

TOWARDS TRUSTWORTHY HEALTH DATA ECOSYSTEMS

How the reuse of data can create new services for the benefit of all

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Data can improve patient outcomes, foster research and accelerate the development of new health services only if it is shared between stakeholders and reused while respecting privacy, strengthening people's control over their data and guaranteeing transparency.

The working paper from the Finnish Innovation Fund Sitra provides guidelines for the future strategic use of sensitive data within European health systems. It addresses ethical, legal and self-regulatory frameworks for balanced data ecosystems, discusses the current challenges and establishes a set of recommendations for a new health and well-being data paradigm.

Sitra working paper

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Towards trustworthy health data ecosystems

This working paper was compiled by Sitra's fair data economy project in collaboration with the commentators:

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Foreword

Trust is a must – a statement often heard when speaking about the reuse of health and health-related data. In the spring of 2020, Sitra published its “35 proposals to make the European data strategy work” as a response to the European Commission Communication “A European strategy for data”. The new data strategy was part of a wider package of strategic documents that also included a communication entitled “Shaping Europe’s digital future” and the “White Paper on Artificial Intelligence – A European approach to excellence and trust”.

These papers support Sitra’s fair data economy vision, which is not state-driven or company-driven but a human-driven model of building successful digital services of the future based on trust and creating value for everyone. The services and data-based products should be created in an ethical and fair manner. Fairness means that the rights of individuals are protected and the needs of all stakeholders are taken into account – the future belongs to data-sharing ecosystems with multiple ecosystem orchestrators.

Enabling the reuse of data is crucial for research, development and innovations, but returning data back to individuals and creating more relevant services for them is equally important to keep the data flowing. To make data reusable, it should be made FAIR. Since 2016, the “FAIR principles” have been used as guiding principles to make data findable, accessible, interoperable and reusable. These principles should be basic requirements for any type of data, regardless of whether the data originates from the healthcare systems or individuals.

The European Health Data Space cannot be built only for public authorities or researchers, but should benefit the individual as well as companies using cutting-edge technologies. Building sustainable public-private-people partnerships are key for resilience. When working for the Nordic Health 2030 vision, we identified three changes needed – new social contracts, new data models and new business models. In a complex world we cannot innovate in silos. Researchers and professionals need to acknowledge the changed role of individuals. When handling sensitive data, like healthcare data, there should be safe ground for innovation. This is created through common rules and by ensuring privacy and transparency as elements of trust.

The aim of the paper is to encourage us all to rethink the role of the individual in healthcare systems. It is intentional that there is no clear discipline in focus in this paper. The future is made today, and it needs to be made in dialogue with a variety of stakeholders. I am honoured that so many high-level experts were willing to contribute to this paper. The commentators all had very different views on the field of health and well-being. I am also extremely thankful for the people who agreed to be interviewed and provided their valuable insight. Only by working together can we make the European data strategy work for us all.

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1. It's getting personal. The role of data in resilient health systems

Since the acceleration of the digitalisation of primary economic sectors, every individual generates ever-increasing data sets, linked to services offered by public and non-public entities. Each of us leaves, consciously or unconsciously, digital trails that then enter the local, national and global data ecosystem.

A data-driven economy also means new information-based health systems. The pooled and analysed data allows personalised decisions concerning prevention or treatment – by healthcare facilities along the care path and the patients themselves. Data is also an essential resource for building new services tailored to current challenges and expectations.

The goal of this working paper is to create guidelines for a person-centric, fair European data economy that fosters the building of new data-driven, privacy-compliant well-being and health services, ensuring a paradigm shift towards a modern health system.

This requires embedding the set of values into the data economy, including person-centricity, trust, a new type of communality and the principles of sustainable development. Under the new strategic approach, the mindset-shift of stakeholders and decision-makers will be triggered while new opportunities for growth and privacy-compliant innovation will be released.

Our vision

- **We believe that person-centred and data-driven healthcare is a matter of setting shared goals, guidelines and developing a clear road map that drives action.** For example, the European data space described in the EU data strategy can support responsible governance of data acquired from smart health and well-being services. This accountability is becoming – for the tech industry – one of the critical factors of market success. A new synergy between the empowered data sources (humans, citizens, patients) and data agents (service providers) – if based on trust – will pave the way to the development of personalised services respecting data privacy.
- **Our ambition is that every person has full transparency over what happens to his or her data, becoming an active co-architect of health and new digital services.** The leading principle of transparent data use should be based on the “four Ws”: **who** wants to know **what**, from **whom**, and for **what reason**. Individualised and tailored to people’s needs, health and well-being services developed on the basis of the principles of fair and transparent data processing will be critical for a sustainable health system of the future. It is also vital for empowering individuals to take greater responsibility for their health and well-being. This is a paradigm shift: from the focus on curing diseases towards data-based integrated and personalised solutions supporting well-being and empowering individuals.
- **We want to lay solid foundations for future healthcare in which more data is generated by every individual outside of the healthcare system.** European Union member states, in close dialogue with all stakeholders in health and social care, including digital technology developers, must start co-operating on shaping a sustainable transformation. Taking personal data, MyData, as a part of the healthcare system decision making process is essential.

2. Background

In February 2020, the European Commission published “A European strategy for data” (COM(2020) 66). The document envisions a European society making bold use of data in the decision-making process, in both the private and public sector, ensuring competitiveness and productivity, and securing the health and well-being of everyone.

The strategy outlines a comprehensive transition towards a harmonised data market based on European values. It describes the various development measures required for the large-scale use of data and data-driven products and services. In the European Health Data Space, interoperable data accelerates the efficient prevention and early diagnosis of diseases, the planning of care services and treatment, and evidence- and knowledge-based decision-making. Data is a valuable resource for healthcare professionals, a prerequisite for sustainable and flexible health and care systems that continuously adapt to the needs of individuals, including the accessibility and quality of health services.

Another strategy we refer to is the European Commission’s Communication on the Transformation of Digital Health and Care, published in 2018. The commission aims to support the secure access and exchange of health data; health data pooled for research and personalised medicine; and digital tools and data for citizen empowerment and person-centred care. Sitra believes that these goals can be achieved if we recognise the changing role of citizens from being simply passive receivers to becoming active co-creators of health and well-being.

Moreover, following the “35 proposals to make the European data strategy work” recently published by Sitra, we recommend the development of data spaces in a co-ordinated way. Although healthcare data is generally sensitive, many other forms of health-related data should be made available to improve prevention and well-being. The healthcare sector could learn a lot by working with other sectors.

This working paper is based on the assumptions of “A European strategy for data”, proposing detailed solutions for the reuse of data.

3. Transformation goals of data-based health systems

Data facilitates innovation

The European strategy for data highlights the access to individuals' health data, guided by appropriate regulations, as a critical factor that drives innovation. Enhancing the use and reuse of data generated by individuals and opening up access to data available in health systems and other sectors could strengthen the innovation capacity of European companies, and research and development organisations. It also applies to data sharing between different sectors of the economy. Much data – yet not seen as health data – can be utilised in healthcare, for example, behavioural or environmental indicators.

The European Commission envisions common European data spaces to support authorities in making better, evidence-based decisions on the accessibility and efficiency of services and the sustainability of health systems. Better access to health data could significantly facilitate innovation on all healthcare ecosystem levels: in public health and prevention, population health management, health resources planning, decision-making, product and services development, education and research.

Access to data can save lives

In the strategy, the European Commission emphasises that every person has the right to manage his or her personal health data and to request the portability of data. When people agree to share their data, they have to be sure that it will be processed in health systems securely and ethically. This is particularly important in health systems – health and well-being-related data contains highly sensitive information that must be strictly protected and that is a key source of knowledge.

Access to data determines access to the right treatment, patient outcomes, high-quality health services, cost-efficiency and resources planning. For example, it can save lives directly, when a doctor needs an overview of a patient's health to provide appropriate help, and indirectly – in the long term – when a service offers prevention guidance. It supports building evidence-, best practice- and knowledge-based health services, as well as fostering effectiveness while reducing costs.

Although the General Data Protection Regulation (GDPR) has created a common basis for the use of personal health data, there are still considerable gaps in the management models governing access to data within and between the member states. The data ecosystem is fragmented and inconsistent. Therefore, the priority is to create new opportunities to collect and combine data between stakeholders, sectors and EU economies.

A democratic, person- and societies-centred approach to data in Europe will improve the health and well-being of individuals and societies, remove some of the health inequalities, strengthen health systems and foster economic growth by:

- enhancing co-operation for data processing;
- leveraging data for well-being;
- delivering new services addressing health and well-being;
- making Europe a leader in data-based innovation.

3.1 Enhancing co-operation for data processing

The European strategy for data highlights two crucial strands:

- The development of measures related to sector-specific regulation and soft law to create a European data space. The aim is to establish standards that can strengthen people's access to health data and data portability, including the removal of barriers to the provision of cross-border health services and products.
- The launch of actions related to the improvement of data infrastructures, the adoption of tools and the development of computing capacity, which will be necessary to build a shared health data space. In particular, member states will be supported in developing national electronic patient information systems. The cross-border exchange of health data will be scaled up and accelerated by using health data combined from secure, official patient databases (federated databases).

An emphasis will be placed on promoting access to essential health data sets, such as electronic patient records, genetic data (10 million genomes by 2025) and imaging data. Another goal is to enable the exchange of the electronic patient record summaries and electronic prescriptions between the 27 member states under the eHealth Digital Service Infrastructure (eHDSI) by 2022. By the end of 2020, Finland, Estonia, Portugal and Croatia will be able to exchange additional sets of data like imaging data, laboratory results and discharge reports. It will improve the opportunities for remote consultations and the use of data registers in the virtual networks of healthcare providers co-operating within European Reference Networks.

These activities will support the Big Data Europe project that aims to build innovative multilingual products and services, as well as facilitate preventive, diagnostic and therapeutic measures. Furthermore, combined data sets

support clinical care and are crucial in the treatment of cancer and rare and multifactorial diseases. Close co-operation between the member states will finally underpin research and innovation initiatives, as well as policy and legislative steps related to public healthcare.

Question:

What measures should be taken to strengthen co-operation on data exchange between the EU member states based on existing legislation and the new approaches planned in European strategy for data? What incentives are necessary to boost the data exchange between different stakeholders?

