



White paper: EU policy on secondary use of health data

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About

This white paper was commissioned by Roche and researched and produced by the Open Data Institute and published in July 2021. The lead author is Mark Boyd, and the wider project team includes Mahad Alassow, Milly Zimeta, and Jeni Tennison.

If you want to share feedback by email or would like to get in touch, contact us at policy@theodi.org.

Background

"Despite progress in recent years, high-quality data are not routinely collected in all settings, major health challenges are not adequately monitored, and effective interventions are not directed to the right people, at the right time and at the right place. This impacts policies and programmes and consequently, the health of entire populations. Similarly, in order to meet the shared SDG commitment to "leave no-one behind", we need disaggregated data to ensure equitable health outcomes. This means we must strengthen comprehensive data systems, collaborate with other sectors, and apply innovative digital technologies to collect, analyse and use data to make informed decisions and deliver impact."

- Dr Tedros Adhanom Ghebreyesus, WHO Director-General¹

The global Covid-19 pandemic has altered many of our societal and economic systems. Health data infrastructure has played a key role in enabling research to be shared, for disease and variant spread to be tracked and monitored, for cross-border care to be managed, and for cross-sector collaboration to be encouraged. However, the pandemic also revealed multiple gaps and barriers that prevented the free flow of data in a manner that is ethical, equitable and respects individual privacy. Concerns with privacy in Covid-19 app contact tracking, the inability for systems to analyse and share data on subpopulations facing greatest inequalities, interoperability barriers in sharing patient data across national borders, and the limited pooling of research data to understand potential treatment options were all evident across 2020².

But even before the pandemic, there was an urgent need to optimise healthcare systems and manage limited healthcare resources more effectively to meet the needs of growing, and often ageing, populations. Global and European-wide priorities to reduce inequalities require new action strategies. Technological advances enabling the use of large datasets coupled with artificial intelligence and machine learning algorithms to assess new therapeutic interventions to be tested and developed at pace need to be matched with ethical review and reimbursement and investment policies. There is also confusion in requirements for data localisation and storage, and impacts of procurement and contract arrangements with technology providers on data privacy and capacity to share data across borders.

Now, coupled with the urgency of the pandemic, there is a heightened need to resolve how health systems will govern and steward health data to develop early diagnostic and health surveillance systems. This need is being matched by accelerated willingness to adopt digital healthcare solutions, and greater societal interest in understanding and ensuring personal data is managed responsibly and ethically.

¹ WHO (2021), "Global report on health data systems and capacity, 2020", https://cdn.who.int/media/docs/default-source/world-health-data-platform/score/who_2021-01-31_global-report-score_tb_v2.pdf

² Secretary-General of the Council of Europe, "State of democracy, human rights and the rule of law", <https://rm.coe.int/annual-report-sg-2021/1680a264a2> and the human rights and COVID-19 website of the Council of Europe: <https://www.coe.int/en/web/portal/covid-19>

The importance of secondary use of health data in the European region

Secondary use of health data plays a central role in enabling all of these potential future trajectories. The Open Data Institute (ODI) has been commissioned by Roche to undertake a policy research project analysing the emerging secondary use of health data in the policy environment. This project seeks to identify opportunities that strengthen the European health data ecosystem. The project focuses on how secondary uses of health data can be enabled, while respecting individual health data privacy, and a final report and associated tools are expected to be published around September/October 2021.

This project defines the secondary use of health data as:

‘The use of aggregated health data from population-level sources including electronic health records, wearables technologies, health insurance claims data, health registry data (or burden of disease registries), drug consumption data, and data collected through research to improve personal care planning, medicines development, safety monitoring, research and policymaking.’

Enabling secondary use of health data is a cornerstone of a health data ecosystem, and it requires a policy and implementation environment that protects personal data while enabling research and innovation.

Secondary use of health data enables a wide range of use cases and benefits across the entire healthcare system, as described in Table 1, below.

