleep medicine and related fields. mementor's digital therapeutic, "somnia" provides access to evidence-based therapy methods targeting insomnia. The company's mission is to offer effective digital health solutions to treat physical and psychological conditions, aiming to bridge current gaps in healthcare and shape the future of digital medicine.

Functionalities, stakeholders, scope of data and enabling technologies

somnia, developed by mementor in collaboration with sleep medicine experts and psychologists, is the first permanently approved digital health application in Germany (DiGA, "App on Prescription") for treating sleep onset and maintenance disorders (insomnia) since October 2020. The app's content is based on Cognitive Behavioural Therapy for Insomnia (CBT-I). It offers personalised solutions based on individual information to sustainably improve sleep behaviour within 90 days.

- Although CBT-I is recommended as first-line treatment for insomnia, less than 1% patients receive it due to lack of experts and healthcare provider bottlenecks. Instead, more than 60% patients receive hypnotics/sedating antidepressants, meant for short-term treatment. somnio addresses the reality of insomnia treatment, delivering scalable solutions that address unmet needs and alleviate healthcare provider bottlenecks.
- somnio consists of an animated sleep expert (Albert), a sleep diary and CBT-I modules which engage, educate and guide patients through their therapy (including sleep knowledge, practical exercises, cycles of insomnia, sleep times, relaxation, sleep behaviours, thoughts and everyday decisions).
- The effectiveness of somnio has been proven through randomised controlled trials (RCTs) and real-world evidence (RWE), demonstrating its positive impact on patient care with:
 - 64% significant improvement in insomnia symptoms;
 - 64 min reduced wake after sleep onset;
 - 29 min reduced sleep onset latency;
 - 12 months stable effects.

Philips: AI-powered cardiac monitoring (ePatch)

Use case

Atrial fibrillation is the most common [cardiac arrhythmia](#). It significantly increases the risk of stroke, dementia, and heart failure, but frequently goes undetected because it often lacks noticeable symptoms and may only occur infrequently. On the other hand, demand of care is growing, and it results in increased pressure on clinicians. In this context, innovative approaches combining software, hardware and services into a powerful ecosystem can empower cardiologists and neurologists and enhance their ability to detect and diagnose atrial fibrillation.

Functionalities, stakeholders, scope of data and enabling technologies

Extended-wear ECG monitoring powered by AI is a newly designed service for continuous remote cardiac monitoring, recently introduced in the Netherlands, Sweden, Denmark and Spain. With this (patch-based) wearable, patients can continue their daily lifestyle (shower, exercise, sleep) while being continuously monitored up to 14 days (instead of one to three days with the current traditional Holter systems). The ECG analysis time can be reduced up to 40%, while the clinically validated algorithms detect over 20 types of arrhythmia events thanks to the deep-learning technology that interprets the whole ECG.

Beyond enhancing patient experiences and diagnoses, this new service aims to significantly alleviate the growing workload on cardiology departments while also driving cost efficiencies and can help to create a new standard of cardiac care.

[Philips: AI-powered cardiac monitoring \(ePatch\)](#)

Roche: connecting digital health solutions

Use case

Roche partners with labs, hospitals and healthcare professionals in healthcare systems to support patient-centric digital transformation, as well as broad access and quality care at the right cost.

[navify](#)® is the name of the Roche portfolio of digital health solutions. It connects the healthcare community, delivering medical, operational and financial value, accelerating innovation and unlocking opportunities. These software solutions strive to securely integrate data across patients' healthcare journeys, facilitating access to insights to help clinicians simplify targeted care decisions. Healthcare practitioners gain peace of mind by leveraging the latest innovation from Roche or other companies, with the support of Roche's healthcare expertise. By combining connectivity, interoperability and robust data privacy and security, Roche enables value-based care models.

Functionalities, stakeholders, scope of data and enabling technologies

The navify digital solutions connect healthcare systems across the care continuum and provide healthcare professionals insights needed to improve patient outcomes. It provides solutions in three main areas:

1. *Digital infrastructure*: These solutions aim to establish the connectivity to instruments, LIS, middleware and other systems in various healthcare settings in order to support efficient, reliable and secure lab operations, and access to operational and medical insights.
2. *Operational excellence*: These solutions drive end-to-end operational excellence across the care continuum, helping healthcare organisations achieve efficiencies, address staff shortages and activate data for insights.
3. *Medical insights*: These solutions provide the right information at the right time to enable better care decisions. They aim to drive additional medical value with lab data and help clinicians improve patient care. They include cutting-edge diagnostic algorithms to customers in various diseases, seamlessly integrated into their clinical workflows.

navify solutions are designed with a certified, multi-layer, secure-by-design cloud architecture, supporting labs with data integration and security, end-to-end operational excellence, and medical insights.

Siemens Healthineers: support to healthcare workforce

Use case

The World Health Organization (WHO) has warned that Europe's health workforce crisis is a "[ticking time bomb](#)". [Recent estimates](#) project a worldwide workforce shortfall of about 10 million health workers by 2030. In Germany alone, the health workforce shortage is projected to be 1.8 million by 2035 (see [PWC study](#)). Addressing the challenge requires a mix of human-capital and technology solutions. Below are examples highlighting technical solutions that can mitigate the growing crisis.

Functionalities, stakeholders, scope of data and enabling technologies

Siemens Healthineers solutions are embedded in the broader digitalisation of healthcare systems. The specifically developed solutions factor in diverse situations and manage the available resources more effectively:

- [WeScan](#). At the push of a button, so to speak, Siemens Healthineers provides additional qualified personnel remotely to support hospitals and radiology practices. This allows for more flexible staffing and shift scheduling to address structural problems and worsening staff shortages, particularly in the event of gaps in the shift schedule, during off-peak and night times, vacation or parental leave replacements, or complex procedures.
- [Varian Advanced Oncology Solutions](#). Remote treatment planning provides treatment planning as-a-service, including CT import, fusion, normal tissue contouring, and plan review with physicians to provide clinics in rural areas or those with skilled staff shortage to provide state-of-the-art RT planning for their radiotherapy care.
- [BEFUND24](#): A provider- and modality-independent platform that can be used to outsource image reporting to externally located teleradiologists. BEFUND24 provides access to radiology expertise and helps manage staff shortages and high utilisation, or when the supply and demand of the resource 'radiological image reporting' by radiologists is not optimally allocated. The platform provides a growing network of experts specialised in neuroradiology, musculoskeletal, gynecology, cardiovascular, oncology. Data exchange as well as administrative and financial processes can also be handled on this platform.

With these solutions, the workload of healthcare staff and shortages of expertise or skills in a given situation can be managed more simply and efficiently. While easing the pressure on the staff, digital solutions ensure that patients continue receiving the medical care and attention they need.



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The paper also benefitted from the contributions of DIGITALEUROPE's Digital Health Working Group involving representatives of corporate members and national trade associations.

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About DIGITALEUROPE

DIGITALEUROPE is the leading trade association representing digitally transforming industries in Europe. We stand for a regulatory environment that enables European businesses and citizens to prosper from digital technologies. We wish Europe to grow, attract, and sustain the world's best digital talents and technology companies. Together with our members, we shape the industry policy positions on all relevant legislative matters and contribute to the development and implementation of relevant EU policies, as well as international policies that have an impact on Europe's digital economy. Our membership represents over 45,000 businesses who operate and invest in Europe. It includes 106 corporations which are global leaders in their field of activity, as well as 41 national trade associations from across Europe.

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