3.2 Leveraging data for well-being

In a fair data-based economy, data is a pillar of health, well-being and social cohesion of individuals. It refers to the broad range of health and well-being data, for example, nutrition, lifestyle or behaviour. The more integrated the various sets of data are, the better they reflect the current state and potential threats to the well-being of each person in the future.

Reliable data is a fundamental element of health literacy, determining decisions made by people, as these are directly or indirectly connected with their well-being. To make the best use of data, they must first be processed and translated into knowledge or actions embedded into new digital services.

The increasing coverage of mobile technologies leads to the growing adoption of mobile services designed to support individuals' lives. The data collected in such digital solutions could be used – with the consent of the owner – to provide users with high-quality, personalised services. Access to up-to-date lifestyle and health data helps to identify potential threats to well-being and enable the undertaking of preventive actions.

The benefits of these preventive measures are essential in terms of the well-being and health of individuals, labour market participation and the costs of the service system. At the same time, the development of new digital solutions is determined by access to data. It is a form of closed-loop data processing in which users and providers are bound to each other and the data flow is based on trust.

Question:

How can we integrate well-being data into healthcare decision-making processes and thus emphasise its importance? How can we promote low-cost, accessible and affordable solutions for collecting well-being data so that all residents are beneficiaries of healthcare, prevention and data-based well-being?

3.3 Delivering new services addressing health and well-being

New digital solutions are transforming the way people are accessing and experiencing health and well-being services. Smart devices and wearables like activity trackers, smartwatches and smart jewellery enable the measurement of vital signs. Some solutions include elements of gamification that enhance the experience with digital services. Advanced tests that a few years ago could only be performed in professional laboratories can now be done at home. This paradigm shift towards *home as a point of care* has accelerated during the COVID-19 pandemic when millions of people switched to telemedicine consultations.

A new generation of smart devices enables tracking of not only the number of steps, but also heart rate, ECG, quality of sleep, mental health and stress levels. Affordable medical-grade mobile devices precisely measure blood pressure and blood glucose level, providing reliable feedback on the user's health status.

People are using these technologies for chronic disease management or for setting personal health and well-being goals. Using mobile applications and smart devices, people are generating and collecting increasing volumes of valuable data. If in turn this data could be used by different market enterprises with the consent of the data owners, an added benefit can be achieved. If seen as an asset for better health and well-being, data use by public organisations and private companies, with the consent of their owners, could benefit individuals in the following ways:

- personalised feedback on the state of health/well-being enables **more informed decision-making**;
- self-generated data can be provided to healthcare professionals – doctors and nurses – to **improve diagnosis and treatment**;
- access to data **empowers patients** to become the co-creators of health/well-being;
- new social and health services can be designed and developed to **match the needs of individuals and societies**.

From the perspective of the health systems, person-generated data allows them to:

- plan, provide and monitor personalised treatment and services;
- increase the effectiveness of medical/well-being interventions;
- exploit untapped data resources and their potential;
- accelerate the shift from reactive to proactive healthcare;
- provide new services in rural areas or areas with a poor healthcare infrastructure;
- boost the value of data by opening it up to other sectors and organisations.

The new human-centred approach puts each person at the centre and enables providers to deliver personalised and targeted services, respecting the right of every human to decide on how the individual data is used and processed. This approach makes it possible to address the most significant health challenges.

Question:

Should some strategies be developed for the use of well-being data in healthcare systems to ensure that a broader set of data is included for decision-making by professionals and patients? Who is eligible to decide which ethical principles should be applied to data processing?

3.4 Making Europe a leader in a data-based innovation

The adoption of person-centred and data-driven health and well-being services, including developing new services and business models, requires new regulations, including universal principles and management frameworks related to the use of health and well-being data.

Following the European Commission's public consultation on the transformation of health and care in the Digital Single Market, 80% of respondents agree that sharing health data can be beneficial. The willingness to share data with public institutions and for scientific purposes has been expressed in many other studies. Under one condition: each person has to have the right, and available instruments to exercise this right, to decide how their data is used.

Data reuse

The secondary use of data, if implemented on a large scale following best practices and respecting core values and transparency, opens up new possibilities for economic, social and scientific development in many fields. Examples include researching new medicines, developing new social services or prevention measures for the most vulnerable groups, restructuring health policies, better planning of resources and more precise epidemiological surveillance.

With a smart regulatory framework constructed around democratic values, promoting the respectful secondary use of data, Europe can pave the way to a unique democratic data economy based on civil society, trust and transparency. Such an ecosystem will boost innovation and research within the member states and in international partnerships. It can become part of a competitive and resilient economy and a best practice for others to follow.

New business opportunities

The European Union, with over 446 million citizens, leading scientific and academic centres, a fast-growing data-exchange infrastructure and a resilient economy, must keep pace with global technological progress to ensure welfare. By strengthening the data economy, it has the chance to improve its investment attractiveness and provide further social development and new jobs.

If accelerated by smart law and ethical principles, innovation "made in Europe" will stand out as perfect examples of something built upon strong human-centric European values. The adoption by many non-European countries of the GDPR demonstrates that values like privacy and data safety are shared in every part of the world and by different cultures.

A new model of a person-centred data European economy offers unique opportunities for tech companies. Ethical code embedded in digital services can be a new trademark for tech companies and start-ups, a mark of trust for customers. It is also a guarantee that such powerful technologies like Artificial Intelligence (AI), machine learning, robotics or genetic engineering will be developed only for the benefits of individuals.

Europe has a historic opportunity to shape the well-being of societies and individuals. For this to happen, new resources in the form of data must be handled carefully and thoughtfully. Europe should set the conditions for an EU health data space in a way that means health industries can be built on business models, in which people are at the centre.

Question:

How can we stimulate a new culture of innovation with a balance between privacy, individual/public interest and economic growth in a data-driven society?

How much data should be collected by third parties (as much as possible – “data maximalism”; or only necessary data – “data minimalism”)?

4. Data-related challenges

Everyone generates data

The well-being and healthcare sector and its associated service system are highly information-oriented and data-dependent. Service providers gather and process large sets of data. They include clinical health data stored in electronic health records (diagnosis, treatment, medications, allergies, health services, laboratory tests, genomics) and well-being data (behavioural and socio-economic data, self-generated metrics like physical activity or calorie intake). Nevertheless, there is a thin line between those two categories: Data showing information such as heart rhythm, blood pressure, blood sugar level, body temperature, etc. might be eligible as health data (if they determine diagnosis or treatment), or as well-being data if monitored by wearables and used for self-tracking and lifestyle optimisation.

Together with the development of new digital technologies, miniaturisation and decreasing costs, there are new forms of data that are being gathered and processed to improve treatment and prevention outcomes. Every person generates terabytes of data in their lifetime. Gradually, that data is becoming available in a standardized and accessible form.

A new data contract between individuals, the private sector and government

The exponential development of medical and consumer technologies leads to a decreasing cost of data acquisition. The cost of sequencing a human genome has fallen from over 100 million US dollars in 2000 to less than 1,000 US dollars in 2020. Some of the new generation of smartwatches have built-in electrocardiograms comparable in quality to those of medical devices. Individually conducted ECGs are now

more available and have become much cheaper compared to ECGs carried out by qualified medical workers in healthcare facilities. But as the availability increases, so do both the associated risks and benefits. It is, therefore, urgent to agree on an ethical framework for their use.

In a data-driven economy, only a new data-based relationship between individuals and organisations/business can support a prosperous digital economy. For the best outcomes, a few conditions must be met: a stable regulatory ecosystem that generates trust for data sharing, access to structured data, an interoperable data infrastructure and a willingness to exchange data. Despite the increasing availability of data, its potential for treatment, decision-making and science has not yet been fully explored – only a small percentage of available data is reused.

The following challenges must be addressed when moving towards the fairer reuse of people's data:

- removing the diversity of national legislation across the EU;
- overturning the lack of data comparability and interoperability;
- changing outdated cultures and non-digitalised health systems;
- lack of data-related skills and digital literacy (including the digital divide and socio-economic inequalities);
- disruption caused by new competitors entering the market;
- overturning a lack of trust and transparency;
- dealing with emerging health threats;
- public health crises (COVID-19).

MyData:**moving towards a human-centric vision of personal data**

One of the initiatives aiming to empower individuals by improving their right to self-determination of their personal data is MyData. This international non-profit organisation's mission is to empower individuals with their personal data, thus helping them and their communities develop knowledge, make informed decisions and interact more consciously and efficiently with each other as well as with organisations. This requires three foundations:

- trust and confidence that rest on balanced and fair relationships between people, as well as between people and organisations;
- self-determination that is achieved not only by legal protection but also by proactive actions to share the power of data with individuals;
- maximisation of the collective benefits of personal data, by fairly sharing them between organisations, individuals and society.

4.1 Heterogeneous national legislation across the EU**Healthcare and digital health**

Data pertaining to health is highly sensitive and subject to national legislation and the privacy rights of citizens in constitutional provisions. Additionally, every EU country regulates the collection and processing of data in health and social services individually. Regulations on healthcare systems remain the competence of the EU member states. But the EU can initiate a harmonisation of laws on specific issues. One example is the Medical Device Directive (Council Directive 93/42/EEC of 14 June 1993).

However, EU health policy has also been the subject of co-ordination in many forms: by setting up specialised agencies (European Medical Agency EMA, European Centre for Disease Prevention and Control ECDC); EU health programmes; EU joint actions or directives (for example, the Tobacco Product Directive); and EU action plans. Regarding digital health, in 2018 the European Commission published the “Communication on enabling the digital transformation of health

and care in the Digital Single Market; empowering citizens and building a healthier society”. The document identifies the core priorities for digitalisation in healthcare.

Data exchange between EU countries exists in cross-border social security and health services related to labour mobility between the EU member states. It primarily focuses on the reimbursement of healthcare costs. EU countries have recently started to exchange data on medication (electronic prescriptions) and electronic patient records in the form of Patients Summaries. This was made possible in 2018 when members of the European Committee for Standardization (CEN) approved the European Standard for Patient Summaries for unplanned, cross-border care.

Nevertheless, data exchange and processing comply with various other national laws making the collection and use of data non-transparent and thus contributing to lower public trust and privacy concerns. The latest initiative to change it is the new European strategy for data, which aims to foster the roll-out of common European data spaces in crucial sectors, including health.