Table 1: Key potential use cases from secondary use of health data and the benefits they enable

Use cases	Optimise health systems	Improve the patient journey	Encourage patient–public participation	Expand innovation
Key benefits enabled	<ul style="list-style-type: none"> • Reduce healthcare costs³ • Increase planning and more efficient resource allocation • Allow equity-focused prioritisation⁴ • Modernise reimbursement and pricing models⁵ • Enable insights for population health management, early diagnosis, prevention and healthy living⁶ 	<ul style="list-style-type: none"> • Early, personalised and advanced diagnostics • Personalised care pathways and clinical decision support systems • Rapid access to personalised interventions • Remote monitoring and care via digital health apps and tools 	<ul style="list-style-type: none"> • Allow patient contribution of personal data • Leverage real-world data for health conversations • Enhance preventative care • Enable self management of chronic illness 	<ul style="list-style-type: none"> • Enable new research • Expand innovative medicine and technology development⁷ • Facilitate predictive modeling • Reduce research risks • Allow new market entrants and encourage startups to work collaboratively with existing stakeholders • Strengthen assessment of health technologies

Health data is often considered for secondary uses in medical research. This use case is expected to grow significantly with the use of artificial intelligence: datasets collected from electronic health records or from other clinical trials and research could be used to train machine learning algorithms when assessing potential effectiveness of new therapies, for example. This requires new ethical models of risk assessment⁸. But health data is also used for other secondary purposes, including to optimise health resource allocation and expenditure.

An emerging use case is the secondary use of health data to support personalised healthcare along the entire patient journey⁹. While electronic healthcare data can be used to improve healthcare decision-making for a patient (for example, by reducing risks of pharmaceutical contraindications when a patient has multiple prescribing healthcare professionals), an emerging use case for secondary use of health data is when an individual patient's healthcare data is compared with aggregated data from others with similar profiles. Drawing on this dataset enables precision medicine to emerge: healthcare professionals can create more personalised care pathways and speed up personalised intervention decisions.

³ HIMSS, D'Amore, Mitchell (2020), '[Electronic Health Record Data Governance and Data Quality in the Real World](#)'

⁴ The Lancet Digital Health (2021), '[Health data poverty: an assailable barrier to equitable digital health care](#)'.

⁵ BMC (2020), '[A systematic literature review of health consumer attitudes towards secondary use and sharing of health administrative and clinical trial data: a focus on privacy, trust, and transparency](#)'.

⁶ Journal of Law and the Biosciences (2020), '[The use of data from electronic health records in times of a pandemic—a legal and ethical assessment](#)'

⁷ European Medicines Agency (2020), '[GDPR and the secondary use of health data](#)'

⁸ Jungkunz et al (2021), 'Secondary Use of Clinical Data in Data-Gathering, Non-Interventional Research or Learning Activities: Definition, Types, and a Framework for Risk Assessment', <https://www.jmir.org/2021/6/e26631>

⁹ Bignens, et al (2020), 'Consensus Paper on the Building Blocks for Personalised Healthcare', https://futureproofinghealthcare.com/sites/default/files/inline-files/PHC%20building%20blocks_Consensus%20paper_FINAL.pdf

The 2021 European Health Data Space consultation

The creation of a European Health Data Space (EHDS) is one of the key priorities of the European Commission in the area of health. It is one of the first initiatives to extend the work outlined in the European Strategy for Data¹⁰. The purpose of the EHDS is to promote health-data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes.

This white paper shares some of our initial analysis on the overall European health policy environment and is intended to support stakeholders understand current issues in enabling secondary use of health data in advance of the [European Health Data Space consultation](#), which currently ends on 26 July 2021.

This public consultation focuses on:

- the access to and use of health data for healthcare provision, research and innovation, policy-making and regulatory decision;
- fostering a genuine single market for digital health services and products, including innovative ones¹¹.

This will be an opportunity for stakeholders to share their perspectives on what key data governance components should be addressed by the European Health Data Space in order to ensure health data creates benefits for everyone, while protecting privacy.

The ODI's recent work on health data policy may also be useful to review when considering responses to the European Health Data Space consultation.

This work includes:

- How [Covid-19 symptom tracker apps](#) can collate health-surveillance data for early diagnostics, without exposing personal health data.
- The role [data intermediaries](#) can play to protect the privacy of health data while also making anonymised, aggregated health data available for scientific research.
- The opportunity of secondary use of health data to [open new markets in physical activity businesses](#), which in turn generate greater preventative health opportunities for local populations.
- How competitive industry stakeholders are able to collaborate and share clinical trial data on global health challenges [such as antimicrobial resistance](#), while still protecting their commercial advantage.
- Summary of the global data governance environment, including current debates on health data as a global public good, and current maturity of data governance globally and emerging best practices, created as [pre-reads for the WHO Data Governance Summit](#), held on 30 June 2021.