Privacy and data sharing

More than two years after the General Data Protection Regulation came into force, most of the EU member states have adopted the new principles and adjusted national legislation. Still, there is much more to do. One of the challenges is ascertaining the individual's right to control the use of data, including their sharing of it – also cross-border – with third parties. Even if fully compliant with the GDPR framework, data collection and processing remain unaligned.

Sector-specific legislation does not provide convergent opportunities for the use of well-being data. Today, the consent of an individual to process the data is not a guarantee that the data processing will be fair and consistent with ethical guidelines. Data circulates in national or international data ecosystems and loses its affiliation with the source (data owner). We can say that in the present data ecosystem, control over data is disrupted and cannot be fully enforced.

Such an ecosystem does not support the changes driven by a digital transformation in health and well-being. Individuals are often willing to share their data if in return they receive services – or can contribute to their development – that allow for improving health and well-being. Many decide to donate data for scientific purposes by taking part in digital clinical studies.

One of the biggest challenges is to regulate data flow management and the well-being and health data transfer between different service providers. It is currently out of the data owner's supervision. As a result, a lack of standard interfaces (data interoperability) and procedures (data portability) results in the fact that data cannot be used in large-scale projects where different parties are engaged.

Another issue is the usage of data in cross-disciplinary, cross-border scientific projects. This occurs when the data is used for primary purposes (treatment) and for secondary purposes (not for treatment), for example for

knowledge-based management (training of medical staff, public health management), research or innovation. Making health data available for purposes beyond its intended primary use is in part addressed in the European Health Data Spaces outlined in “A European strategy for data”. Here also, transparency of the data flow is required for a more person-oriented data economy.

4.2 Incompatibility of data and interoperability shortfalls

Uneven standards

The basic condition for the exchange and processing of data from different sources is its compatibility. To date, most attempts in the European Union to create a common framework for well-being data in this regard have failed. One exception is the exchange of essential health data in cross-border healthcare that was recently regulated upon by the eHealth Digital Service Infrastructure (eHDSI) and implemented by the European Commission and member states through the Connecting Europe Facility (CEF) Programme. The eHDSI allows the exchange of two sets of health data: patient summaries and ePrescriptions.

Still, there is much work to do to achieve broad, pan-European data compatibility. It is necessary to achieve legislative compatibility (common interpretations of the GDPR) and data compatibility between organisations. This requires a harmonised set of basic concepts. Although many EU member states have recently undertaken some initiatives to introduce interoperability standards, some data classifications and definitions, the strategies and adapted solutions vary by country in the EU. It is essential to perceive the compatibility of data from the four angles of interoperability: foundational, structural (both of which are technical), semantic and organisational (see the definition of *interoperability*).

Data saved in different formats

There are also shortcomings in technical interoperability. The implementation of standards such as HL7, FHIR (Fast Healthcare Interoperability Resources) or SNOMED CT (Systematized Nomenclature of Medicine Clinical Terms) is still ongoing. Many mobile applications or systems that are collecting and processing well-being data are developed in silos – they are unable to communicate with other systems.

Example: if software developer A does not share the application programming interface (API), developer B cannot integrate its own applications with solution A. The result of this lack of harmonisation is that the export of data from one digital application to another is often only possible within the solutions of one developer.

This unaligned data environment neither creates favourable conditions for the development of SMEs in a data-based economy nor empowers individuals to use digital applications to support their well-being.

4.3 Outdated culture and delays in the digitalisation of health systems

Healthcare is a sector that generates one of the largest shares of human-related data. The growth of data sets is accelerated by the digitalisation of health records, new diagnostic devices and emerging technologies like smart devices, wearables and digital health services. Digitalisation of health systems among the EU member states is, however, progressing at different speeds. It is strongly dependent on economic development and other factors like culture, acceptance of data processing and public trust in state institutions.

Forerunners like Finland and other Nordic countries already have comprehensive, high-quality data available in digital-form healthcare registers (such as disease-specific registries and birth registries) and electronic health records

(EHRs). In some EU countries, there are government-administered registers that include data stored in the EHRs detailing information on diagnosis and procedures, such as in the Norwegian Patient Registry, the Danish National Patient Registry and the Swedish National Patient Register. Some of the registries even exist on a cross-border, European level – the European Platform on Rare Diseases Registration (EU RD Platform) is one example.

In contrast, some countries have not yet even developed essential digital services such as electronic health records or electronic prescriptions. In most of the EU member states, well-being data remains outside of the data-exchange system in health systems. These differences result from, among other things, the different priorities of health systems, financial shortages, regional approaches to data protection issues and public trust in digital services.

Culture and readiness to share data

Depending on the approach to data sharing, either data/organisational silos or an open data infrastructure have developed and become established in the EU countries over time. Data is often perceived as the property of a particular organisation, and therefore the readiness to share it with other stakeholders is relatively low. In addition, different models of co-operation between the state and the private sector, politically and culturally determined, must be taken into account.

Digitalisation is a change process determined by many factors – and leadership can play a crucial role. It is less about replacing manual processes with digital ones, and more about changing the attitudes to data processing and sharing, since data is at the heart of the digital economy.

The results of the Sitra study “The future of European companies in the data economy” published in 2019 show that only about half of the companies in Germany, the Netherlands and France consider themselves to be part of an ecosystem or network, and half see themselves as part of a conventional value chain. In Finland, even fewer companies consider themselves ecosystem members (38%). Future economies require the ability to operate in networks and ecosystems to become competitive.

4.4 Digital literacy

Gathering, using, analysing and interpreting data requires digitally skilled societies. One of the challenges is to bridge the gap in digital skills among different groups of individuals, so everybody can benefit equally from the data-driven economy. While digital natives fluently use new technologies to support their well-being, some groups lack the skills to access services that could improve their quality of life. Health literacy also determines the willingness to use digital services and the acceptance of data exchange. In contrast, many fears and prejudices are associated with a lack of digitalisation-related knowledge.

Equally important is strengthening the skills on a professional level.

- The education of physicians should be complemented with knowledge on how to include an individual’s data to bolster disease prevention.
- Local authorities responsible for health policy should employ a digitally skilled workforce to interpret data, combining different sources in planning new initiatives.
- Public health and research institutions should make the best of the data they have. This requires creating new positions like data experts in healthcare settings.
- Governments and academia should think from a broader perspective when creating new specialisations in medical studies, combining medical and technological competences, but also offering courses for physicians to strengthen their expertise in digital health.

- Hospital managers should enhance the digital competence of their organisations by promoting positions like Chief Clinical Information Officer or Chief Information Officer.

Case study. The UK’s National Health Service (NHS) created in 2018 a Digital Academy, which aims to develop a new generation of digital leaders who can drive the information and technology transformation of the national health system. The NHS Digital Academy is a year-long world-class digital health training course for Chief Clinical Information Officers, Chief Information Officers and aspiring digital leaders from clinical and non-clinical backgrounds.

Low digital literacy can also be associated with socio-economic inequalities. In order to avoid exclusion from the data-based economy, particular emphasis should be placed on equal opportunities between different social groups and the development of digital services aimed at those from vulnerable groups.

4.5 New players entering the market

According to the World Health Organization, global health spending was 6.77 trillion euros in 2017 (10.2% of gross domestic product). It is expected to rise at a CAGR (Compound Annual Growth Rate) of 5% between 2019 and 2023. The healthcare sector continues to expand faster than the economy. The growth prospects for the health and well-being sector will attract new operators.

In recent years, some of the world's largest companies, whose business models are based on data use, have shown interest in entering the health market. Among them, Google, Amazon, Facebook, Apple, Alibaba and Tencent. Some examples are Google's acquisition of wearable company Fitbit or Apple's new well-being features introduced to the Apple Watches, such as ECG and blood oxygen measurement, irregular heart rhythm detection, and quality of sleep tracking. Recently, Google and Apple developed a new function (exposure notifications) for the Android and iOS systems that enable contact tracing to support the fight against COVID-19 pandemic.

These "Big Tech" companies have a track record of outstanding experience in service delivery tailored to the consumers' needs, which is still often missing in healthcare. They also have the financial and infrastructural resources to expand their business by transferring the excellence in service quality and personalisation to other markets. Google and Amazon already have large data sets on their users.

There is a concern that by extending the scope of data with health and well-being information, they would be able to create more precise user profiles for better targeting of advertisements or developing new commercial services. In globalised economies, there is nothing wrong with new entrants to the health and well-being space as long as they are willing to follow the rules, including sharing data with other stakeholders and respecting consumers' privacy. In doing so, they become a part of a broader data ecosystem co-created with SMEs, healthcare and well-being providers, the

pharma industry, contract research organisations (CROs), med tech companies, academia and science.

On the other hand, Big Tech companies attract a negative image when it comes to healthcare. This is because they primarily perceive the sector in terms of business opportunities. When employees of the UK's National Health Service (NHS) were asked whether they would trust the major multinational technology companies to analyse patient data, only 12% said they would. Only 17% said they would trust companies to process data confidentially. Negative opinions about Big Tech companies can also strongly determine the willingness of residents to share data, undermining their trust.

"The future of European companies in the data economy", a survey commissioned in 2019 by Sitra, reported that only half (49%) of the small and medium-sized enterprises were able to identify potential sources of competitive advantage in the data economy now or in the future. The gap between these businesses and large corporations was considerable (19%). As SMEs are the backbone of the European economy and the future competitiveness of the European market depends on their capacity and innovation, Sitra has developed a six-month IHAN business programme concept to help companies create new data-driven businesses. The aim is to expand the concept internationally. All the legal, commercial, technical, ethical and administrative principles of organisations in the data network are described in a rulebook signed by the members.

4.6 Lack of trust and transparency

Trust in health and well-being data processing is as important as technical know-how and cultural factors.

In 2018, Sitra commissioned a survey “The use of digital services”, carried out with 8,000 respondents from Finland, France, Germany and the Netherlands. The results show that a lack of trust in service providers prevents people from using digital services, with 42% of the respondents agreeing or completely agreeing.

While the technical conditions for data exchange are relatively easy to set up, gaining trust is a much more complicated challenge. Among critical trust-building traits are transparency, reliability, citizen–government and citizen–business relations, competency, fairness and authenticity when it comes to social and commercial transactions, and leadership.