¹⁰ European Commission (2020), European Strategy for Data, <https://digital-strategy.ec.europa.eu/en/policies/strategy-data>

¹¹ Description of EHDS and the goals of the public consultation were taken from the background paper for the public consultation: https://ec.europa.eu/commission/presscorner/api/files/document/print/en/ip_21_2083/IP_21_2083_EN.pdf

EU policy on secondary use of health data

Overall, Europe presents an exciting policy base for the creation of secondary use of health data. In the last two years, in line with the European Strategy for Data¹², a health data policy environment conducive to enabling secondary use cases has started to emerge. Policies and strategies increasingly take a joined-up approach. Our research has identified that four biggest challenges remain:

- Differing interpretations of GDPR and lack of legislative clarity on how to enable secondary use of health data while maintaining Europe's strong foundation of data privacy
- Fragmentation in initiatives and approaches across Europe negatively affecting member states' ability to support each other and encourage participation from all stakeholders
- Lack of agreed common data models and open standards creating barriers for interoperability and reuse of health data
- Limited focus on identifying opportunities to leverage secondary use of health data to reduce health inequalities.

Relevant EU-wide policy

There are two main policy areas that impact on secondary use of health policy, as shown in Table 2 below. We have categorised these as:

- **European vision for a data-enabled future:** These policies and directives recognise the importance of data for enabling an open, innovative society and economy. This group of policies and legal instruments seeks to create the appropriate regulations, policy supports, investment and strategic direction that enable data to be shared to improve health outcomes for all people living in Europe.
- **Digital transformation of healthcare:** These policies, initiatives and institutions look to modernise aspects of the healthcare sector and increase interoperability, within a member state and across borders, and to encourage collaborative networks that create new solutions for healthcare challenges.

¹²European Commission (2021), '[A European Strategy for Data. Shaping Europe's Digital Future](https://digital-strategy.ec.europa.eu/en/policies/strategy-data)', <https://digital-strategy.ec.europa.eu/en/policies/strategy-data>

Table 2: Relevant European policies categorised by main theme

European vision for a data-enabled future	Digital transformation of healthcare
<ul style="list-style-type: none"> • General Data Protection Regulation¹³ • European Strategy for Data¹⁴ <ul style="list-style-type: none"> ◦ Data Governance Act¹⁵ • White Paper on Artificial Intelligence¹⁶ • Final Report and Action Plan from the Commission Expert Group on FAIR Data¹⁷ • Europe's Digital Decade¹⁸ 	<ul style="list-style-type: none"> • Communication on enabling digital transformation of health and care¹⁹ <ul style="list-style-type: none"> ◦ Commission Recommendation on a European Electronic Health Record exchange format²⁰ • 1+ Million Genomes initiative²¹ • European Reference Networks²² • Electronic Exchange of Social Security Information²³ • Integrating Healthcare Enterprise²⁴ • eHealth Network²⁵ • One Health Action Plan Against AMR²⁶

In many instances, over the past three or four years, these two categories of work have been operating independently of each other. And while the strategies that are related to 'Europe's vision for a data-enabled future' often reference other policies within that grouping, policies and initiatives within the 'digital transformation of healthcare' category often have a more independent implementation approach.

This can be seen in the fragmentation, lack of common data models, and complexity of individual pilot and research studies being undertaken within healthcare digital transformation efforts. The shortcomings of integrating this policy work were sorely tested during Covid-19, where implementations of electronic health records by EU member states often led to a lack of interoperability and data fragmentation across borders, and limitations in the ability to collect and compare data from different regions to assess Covid-19 rates and healthcare access.

There is a third emerging grouping of policy work that could create a bridge between these two often disconnected areas. The following initiatives represent **an opportunity for a new dialogue and a new collaborative approach focused on enabling the secondary use of health data.** To achieve many of the intended health policy goals described in the following European policies, access to health data for secondary use purposes will be essential. This will involve multiple stakeholders from across the digital, healthcare, and privacy domains. The key policies and initiatives driving this joined-up approach are:

¹³ EUR-Lex (2018), [General Data Protection Regulation \(GDPR\)](#)

¹⁴ European Commission (2021), ['A European Strategy for Data. Shaping Europe's Digital Future'](#)

¹⁵ European Commission (2021), ['European data governance'](#)

¹⁶ European Commission (2020), ['White Paper On Artificial Intelligence - A European approach to excellence and trust'](#)

¹⁷ European Commission (2018), ['Turning FAIR into Reality'](#),

¹⁸ European Commission (2021), ['Europe's Digital Decade: Commission sets the course towards a digitally empowered Europe by 2030'](#)

¹⁹ European Commission (2019), ['Communication on enabling the digital transformation of health and care in the Digital Single Market'](#)

²⁰ European Commission (2019), ['Recommendation on a European Electronic Health Record exchange format'](#)

²¹ European Commission (2021), ['European "1+ Million Genomes" Initiative'](#)

²² European Commission, n.d., ['European Reference Networks'](#)

²³ European Commission, n.d., ['Digitalisation in social security coordination - Employment, Social Affairs & Inclusion'](#),

²⁴ EUR-Lex (2015), ['Commission Decision \(EU\) on the identification of 'Integrating the Healthcare Enterprise' profiles for referencing in public procurement'](#)

²⁵ European Commission, n.d., ['eHealth Network | Public Health'](#)

²⁶ European Commission (2017), ['A European One Health Action Plan against Antimicrobial Resistance \(AMR\)'](#),

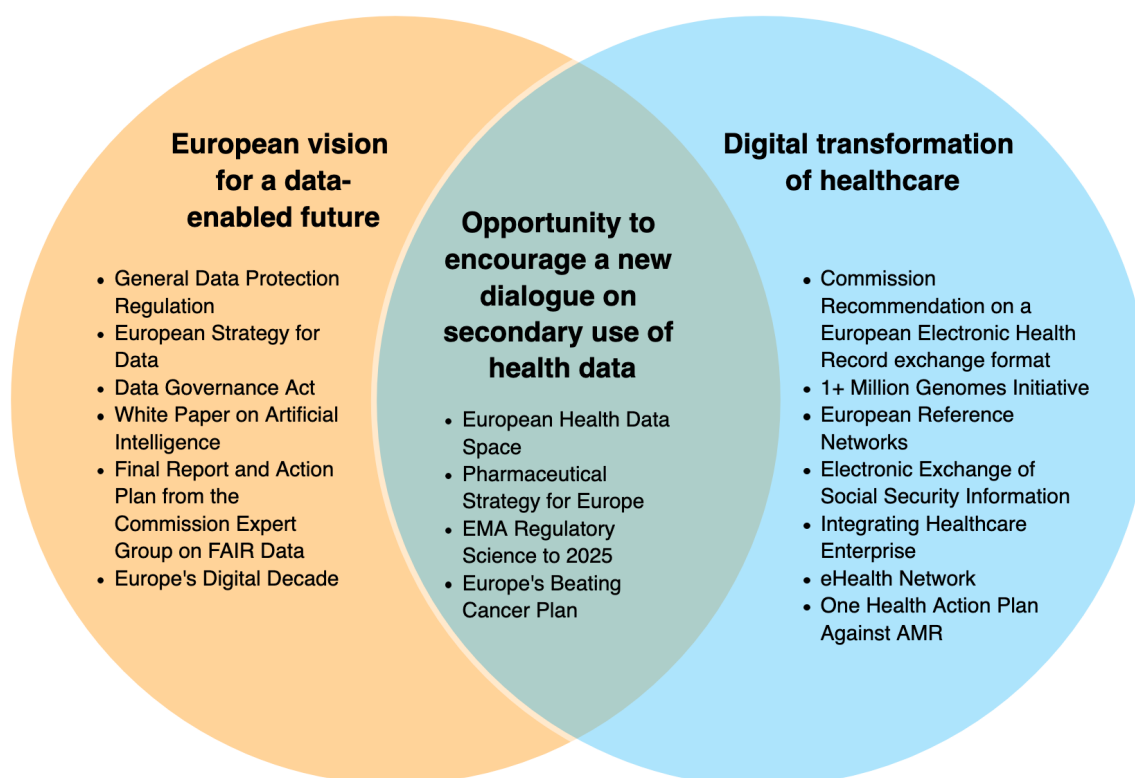
- European Health Data Space²⁷
- Pharmaceutical Strategy for Europe²⁸
- European Medicine Authority Regulatory Science to 2025²⁹
- Europe's Beating Cancer Plan³⁰.