It is easy to lose trust, but it is tough to gain it back. Trust can be quickly undermined by data leakage scandals like Facebook–Cambridge Analytica (2018) or even legal health data transfers between organisations, for example, a partnership between NHS trusts and Google to process sensitive patient records (2019).

In the health and well-being sector, a lack of trust has become apparent in several countries. For example, the UK’s Care.data programme, which was intended to combine the patient records held by general practitioners and hospitals on a national level, was criticised for having an ambiguous opt-out mechanism, inadequate protective measures to guarantee privacy and the option of selling personal data to commercial operators. As a result, the programme was abandoned in July 2016.

“Public opinions and behaviour around health data in the GDPR era”, a study from 2018 by Decision Resources Group (DRG), found

that people have greater concerns over privacy in matters of health than for other types of personal data. Some 45% of people in France, Germany, Italy, Spain and the UK reported feeling more concerned about the privacy of their health data than other types of personal data.

In order to maintain trust in the processing of personal data, individuals must:

- be able to monitor the processing in real time;
- stay informed on the phase and scope of the processing of their data;
- be given an opportunity to withdraw their consent in real time;
- have a guarantee that their data is protected by default, meaning that the control over data is as easy as possible;
- have the authority to control who, why and for what purpose their data is used.

4.7 Emerging health and well-being threats

Healthcare spending is on the rise in most of the EU member states and is being driven by ageing populations and the growing burden of non-communicable diseases. Therefore, governments in European countries are looking for innovative solutions that could help increase the quality of care and maximise access to care services, taking into account the limited human and financial resources. By monitoring health and well-being data, many conditions could be recognised at an early stage, so personalised interventions through digital services could be applied.

One of the challenges that must be addressed urgently is the increase in psychological conditions. According to the Finnish Centre for Pensions, the percentage of pensions granted for mental health-related disorders increased by 20% year-on-year in Finland in 2020. The growing trend of social inequality is leading to an increasing number of young people at risk of exclusion from society. According to calculations by the Finnish

Ministry of Education, the cost to society of one young person affected by social exclusion is 1.2 million euros. Knowledge management offers increasingly effective means of intervention in both of these problems; high-quality data and analyses based on this data can be used to invest more in preventive measures that lead to savings for society and benefit for individuals.

Furthermore, lifestyle-related diseases are a severe threat to health systems. Obesity, strokes, type 2 diabetes and conditions associated with smoking, drug and alcohol abuse are in part avoidable. Smart digital services could support their prevention.

4.8 Public health crises (COVID-19)

The novel coronavirus pandemic has put many sectors to the test. In the short term, it will cause the biggest economic recession in the decades. However, it is still hard to precisely predict the future expansion of the pandemic and its long-term influence on the global economy and on people's health and well-being.

According to the Global Preparedness Monitoring Board (GPMB) established by the World Health Organization and the World Bank, epidemics and pandemics will become common in the future.

COVID-19 has stretched health systems' capacities to the limit. We have learned that sustainable health systems must be flexible to adapt to changing conditions. Thanks to the digital infrastructure and data exchange, citizens under lockdown could use safe teleconsultation services and even receive an electronic prescription without any need to visit a doctor personally. Patients with chronic conditions and those diagnosed with COVID-19 could be monitored continuously at their homes. People have started using mobile applications for contact tracing to help fight the COVID-19 pandemic.

For example, in Germany, the Corona-Warn-App had been downloaded 16 million times within a month of its launch. Over four million volunteers reported their COVID-19 symptoms through a mobile application, COVID Symptom Study. The app shared the data with King's College London and the NHS and helped scientists to speed up research into the virus. The data helped to identify six distinct types of COVID-19. With access to data, public health institutions can follow the dynamics of pandemics in real time and take preventive measures.

All the measures mentioned were possible as a result of secure data exchange, public trust in data processing and close co-operation between governments, civil society, business, academia and researchers.

The capacity to use data will be a key competence of future health systems for tackling similar threats to public health. Health and well-being monitoring, as well as pandemic management, will be efficient and precise, provided access to high-quality person-generated data is possible.

5. Recommendations for new person-generated data

EUROPEAN COMMISSION

Implementation of data reuse principles in legislative and funding instruments at EU level

The European Commission should act as an advocate for the reuse of data using the available regulatory tools. The European data spaces, in particular health data spaces, should be based on the principles included in this working paper. A code of conduct for processing and sharing person-generated well-being data must be formed in a dialogue with all stakeholders in the European data space. The European Union's Health Programmes or other European research and innovation funding programmes should focus on the projects promoting data sharing between different stakeholders. Financing should require the implementation of a relevant code of conduct, for example.

MEMBER STATES

Establishing a common European approach

Member states should enable the broader use of well-being and health data and develop a shared European network and management model for processing well-being and health data based on individual consent. The COVID-19 pandemic has triggered an urgent need for establishing pan-European services for resilient, connected health systems.

National digital infrastructures provide country-specific tools to tackle epidemiological challenges or public health threats. Access to combined data sets can strengthen infectious disease surveillance in Europe and initiate joint actions to address non-communicable disorders. National digital platforms and

infrastructure developed by the EU member states to monitor epidemics and infectious diseases should be compatible with each other. This will not only improve the response to cross-border health threats but will also help to co-ordinate measures introduced by the member states.

INDUSTRY

Ensuring that new services entering the market are reliable

We recommend increasing the transparency of entities through self-regulation, highlighting best practices and creating a legally binding code of conduct for services that use person-generated data. It is necessary to place the individual at the centre of all operations (data transparency by default), ensuring that individuals benefit from new services. By implementing the approach, the market for digital well-being services could develop more organically covering people's different needs and well-being goals. An individual should be able to trust that service providers act ethically and that the solution is compliant with best practices regarding data safety and sharing. The priority is to create and test digital services in data environments in which users' privacy and service interfaces are naturally aligned and tuned, while the user experience is enhanced.

Advancing new best practices and operating models of applying data

Public- and private-sector bodies should develop services and business models based on in-house and shared data, following the control over data by default guidelines. The GDPR, self-regulation honed over time by companies and organisations following ethical principles, and a shared consent for the use of the person-

generated data will all stimulate service providers and companies to develop new solutions based on transparent foundations. Sustainable solutions are based on open interfaces, follow innovation-friendly legislation and respect individual rights secured by the GDPR (trustworthy data business). Operating models, rules and ethical guidelines developed by companies and organisations will allow the regulations laid down by legislation to be adopted more quickly in practice. Companies and organisations will form data ecosystems where data moves seamlessly, transparently and safely between ecosystem members.

Ensuring that individuals, companies and societies benefit from the use of personal data

Person-generated data enables developing services and care plans that support well-being and health following the individual's needs. Companies can develop reliable personalised products and services.

Targeted treatment and prevention bring social benefits in terms of increased cost-effectiveness, quality and outcomes. National authorities can allow access to anonymised health data repositories for application developers, and innovators will gain new opportunities to advance their solutions, generating added value for consumers. In parallel with efforts to establish technical readiness, methods and criteria for gathering and processing data in these repositories are being developed.

INDIVIDUAL

Building awareness of data usage

In the turmoil of extended data usage, it is paramount that people's awareness about their data usage is improved. This is fundamental to gaining trust. Trust can only be built upon transparent information about the usage of data and people must have the right and the ability

to know where and when their health and well-being data is used. Understanding complex issues – such as AI, social media data usage, and the GDPR regulation and its associated rights – can be an issue throughout Europe, but a lot can also be done at the national level to improve the skills for digital understanding.

Developing skills in a digital world

Through awareness, people can extend their skills for a digital world. Some countries have also provided easily accessible tools for improving digital skills, such as understanding the basics of AI (Elements of AI course in Finland). The same method could be used to make people aware of their data rights and the basics of the data economy. These new skills will increase every person's understanding of their personal data value and finally empower them to demand better services and payback from service providers on the data they share.

Demanding value and better services for shared personal data

Data sharing needs to create reciprocal value. The continuous flow of data demands that individuals benefit from data by more tailored services or through precision medicine. Sustainable data donations only happen when focus is also on the individuals, not just on the needs of research, development and innovation professionals.

People have the right to know what the expected impact will be when they give consent to use their data. Personalised solutions now allow many more people to play an interactive role in their own health and well-being. They are also more willing to share their data when they can see the added value it generates for their life.

6. Call to action

Along with the development of new health and well-being technologies and the growing adoption of digital solutions, individuals are becoming a valuable source of data for healthcare providers, health systems and companies/organisations developing new services. Still, data is private property and must be collected, processed and exchanged following precise rules that respect democratic values, ethical principles and transparency.

Five vital elements need to be considered to maximise the potential of data in the European ecosystem.

1. Managing the cross-sectoral use of data

There needs to be a new culture of ethical data sharing to break data silos and span sectoral boundaries. Open data, open science and data donation initiatives should be supported in order to strengthen an individual's involvement in creating new digital services and developing research.

New co-operating models, including codes of conduct, for example, need to be created to allow companies and other bodies from various sectors to co-operate transparently in areas requiring data synchronisation, fully respecting the individual's right to control.

2. Creating a scalable infrastructure for viable data markets

There should be standardised and shared regulation within the EU member states, based on European values and relevant legislation for data processing and data exchange. This can be developed under the European strategy for data and the European Health Data Space (EHDS).

Standardising person-generated well-being data will allow it to be processed further and also used in health services.

3. New incentives to promote the use of person-generated data

Extending the range of data collected in electronic patients' records by person-generated data will allow a 360-degree image of health and well-being for every person, which is necessary to make the shift towards person-centred health systems.

The data- and digital-related competences of individuals, professionals, companies and public-sector entities and decision-makers need to be strengthened. Digital literacy should be included in educational programmes. Data science should become an integral part of medical education.

4. Activating individuals and businesses to share data

There need to be clear business-to-business (B2B), business-to-government (B2G), person-to-business (P2B) and person-to-government (P2G) rules on data sharing.

Investment should be encouraged to develop data-based digital services and to enhance new co-operation models by innovation-friendly and privacy-compliant regulations.

A new culture of ethical data sharing to break data silos and span sectoral boundaries is needed. Open data, open science and data donation initiatives should be supported in order to strengthen an individual's involvement in creating new digital services and developing research.