While these policies have other primary goals, a key common element of the strategic work required for successful implementation of each of these initiatives is the availability of health data for secondary use cases. Improving the secondary use of the health data ecosystem will help ensure the success of the wider goals articulated in these policies. It is encouraging that, in contrast to the earlier healthcare modernisation policies, these more recent papers are able to identify the other, current, related bodies of work that are encouraging the acceleration of data and digitally enabled healthcare systems.

These documents, as shown in Figure 1, below, tend to be more recent, and ask:

- What are the health sector implications of those policies that outline the **European vision for a data-enabled future**?
- How can current initiatives focused on **digital transformation of healthcare** incorporate the policy directions of the vision for a data-enabled future?

Figure 1: How relevant European health data policies are connected when categorised by main theme



²⁷ European Commission, n.d., '[European Health Data Space | Public Health](#)'

²⁸ European Commission (2020), '[A pharmaceutical strategy for Europe | Public Health](#)',

²⁹ European Medicines Agency (2020), '[EMA Regulatory Science to 2025](#)'

³⁰ European Commission (2021) '[Europe's Beating Cancer Plan v.24](#)'.

Overview of current strategic direction

The European Commission has significant potential to create a cohesive ecosystem enabling the secondary use of health data. This will require supporting member states to implement standardised, interoperable, and collaborative health data strategies. The Commission's 'European Strategy for Data' aims to create a consciously ethical approach, including robust data protections for people and a commitment to strengthening data access and enabling data sharing for social benefit. Policies recognise the move towards collecting and managing 'big data' as an input source for innovation.

However, the paradigm shift of the 'big data revolution', which has enabled large-scale and rapid data collection of rich or granular data, and new kinds of advanced data analysis or digital products and services, also brings challenges. Much of the legislation and regulation around data collection, management, governance and use was developed and ratified before big data technological developments. Their rapid growth and uptake, and the associated rate of change, can make it difficult for policymakers to feel confident that they are anticipating future needs, risks, and opportunities. Similarly, new potential uses of health data – including the secondary uses of health data for personalised healthcare – are not always easily navigated within existing health data policies.

Much hope is being placed on the ability of the proposed European Health Data Space to overcome current fragmentation and create a new open health data ecosystem for Europe. The European Health Data Space³¹ will aim to:

- promote safe exchange of patients' data (including when they travel abroad) and citizens' control over data about their health
- support research on treatments, medicines, medical devices and outcomes
- encourage the access to and use of health data for research, policymaking and regulation, with a trusted governance framework and upholding data-protection rules
- support digital health services
- clarify the safety and liability of artificial intelligence (AI) in health.

The European Health Data Space is intended to become 'a system for data exchange and access which is governed by common rules, procedures and technical standards to ensure that health data can be accessed within and between Member States, with full respect to for the fundamental rights of individuals'³².

The Joint Action Towards the European Health Data Space³³ is the initial step to create this network. Ideally, this network will take a multi-stakeholder approach that encourages participation by industry, regulators, healthcare providers, health surveillance and data system operators, patient advocacy and consumer groups, emerging health tech startups, privacy and digital rights advocates, and researchers. Drawing on examples for digital government frameworks,³⁴ this network could identify key use cases and priorities of work,

³¹ EUR-Lex (2016), '[EU eGovernment Action Plan 2016-2020 Accelerating the digital transformation of government](#)'

³² European Commission (2019), '[Assessment of the EU Member States' rules on health data in the light of GDPR](#)'

³³ TEHDAS (2020), '[Joint Action for the European Health Data Space](#)'

³⁴ Publications Office of the EU (2020), '[An Application Programming Interfaces \(APIs\) framework for digital government](#)'.

facilitate the use of open standards and common data models, and agree to build shared services and common datasets that could be used as the backbone for industry innovation.