5. Developing data spaces

Bold leadership is needed on a European level to harness data in the European data spaces. Knowledge extracted from data will become fundamental for individual well-being and health, and data will be an essential component of services that provide added value. Privacy and the individual's right to decide about data use are the underlying principles on which new services and the use of data must be based.

7. Conclusions

To enhance the development of robust health systems in the data-based economy, Europe needs to adjust the legal framework to tackle current data-related challenges, develop shared ethical guidelines and codes of conduct, and advocate self-regulation of stakeholders. The appropriate measures must be taken immediately since public trust in digital services, the benefits of data reuse and the health and welfare of European citizens are at stake.

The working paper “Towards trustworthy health data ecosystems. How the reuse of data can create new services for the benefit of all” by Sitra lays solid foundations for future health ecosystems in which data facilitates innovation, enables the development of new innovative products and services, and accelerates economic growth. Access to information is vital – it saves lives, supports healthcare professionals in evidence-based decision-making, empowers patients and accelerates research in medicine. This working paper is an attempt to establish basic guidelines based on best practices. We have brought together different approaches, providing a starting point for further discussion and initiatives at EU and member state level.

Creating a fair data ecosystem is both a responsibility and a challenge. It requires leveraging individuals’ data transparently while ensuring everyone has control over the data. In our vision of data-based health systems, citizens can fully govern how third parties use their data and their privacy-related rights are well protected. This puts each person in the role of a co-creator of health and well-being and of new digital services. Private companies, research institutions and governments should be allowed

to access and share data made available by private individuals, and to use that data for the benefit of those individuals and the public as a whole. In this model, those who process information must compete for people’s data, which requires, among other things, the building of trust.

There should be no compromise on privacy. Every person must be guaranteed access to adequate tools to allow them to withdraw his or her consent for data processing at any time. Privacy and ethics compliance “by default” means that control over data (who has access to data, why, how long and for what reason) is as simple as possible, regardless of a person’s level of digital literacy.

Developing new standards requires the recognition and removal of some obstacles on the way to a trustworthy European health data ecosystem: the existence of heterogeneous national legislation, insufficient data compatibility and interoperability, contrasting levels of digital infrastructure in the EU member states, culture-related issues, a lack of data-related skills and digital literacy, and insufficient trust in the sharing of data. To ensure the benefits of data-driven health services, a broader range of health data should be available for reuse.

This change is possible with bold leadership at the European level, standardised and shared regulation within the EU member states, new co-operation models, a culture of ethical data sharing and the more extensive use of person-generated data. It requires opening up data silos at every level of the health system, investment in developing data-based digital services, and data- and digital-related competences.

8. Experts' opinions and reviews

Maritta Perälä-Heape, PhD, Professor of Practice in Data- enabled Healthcare Solutions and Innovation Ecosystems, University of Oulu (Finland)

There is a need to transform the management of health information from the point of view of self-care. The change cannot be just from the system level to the individual level; instead, it must be a combination of both. Today, people use well-being and health applications to gain personal information and for the use of service providers.

The health applications may be seen as a real-life evaluation of people's well-being and quality of life and could ensure better healthcare for the future. The real-life assessment and support of people's well-being will create value for everyone only if people have trust in digital services and health applications.

From the professional point of view, person-generated data is a new form of information for which there are as yet no validation mechanisms. Thus, trust in its validity is insufficient. Person-generated data and data-sharing principles need validation via research, which could be a priority area in the future Horizon Europe programmes. There is also a need to investigate the operating models for data sharing and knowledge transfer between higher education, research and businesses, and to build competences in the start-up and SME ecosystem. There is a need for guidance to catalyse the best, most efficient and trustworthy uses of health data in the interaction between patients and caregivers. The foundation of human-centred, data-driven care is the clarity of data-sharing purpose and ensuring that individuals are in a position to understand their personal data and the principles behind human-centred consent management.

A new culture of innovation with a balance between privacy and individual versus public interest is already here. Namely, an application called Koronavilkku, developed by the Finnish Institute for Health and Welfare in Finland, which tracks whether users have been exposed to COVID-19. The app also allows individuals to share any COVID-19 diagnosis anonymously with those they have been in close contact with.

This type of social innovation can have a big impact, since it offers direct benefits to the individual level and privacy is strongly protected. An innovation culture around the use of data generated by people has been recognised in a recent research study (TemPredict) carried out by the University of California, San Francisco. Also, the personal health tracking device OuraRing owners can share forward their daily measurement linked to possible experienced symptoms, which are typical if exposed to COVID-19. Even when there may be no direct benefit for the individual, the owners of the wearable devices can easily participate in public health research. Thanks to research studies based on the data generated by individuals, the public and economic benefit as a whole can be huge in the future.

Future solutions should serve the collective needs of multiple stakeholder groups and be readily adopted and to scale. Digital self-care services and the associated management of personal data can support the prevention of health problems and the self-assessment of the need for services, which in turn is generating significant cost savings in healthcare.

However, the development of data-driven care needs co-ordination at the European level. There is an urgent need to accelerate the efficient development and deployment of seamless eHealth solutions and mobile health applications linked to health data strategies. By employing best practices and sustainable integrated person-centred healthcare, we will be able to optimise health and wellness in Europe.

Dipak Kalra, President of The European Institute for Innovation through Health Data (i~HD); Professor of Health Informatics, University College London; Visiting Professor, University of Gent (Belgium)

This Sitra working paper is important and timely, given the growing recognition of the value across stakeholder groups of reusing health data for individual patient care, health and care improvement and for research.

The report rightly adopts a comprehensive understanding of health, well-being and social data. It emphasises, throughout, the continuum between healthcare and wellness, even though today's health systems underinvest in supporting patients with prevention and wellness management. There are well-articulated questions, to which there are no easy answers, about how best to integrate well-being data into healthcare decision-making processes and thus emphasise its importance for decision-making by professionals and patients.

There is an important recognition that data collected by citizens and patients will play an increasing role in the totality of the health data that is available for use and reuse. From my perspective, both data generated by citizens at home and by healthcare professionals have an essential role to play. However, I would agree that person-generated data is becoming more reliable and decision-making more valuable than in the past.

It is stated in the working paper that scaling up person-generated data is expected to increase autonomy and engagement in decision-making. I believe that individual access to professionally generated data will also increase autonomy and engagement. However, the major barrier will not be access to information but changing the culture to promote more inclusive decision-making. I would like to think that both patients and their healthcare professionals would benefit more from the totality of their jointly generated data.

This, of course, requires mutual respect of each other's data.

There is a welcome emphasis on patient-centred digital services and digital tools to bring health status monitoring, disease self-management and prevention strategies into the hands of patients on a day-to-day basis. These need to be scaled up. The report rightly highlights some of the key barriers to making the best use of data, including the fragmentation, the limited amount of data that exists in a structured and coded form, the limited extent of standards adoption (especially within innovations for person-generated data), poor data quality and heterogeneous national laws despite our common overarching GDPR. There also needs to be a willingness to share data, which is a different challenge to that of legislation and interoperability.

Patients and the public need health literacy and digital literacy skills in order to become better empowered to drive their own health and wellness trajectories. The report presents clear arguments for why investments are also needed in upskilling health professionals on digital tools and on prevention and patient empowerment.

The report states: "Our ambition is that every person has full transparency over what happens to his or her data becoming an active co-architect of health and new digital services". In reality, health data, especially that which is professionally generated, is also evidence for professional accountability. It might be seen as co-created information, even though there is one data subject. However, for every other downstream use of the data the wishes of the data subject should be paramount. The challenge is how to enable this in practice on a European scale. The planned European Health Data Space may play a valuable role in influencing the governance ecosystem across Europe relating to health data use. This includes building consensus and formalising European values around the uses and protection of health data.

Nick Schneider, German Federal Ministry of Health, Head of Division 511 – New technologies and data use (Germany)

The working paper offers a thorough and comprehensive analysis on the potential impact of the EU data strategy in the field of health, asks relevant questions and proposes concrete actions based on use cases. In particular, the solid foundation of recommendations on member state experiences offers an added value, which could be considered as valuable input to further national and EU action. It comes in a timely manner, as the European Commission has been mandated with the creation of the European Health Data Space and addresses a high priority of the current German Presidency.

It demonstrates the value of European integration and collaboration in the processing of and secondary use of data in the European Health Data Space. It also shows that the European Health Data Space should be shaped as a common policy area governed by the same understanding of the values and rules applicable to health data use and protection. A policy framework that strengthens the ability of those in Europe to use and reuse health data for research and innovation, to support health authorities and regulatory bodies in evidence-based decision-making, and to contribute to the competitiveness of the EU's industry. It highlights the need for interoperability on all levels, from legal interoperability on the political level through common rules, codes of conduct and joint actions, to the semantical and technical interoperability on the ground. It also addresses the need to integrate data from different sectors and to supplement the electronic health records with person-generated data through lifestyle applications and other sources. In addition, it addresses the need for rules for data exchange and access between different bodies vis-à-vis the digital transformation and the emergence of new players in the European health sector.

To conclude, the report presents all those interested in building a resilient and sustainable health system in Europe with valuable food for thought and a good starting point for discussions on how to shape a person-oriented and privacy-compliant European Health Data Space.

Disclaimer: This expert opinion was prepared by Mr Nick Schneider, Head of Division 511 – New technologies and data use at the German Federal Ministry of Health, in his personal capacity. The opinions expressed in these comments are the author's own and do not necessarily reflect the views of the German Federal Ministry of Health, or the German government.

Michael Rebhan, Senior Principle Scientist at Novartis (Switzerland)

The working paper by Sitra provides an excellent starting point for designing a European approach to the data-driven innovation ecosystems of the future, where they touch on topics related to health and well-being. While we have many of the fragments already, we need to find a better way of combining them in a meaningful way, into systems that provide sustainable value to many.

How can we overcome the many obstacles on the way, when data needs to cross borders and the walls of institutions or be better integrated around the whole patient experience? Data can save lives, but that is not enough to find that path and the shared goals that drive its realisation. As there is a limited history of aligning goals and incentives between many stakeholders in health, we need to create better conditions for faster distributed learning in this area, including ways of measuring value more inclusively, experimenting with incentives that may work for some “personas”, but not all.

If you cannot measure (or visualise) it, you cannot improve it. Such an innovation ecosystem may then create new innovative (digital) services if the economic conditions are favourable to attract innovation. New kinds of product-service bundles may also emerge, including the partnerships and aligned goals

that enable them to grow, creating even more value, more sustainably. As a philosophical basis, European values are great, but may also complicate the global scale-up of such product-service bundles if we fall back into a local mindset.

But what could happen if we learn how to make this exciting for many future non-European customers as well, inspiring and engaging for many? Enabling better prediction may play a crucial role in the initial phase of ecosystem building, to help us see risks earlier and prevent bad outcomes in health. Suppose we can validate potentially value-generating hypotheses better and faster, in new areas; that we learn how to embed them into a real-world context, using a deeper understanding of the patient journey. By selecting a participatory approach, that is, using methods similar to Design Thinking, we may come up with totally new solutions we cannot even imagine right now, which are human-centric by design and more value-centric from the start. Unleash the creativity that is waiting to be engaged.

How do we get started, with all this complexity? How about first prioritising the questions that have a significant impact at the population level, those that are currently challenging to solve, but easy to understand for many. And then go creative, show what we are made of, and put the fragments together, in new ways. Connect the visionary idealists with pragmatic reformers, learn how to be more inclusive and agile along the way, as we keep our eyes firmly on understanding what quality means in this new ecosystem context. As we learn this, we will face many difficult trade-offs, which we can make more transparent, understandable and manageable, if we tap into all those brains who care about solutions. I do not think that this is impossible, even if I admit it sounds a bit idealistic.

Professor Dr Jörg F. Debatin and Lars Roemheld, health innovation hub, Federal Ministry of Health (Germany)

We applaud the authors' commitment to improving care delivery through better data. In this opinion, we want to outline three specific requirements for regulatory work, and to suggest potential solutions.

1. Despite widespread agreement that "anonymous" data is of vital importance for the advancement of medical research, surprisingly little principled thought has gone into how this idea might be realised. Anonymising increasingly comprehensive health data in ways that stand the test of time is quite challenging, even if problematic cases such as genetic data are excluded. To mitigate these issues, we suggest continuing investment into infrastructure and research around useful and pragmatic approaches such as the federation of analysis, synthetic data and robust, automated query-based systems for privacy-preserving data analysis.

Where strong anonymisation is not possible, the GDPR still allows for public interest to outweigh individual risks. Despite citizens' absolute authority over their personal data, large societal benefits might justify small risks to individuals' privacy. These exceptions require explicit regulatory approval; it is on innovators to reason convincingly for the societal benefit, and it is on national regulators to take measured risks in allowing exceptional use cases.

In allowing valuable data uses that can reasonably be expected to avoid disproportionate risks to personal privacy, we can, piece by piece, create areas of innovation. From a regulatory perspective, we would like to see more stringent punitive deterrence for infractions of data privacy – dealing with citizens’ health data should force the data processor to accept some of the risk associated with handling it. Even so, some personal data might eventually leak. To prepare for this scenario, we also need prescient legal bans on data abuse – from certain forms of insurance pricing to using ancestral health data without an individual’s explicit consent. Again, to be effective, these bans require sufficient deterrents.

2. We require a more basic infrastructure. While economic incentives might suffice for some roads to be built, a reliable and ubiquitous infrastructure has always depended on the social co-ordination provided by governments. Today, entire industries depend on access to data. It should not be surprising. Therefore, government intervention is required to provide a reliable data infrastructure. We think that mandatory interoperability and standardised, open interfaces constitute such a crucially missing infrastructure.

Requiring data handlers to offer complete and timely data in standardised, open formats builds data roads for innovation. While a code of conduct can provide a welcome start to co-operation, we believe that obligatory standards are required to overcome economic incentives to create yet another walled garden. And we freely admit our own country could have been a more effective champion of international standards in the past.

3. Europe’s strong safeguards around patient privacy make it more difficult for stakeholders to collect representative data. This inhibits transparency over the fairness of care access and of outcome quality in general. The lack of an adequately representative test further complicates the development of practical AI applications. Here, too, lies an opportunity for infrastructure. We suggest the collection and curation of a sample of high-quality clinical data from across the EU exclusively for testing and approving novel AI applications for general use in care. This measure would support the notoriously difficult transfer of AI from the lab to patients safely.

This working paper has identified several specific needs for better care delivery through data. Let’s get to work!

Summary

A fair data economy is a concept created by Sitra for a European human-driven data economy. A human-driven data economy is an alternative to a state-driven or company-driven data economy and well suited to Nordic welfare state ideals. Our digital everyday life generates data, the refinement of which into knowledge demands a wide range of competence and resources, but also enables innovation and competitiveness.

The purpose of this working paper is to create guidelines for how data can be used to promote health and well-being and what this requires from us, decision-makers and the entire sector.

The authors believe that a human-driven, fair data economy that creates new data-based, privacy-protected well-being and health services guarantees a transformation towards modern health-service systems. The target state is a human-driven healthcare system that uses data extensively. This requires the setting of shared targets, the definition of rules and the creation of a clear and shared plan to guide actions. A new kind of co-operation is needed between data administrators and data users.

There should be full transparency so that everyone sees what happens with their personal data and how it is used. With the aid of transparency and good data literacy, individuals may become active agents in promoting their own well-being as well as co-developers of new digital services.

Digitisation and the versatile use of data lay the foundation for multi-local healthcare of the future, in which data produced by the individual outside institutions and care facilities is as valuable a part of care, treatment, people's engagement and service planning as data generated by conventional systems. States, service-providing stakeholders and technology developers must jointly initiate a sustainable transformation towards more human-driven services.

In spring 2020, the European Commission outlined Europe's digital future in three key communications related to the digital strategy and, as part thereof, the European strategy for data and the ethical use of artificial intelligence. The data strategy defines the path towards a European single market of data. Its goal is to improve the availability and sharing of data to fuel new services and innovations. The COVID-19 crisis further highlights the significance of innovations, but in post-crisis actions the protection of people's privacy and the shared value base must still be taken into account.

With the aid of examples, this working paper describes the significance of data as an enabler of change. An adaptable and sustainable healthcare system of the future needs data as a basis for innovations. Efficiency and impacts cannot be reached without a solid knowledge base. Data must be made more easily available and it cannot be used in silos. Instead, good use must be made of all competence in the production of more personalised services. This requires extensive co-operation among public and private parties as well as a wide range of actions, from soft regulation and rules to a new infrastructure and the integrated use of smart devices in healthcare processes. This is a considerable change in attitudes and culture, which also opens up significant new business opportunities. Could mission-based technological development be a new chance for Europe?

The working paper also provides extensive descriptions of challenges related to the use of data. Actions are required to harmonise the EU's fragmented legislation and to ensure data interoperability. Digital literacy must be constantly developed and related lessons must be learned from new operators in the sector. A lack of transparency and societal discussion erodes trust in the actions of authorities. Threats to public health, such as COVID-19,

increase the importance of privacy protection at the same time as joint operational capabilities are improved.

The publication provides key recommendations to the European Commission, the member states, the sector and all of us. A systemic change requires actions at all levels of society. That is why the discussion about the actions required and their execution in line with the European value base must begin now.

Finally, the working paper presents five key factors that enable society to make full use of the potential of data in European healthcare ecosystems.

- Creation of a management model for the cross-sectoral use of data.
- Creation of a scalable architecture for data markets established under joint rules.
- Promotion of the use of personal data with new incentives and training actions.
- Encouragement of individuals and companies to create data-based innovations. Companies must be capable of commercialising innovations and individuals must find relevant and useful new digital services. Open science and citizen science are trends that should be taken into account in European decision-making.
- Long-term, human-driven planning of data spaces using multidisciplinary competence and the European value base.

One of the key goals of the working paper is to prove the need for a pluralistic and diverse discussion. For this reason, we wanted to include both expert opinions and co-authors from different sectors and professional backgrounds. The future is made together. In uncertain times, even the best experts do not have sufficient competence to produce sustainable proposals for solutions alone. We hope that this paper initiates a long-term and extensive dialogue that leads to concrete and jointly agreed actions.

Tiivistelmä

Reilu datatalous on Sitran luoma konsepti eurooppalaiselle, ihmislähtöiselle datataloudelle. Ihmislähtöinen datatalous on vaihtoehtoisia valtio- tai yritysälähtöiselle datataloudelle ja se sopii hyvin pohjoismaisiin hyvinvointivaltion ihanteisiin. Digitaalinen arkkitehtuuri synnyttää dataa, jonka jalostaminen tiedoksi vaatii monipuolista osaamista ja resursseja, mutta myös mahdollistaa innovoinnin ja kilpailukykykkyyden.

Tämän työpäpaperin tarkoituksena on luoda suuntaviivoja sille, miten terveyden ja hyvinvoinnin edistämiseksi voidaan hyödyntää dataa ja mitä se vaatii meiltä, päättäjiltä ja toimialalta.

Kirjoittajat uskovat, että ihmislähtöinen, reilu datatalous, joka luo uusia datapohjaisia, yksityisyydensuojan tarjoavia hyvinvointi- ja terveyspalveluita varmistaa muutoksen kohti moderneja terveyspalvelujärjestelmiä. Tavoite-tila on ihmislähtöinen ja dataa laajasti hyödyn-tävä terveydenhuoltojärjestelmä. Tämä edellyttää yhteisten jaettujen tavoitteiden asettamista, pelisääntöjä ja toimintaa ohjaavan selkeän yhteisen suunnitelman luomista. Tarvi-taan uudenlaista yhteistyötä datan hallinnoijien ja sen hyödyntäjien välille.

Jokaisella tulisi olla täysi läpinäkyvyys siihen mitä henkilökohtaiselle datalle tapahtuu ja kuinka sitä hyödynnetään. Läpinäkyvyyden ja hyvän datalukutaidon avulla yksilöistä voi tulla aktiivisia toimijoita oman hyvinvoinnin puolesta sekä uusien digitaalisten palveluiden yhteiskehittäjiä.

Digitalisaatio ja datan monipuolinen hyödyntäminen luovat pohjan tulevaisuuden monipaikkaiselle terveydenhuollolle, jossa instituutioiden ja hoitolaitosten ulkopuolella kertyvä, yksilön tuottama data on yhtä arvokas osa hoitoa, hoivaa, ihmisten osallistumista ja palveluiden suunnittelua kuin perinteisten järjestelmien tuottama data. Valtioiden ja palveluita tuottavien sidosryhmien sekä tekno-logiakehittäjien tulee yhdessä aloittaa kestävä muutos, kohti aiempaa ihmislähtöisiä palveluita.

Keväällä 2020 Euroopan komissio linjasi Euroopan digitaalista tulevaisuutta kolmessa keskeisessä tiedonannossaan, jotka liittyivät digitaaliseen strategiaan ja sen osana Euroopan datastrategiaan sekä keinoällyn eettiseen käyt-töön. Datastrategia määrittää askeleet kohti eurooppalaisia datan sisämarkkinoita. Sen tavoitteena on parantaa datan saatavuutta ja jakamista uusien palveluiden ja innovaatioiden polttoaineeksi. COVID-kriisi korostaa entises-tään innovaatioiden tärkeyttä, mutta kriisin jälkeisissä toimissa tulee edelleen huomioida ihmisten yksityisyydensuoja ja yhteinen arvoperusta.

Tässä työpäpaperissa käydään esimerkein läpi datan merkitystä muutoksen mahdollistajana. Muutoskykyinen ja kestävä tulevaisuuden terveydenhuoltojärjestelmä tarvitsee dataa innovaatioiden pohjaksi. Tehokkuutta ja vaikut-tavuutta ei synny ilman hyvää tietopohjaa. Datan saatavuutta tulee parantaa ja sen hyödyn-tämistä ei voida tehdä siiloissa, vaan kaikki osaaminen on saatava käyttöön nykyistä henki-lökohtaisempien palveluiden tuottamisessa. Tässä tarvitaan laajaa julkisten ja yksityisten toimijoiden yhteistyötä sekä erilaisia toimia pehmeästä regulaatiosta ja pelisäännöistä uusiin infrastruktuureihin ja älylaitteiden integroituun käyttöön terveydenhuollon prosesseissa. Kyseessä on merkittävä asenne- ja kulttuurimuutos, joka myös avaa merkittäviä uusia liiketoimintamahdollisuuksia. Voisiko missiopohjainen teknologian kehittäminen olla Euroopan uusi mahdollisuus?

Työpäpaperissa kuvataan laajasti myös datan hyödyntämiseen liittyviä haasteita. Vaaditaan toimia, joilla yhdenmukaistetaan EU:n sirpa-leista lainsäädäntöä ja varmistetaan datan yhteentoimivuus. Digitaalista lukutaitoa tulee kehittää jatkuvasti ja oppia toimialan uusilta toimijoilta. Läpinäkyvyyden ja yhteiskunnal-lisen keskustelun puute rapauttaa luottamusta viranomaisiin. Kansanterveydelliset uhat,

kuten COVID-19 nostavat yksityisyydensuojan merkitystä samalla, kun yhteisiä toimintavalmiuksia parannetaan.

Julkaisussa esitetään keskeisiä suosituksia Euroopan komissiolle, jäsenvaltioille, toimialalle ja meistä jokaiselle. Systeminen muutos edellyttää toimia kaikilla yhteiskunnan tasoilla. Siksi keskustelu tarvittavista toimista ja niiden eurooppalaisen arvopohjan mukaisesta toteutustavasta on aloitettava nyt.

Lopuksi työpaperissa esitetään viisi keskeistä tekijää, joilla datan potentiaali saadaan täysimittaisesti käyttöön eurooppalaisissa terveydenhuollon ekosysteemeissä.

- Hallintamallin luominen sektorirajat ylittävään datankäyttöön.
- Skaalautuvan arkkitehtuurin luominen yhteisin pelisäännöin toteutettuja datamarkkinoita varten.
- Henkilökohtaisen datan käytön edistäminen uusien insentiivien ja koulutustoimien avulla.
- Yksilöiden ja yritysten kannustaminen datapohjaisiin innovaatioihin. Yritysten on kyettävä kaupallistamaan innovaatiot ja yksilöiden on löydettävä relevantit ja hyödylliset uudet digitaaliset palvelut. Avoin tiede ja kansalaistiede ovat suuntauksia, jotka tulisi huomioida eurooppalaisessa päätöksenteossa.
- Data-avaruudet tulee suunnitella pitkäkestoisesti ja ihmislähtöisesti hyödyntäen monialaista osaamista ja eurooppalaista arvopohjaa.

Yksi työpaperin keskeisistä tavoitteista on ollut osoittaa tarve moniarvoiselle ja monipuoliselle keskustelulle. Tämän vuoksi halusimme mukaan sekä asiantuntijanäkemyksiä että kansakirjoittajia eri toimialoilta ja eri ammatillisista taustoista. Tulevaisuus tehdään yhdessä. Epävarmoina aikoina yhdelläkään edes parhaista asiantuntijoista ei yksinään ole riittävästi osaamista kestävien ratkaisuehdotusten tuottamiseen. Toivomme, että tämä paperi käynnistää laajan ja pitkäkestoisen dialogin ja johtaa konkreettisiin, yhdessä sovittuihin toimiin.

Sammanfattning

Rättvis dataekonomi är ett koncept för en europeisk, människoorienterad dataekonomi som Sitra utvecklat. En människoorienterad dataekonomi är ett alternativ till en stats- eller företagsbaserad dataekonomi och ligger bra i linje med de nordiska tankarna om välfärdssamhället. Vår digitala vardag ger upphov till data. Att förädla dessa data till information kräver mångsidigt kunnande och stora resurser, men skapar också förutsättningar för innovationer och konkurrenskraft.

Syftet med detta arbetspapper är att gestalta hur det vore möjligt att utnyttja data för att främja hälsa och välfärd och vad detta skulle kräva av oss, beslutsfattarna och branschen.

Författarna är övertygade om att en människoorienterad, rättvis dataekonomi som skapar nya databaserade integritetsskyddande tjänster för hälsa och välfärd säkerställer utvecklingen mot moderna system för hälsotjänster. Målet är ett människoorienterat hälso- och sjukvårdssystem som bygger på ett vidsträckt utnyttjande av data. Detta förutsätter att gemensamma, delade mål och spelregler formuleras och en tydlig gemensam plan som styr verksamheten tas fram. Det behövs ett nytt slags samarbete mellan dem som administrerar data och dem som använder den.

Alla borde ha fullkomlig insyn i hur deras personliga data behandlas och utnyttjas. Genom transparens och god dataläskunnighet kan individerna bli aktiva aktörer som agerar för sitt eget välbefinnande och deltar i den gemensamma utvecklingen av nya digitala tjänster.

Digitalisering och mångsidigt utnyttjande av data skapar grunden för framtidens polycentriska hälso- och sjukvård där data som ackumuleras utanför institutionerna och vårdanstalterna och som produceras av individen är en lika värdefull del av vården, omsorgen, delaktigheten och planeringen av tjänsterna som data som produceras av de traditionella systemen. Staterna, de

intressentgrupper som producerar tjänster och teknologiutvecklarna ska tillsammans initiera en hållbar förändring mot mer människoorienterade tjänster än tidigare.

Våren 2020 utfärdade Europeiska kommissionen riktlinjer för Europas digitala framtid i tre centrala meddelanden som handlade om den digitala strategin samt om Europas datastrategi och den etiska användningen av artificiell intelligens som en del av den digitala strategin. Datastrategin är en vägkarta mot en europeisk inre marknad för data. Dess mål är att förbättra åtkomsten till och delningen data som drivkraften för nya tjänster och innovationer. COVID-krisen understryker behovet av innovationer ytterligare, men vid åtgärderna efter krisen gäller det fortsättningsvis att tänka på medborgarnas integritet och på den gemensamma värdegrunden.

I det här arbetspappret behandlas betydelsen av data som en faktor som möjliggör förändring med hjälp av exempel. Framtidens hållbara hälso- och sjukvårdssystem som har förmåga att förändras behöver data som grund för innovationer. Effektivitet och genomslag uppkommer inte utan ett starkt kunskapsunderlag. Åtkomsten till data ska förbättras och data kan inte användas i silor, utan allt kunnande ska kunna utnyttjas vid produktionen av tjänster som är mer individuella än i dag. Detta förutsätter ett vidsträckt samarbete mellan offentliga och privata aktörer, åtgärder av olika slag från reglering och spelregler till nya infrastrukturer samt integrerad användning av smarta utrustningar i processerna inom hälso- och sjukvården. Det handlar om en betydande attityd- och kulturförändring som samtidigt öppnar betydande nya möjligheter att skapa affärsverksamhet. Kan missionsbaserad utveckling av teknik vara Europas nya chans?

I arbetspappret ges också en omfattande beskrivning av de svårigheter som förknippas med användningen av data. Åtgärder efterlyses i syfte att göra EU:s splittrade lagstiftning mer enhetlig och säkerställa datans kompatibilitet. De digitala läsfärdigheterna ska utvecklas hela tiden och lärdomar ska hämtas av de nya aktörerna i branschen. Avsaknaden av transparens och samhällsdebatt minskar förtroendet för myndigheternas åtgärder. Folkhälsomässiga hot, såsom COVID-19, ökar betydelsen av integritet samtidigt som åtgärder vidtas för att förbättra den gemensamma aktionsberedskapen.

I publikationen framförs centrala rekommendationer för Europeiska kommissionen, EU-medlemsstaterna, branschen och var och en av oss. En förändring på systemnivå kräver åtgärder på alla nivåer i samhället. Därför ska diskussionen om vilka åtgärder som behövs och hur de kan genomföras i enlighet med den europeiska värderingsgrunden inledas nu.

Avslutningsvis presenterar arbetspappret fem centrala faktorer med hjälp av vilka potentialen hos data kan utnyttjas fullt ut i de europeiska ekosystemen för hälso- och sjukvård.

- Skapa en administrationsmodell för sektorsöverskridande användning av data.
- Skapa en skalbar arkitektur för datamarknader som byggts upp enligt gemensamma spelregler.
- Främja användningen av personliga data med hjälp av nya incitament och utbildningsåtgärder.

- Uppmuntra individer och företag till databaserade innovationer. Företagen ska kunna kommersialisera innovationer och individerna ska hitta de relevanta och nyttiga nya digitala tjänsterna. Den öppna vetenskapen och medborgarvetenskapen är strömningar som borde beaktas inom beslutsfattningen i Europa.
- Datarymderna ska planeras långsiktigt och människoorienterat med hjälp av multiprofessionellt kunnande och utifrån den europeiska värdegrunden.

Ett av de främsta målen med arbetspappret har varit att visa att det finns ett behov av en pluralistisk och mångsidig diskussion. Därför ville vi ha inlägg av både experter och medförfattare från olika branscher och med olika yrkesbakgrunder i arbetspappret. Framtiden skapas tillsammans. Under osäkra tider har inte ens den bästa experten ensam allt det kunnande som behövs för att formulera hållbara lösningsförslag. Vi hoppas att detta arbetspapper ger startskottet till en vidsträckt och långvarig dialog och leder till konkreta åtgärder som överenskommit gemensamt.

Glossary

Aggregated data – Refers to numerical or non-numerical information that is (1) collected from multiple sources and/or on multiple measures, variables or individuals and (2) compiled into data summaries or summary reports, typically for the purposes of public reporting or statistical analysis – i.e., examining trends, making comparisons or revealing information and insights that would not be observable when data elements are viewed in isolation. (*The Glossary of Education Reform*)

Anonymised data – Anonymisation is the process of removing personal identifiers, both direct and indirect, that may lead to an individual being identified. (*UCLA*)

Application Programming Interface (API) – A set of functions and procedures allowing the creation of applications that access the features or data of an operating system, application or other services. (*Oxford Dictionary*)

Big Data Europe – A project funded under Horizon 2020 that aims to undertake the foundational work for enabling European companies to build innovative multilingual products and services based on semantically interoperable, large-scale, multilingual data assets and knowledge, available under a variety of licenses and business models. (*Big Data Europe*)

Data economy – The data economy is a universe of initiatives, activities and/or projects whose business model is based on the exploration and exploitation of the structures of databases to identify opportunities for generating products and services. (*Sitra dictionary*)

Data ecosystem – Several data networks can form a data ecosystem, “a network of networks”, in which the members collaborate with each other to share and use data, as well as to boost innovation and new businesses. (*Sitra dictionary*)

Digital health – Connects and empowers people and populations to manage health and wellness, augmented by accessible and supportive provider teams working within flexible, integrated, interoperable and digitally enabled care environments that strategically leverage digital tools, technologies and services to transform care delivery. (*Healthcare Information and Management Systems Society HIMSS definition*)

eHealth Digital Service Infrastructure (eHDSI) – Both ePrescriptions and Patient Summaries can be exchanged between EU countries thanks to the new eHealth Digital Service Infrastructure. By 2021, both services will gradually be implemented in 22 EU countries: Austria, Belgium, Croatia, Cyprus, the Czech Republic, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovenia, Spain and Sweden. (*European Commission*)

European Reference Networks (ERNs) – Virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment and concentrated knowledge and resources. (*European Commission*)

European strategy for data, A – A plan for policy measures and investments to enable the data economy in the European Union for the coming five years. The document published by the European Commission on 19 February 2020 announced the creation of sector- and domain-specific data spaces, including the European Health Data Space (EHDS). The EHDS emphasises the critical importance of use and reuse of health data for innovation in the healthcare sector.

FAIR – Guiding principles for scientific data management and stewardship. FAIR stands for “Findable, Accessible, Interoperable and Reusable”.

Fair data economy – The part of an economy that focuses on creating and offering services and data-based products in a fair manner. An ethical stance on matters of privacy and data sharing, empowering individuals and business with the reuse of data. In the fair data economy, all stakeholders benefit.

Gamification – The use of game design elements in non-game contexts. (*Deterding S., Dixon D., Khaled R. and Nacke L., From game design elements to gamefulness: Defining gamification*)

General Data Protection Regulation (GDPR) – Regulation (EU) 2016/679, the European Union’s (“EU”) new General Data Protection Regulation (“GDPR”), regulates the processing by an individual, a company or an organisation of personal data relating to individuals in the EU. The regulation entered into force on 24 May 2016 and has applied since 25 May 2018. (*Sitra dictionary*)

Health (well-being) applications – Software designed for smartphones, tablets or smartwatches that gathers, processes and exchanges health (well-being) data. (*Original definition*)

Health data – Data strictly related to a patient’s conditions, including medical diagnosis, medications, allergies, medical images, genetic data and provided services. It can be objectively specified by using clinical metrics and is used by medical professionals in the decision-making process. (*Original definition*)

Health system – Organisations, people and actions whose primary intent is to promote, restore or maintain health. This includes efforts to influence the determinants of health as well as more direct health-improving activities. A health system is, therefore, more than the pyramid of publicly owned facilities that deliver personal health services. (*World Health Organization*)

Interoperability – The ability of different information systems, devices and applications (“systems”) to access, exchange, integrate and co-operatively use data in a co-ordinated manner, within and across organisational, regional and national boundaries, to provide timely and seamless portability of information and optimise the health of individuals and populations globally. There are four levels of interoperability: foundational (establishes the interconnectivity requirements needed for one system or application to communicate data to and receive data from another securely); structural (defines the format, syntax and organisation of data exchange including at the data field level for interpretation); semantic (provides for common underlying models and codification of the data including the use of data elements with standardised definitions from publicly available value sets and coding vocabularies, providing shared understanding and meaning to the user); organisational (includes governance, policy, social, legal and organisational considerations to facilitate the secure, seamless and timely communication and use of data both within and between organisations, entities and individuals. (*HIMSS*))

Mobile health (mHealth) – Medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs) and other wireless devices. (*Global Observatory for eHealth*)

Quantified Self – Self-knowledge through numbers. A domain where people are tracking their health for any reason – to answer a health question, achieve a goal, explore an idea, or simply because they are curious. (*Quantified Self website*)

Reuse, or secondary use, of data – Concerns the use of clinical data for a different purpose than the one for which it was originally collected. The data being reused are usually those owned by hospitals and health systems – large databases containing administrative, claims, and patient health data. Oftentimes this data is reused for research and applications in quality of care and patient safety. (*National Center for Biotechnology Information NCBI*)

Well-being data – Data that reflects a person's subjective state of health and/or vital signs not related directly to the patient's condition but essential for preventive measures. For example, blood pressure, heart rhythm, physical activity, diet, quality of sleep, etc. Gathered by individuals for well-being-related goals. (*Original definition*)

Commentators

Bogi Eliassen, Director of Health at the Copenhagen Institute for Futures Studies (CIFS)

Bogi Eliassen graduated in Political Science at the University of Aarhus, Denmark. Among many activities, he has worked as a consultant in the Faroe Business Affairs and Ministry of Foreign Affairs and been an adviser to politicians, the public sector and private companies. Bogi is one of the initiators of the first population genome project FarGen, which aims to sequence the genomes of the whole population of the Faroe Islands. As a CIFS health expert, Bogi sets the stage for genomics, data, digital functions and health, framed within a holistic vision of shaping the future personalised health paradigm as part of ambitious projects and networks around the world, including Nordic Health 2030 agenda. His focus is on the use of new technologies and improvement of quality of life and well-being for all. He calls himself a knowledge broker whose expertise lies in combining various fields of knowledge. He received the HIMSS Global Achievement Award 2019.

Thomas Plochg, Director of the Netherlands Federation for Health

Thomas Plochg has been combining policy and academic work for many years. He has been the director of the Federation for Health since 2014 and also the owner of Thomas Plochg Advisory. As the director of the Federation for Health, he is governing a public-private network of more than 70 organisations whose mission is to transform Dutch healthcare by shifting its focus to the upstream of health problems. Currently, key focal points are the national prevention agreement and developing business models for health (rather than disease). As an academic, he gives classes in medical and public health curricula as well as participates in various research projects. His primary expertise is

interdisciplinary and builds on complex adaptive system theory. His key themes of interest are public health, innovation, organisation of healthcare and public health, and sustainable health systems.

Eric Pol, Chairman of the aNewGovernance

Eric Pol started what would become the Brussels-based aNewGovernance international association in February 2019, bringing together public bodies, associations, academics, start-ups and corporates, in total 250 organisations from 53 countries. This initiative is accompanying the shift to fair data, and especially the European data strategy and the development of Sectoral Data Spaces. The association's aim is to help build those Sectoral Data Spaces in their Governance and Personal Data dimensions, as well as the Personal Cross-Sectoral Data Space. aNewGovernance believes in a new paradigm that should be shared across European borders. Eric has 25 years' experience in healthcare mergers and acquisition, working in Europe and the USA with funds and corporates, from biopharma and med tech to genomics and personalised medicine.

Stephan Schug, Chief Medical Officer at the European Health Telematics Association (EHTEL)

Dr Stephan H. Schug, MD MPH, started his medical practice in internal and family medicine. After 25 years in digital health, his focus today is on European and national strategies, interoperability, the seamless use of interoperable EHRs and the shift towards European Health Data Spaces. As the CMO at EHTEL, Stephan empowers the multi-stakeholder platform by managing the agenda of the yearly symposium, supporting thought leadership debate. In the role as the Chief

Consultant and Owner at IQmed, Stephan provides global policy, project and event support to digital health bodies in Germany. For nearly 20 years, he has been a secretary to the joint eHealth working group of the Federal Health Ministry and the German Länder – led by the NRW Health Ministry. As President and Acting Board Member of the German eHealth Association DGG e.V., he provides eHealth networks throughout Germany with a cross-border and EU dimension.

**Robert Schuschnig-Fowler,
Expert Support Engineer at SAP**

Robert Schuschnig-Fowler is an American who has been living in Europe for over 35 years. After completing his studies in Heidelberg in Germany, he moved to Finland to teach full time at Metropolia (focus Healthcare) and part-time at Helia (focus Business) in Helsinki. In 1998, Robert returned to Heidelberg in Germany to work at SAP. He later became heavily involved in employee representation at SAP (Works Council Germany, SE Works Council Europe and SAP Supervisory Board) where he developed a keen awareness for data privacy. Subsequent to his engagement in employee representation, he became the project lead for TradeMyData: Human-Centric Data Management & Processing.

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