On 23 June, the project group overseeing Towards the European Health Data Space released a progress report that confirms the fragmentation challenges that occur when attempting to share health data for secondary uses³⁵. They note that current fragmentation in General Data Protection Regulation (GDPR) implementation approaches at the member state level and the complex legislative context at the European level (in which at least 15 legal provisions across multiple legislations were identified) are preventing new public goods to be generated from sharing and reusing health data for secondary purposes. The report recommends that secondary use of health data be governed by specific legislation and eight key elements are discussed where health data governance legislation could be applied, including:

- Patient, consent, and rights of the citizen
- Protection and promotion of public health
- Health research and specific data types
- Health data as highly sensitive data
- Exceptional need for data and cyber security
- Health data in the private sector
- Complex semantic interoperability
- Fragmented regulatory framework at national level.

The work of the European Medicine Agency (EMA) and strategies detailed in the Pharmaceutical Strategy for Europe outline how foundations could be built to enable this collaborative data ecosystem model:

- EMA has supported the Ethics Guidelines for Trustworthy AI³⁶ and, through its Heads of Medicines Agencies (HMA)/EMA Big Data Steering Group,³⁷ has outlined how these guidelines could help inform the work of an ethics committee to oversee secondary use of healthcare data, and help in the creation of a code of conduct for the health industry on secondary use of health data
- Investment has led to the development of real-world data infrastructure (DARWIN EU: the Data Analysis and Real World Interrogation Network)³⁸ and has supported pilot models that test use of real-world data infrastructure for detecting drug safety issues
- The need to create standardised tools for health technology assessment for use across Europe has been identified.

³⁵ TEHDAS (2021), 'Why health is a special case for data governance,' <https://tehdas.eu/app/uploads/2021/06/tehdas-why-health-is-a-special-case-for-data-governance-2021-06-23.pdf> available from:

<https://tehdas.eu/news/tehdas-analysis-health-data-needs-dedicated-eu-regulation/>

³⁶European Commission (2019), '[Ethics guidelines for trustworthy AI](#)',

³⁷European Medicines Agency (2020), '[Big data](#)'

³⁸European Medicines Agency (2020), '[2.2. Proposal for a Data Analytics and Real-World Interrogation Network \(DARWIN\)](#)'.

Analysis of key aspects of EU policies and implementation

The following common themes were identified as risks and blockers in the current policy environment that may impact on the development of open and trustworthy secondary use of health data ecosystems.

Governance: There are high expectations that the forthcoming European Health Data Space will build common data governance systems. Various European-wide policy documents, and research papers aimed at understanding the secondary use of health data policy context, have come to similar conclusions:

- that there needs to be shared agreement on data consent mechanisms, codes of conduct for use and sharing of data, common data models and data standards
- that common infrastructure needs to be built
- that greater multi-stakeholder collaboration must be facilitated.

As this work commences via the Joint Action Towards the European Health Data Space, stakeholders will be required to share their opinions and implementation practices. This will require industry stakeholders and member states themselves to share and agree on various models and ways forward.

One of the challenges to date, and part of the reason for the cycle of recommendations in recent years, is that there are limited examples of implementation and there is a reticence to express clear opinion on how to implement the specific components being proposed. For example, open standards are proposed, but which open standards to implement are often not stipulated. Multiple data models exist, but there is no agreement on which should be adopted. Sample codes of conduct are also often unavailable or unspecified. In the past two years, including in a major review of the fragmentation in implementing the GDPR³⁹ as it applies to health data use cases, report findings have returned to noting the need for codes of conduct and data infrastructure, yet avoid stating what code of conduct principles should be adopted or how data infrastructure should be organised.

One example of how the lack of data governance maturity is in the area of data sharing. Data sharing is still fairly minimal across Europe, outside specific initiatives. The ambitious 1+ Million Genomes initiative,⁴⁰ signed by 23 countries across Europe, with the aim ‘to make the personal genomic datasets accessible in a secure manner for collective diagnostic purposes and prevention, and for research and innovation’ found that the greatest challenge was using existing datasets consistently and with the consent of patients. Electronic health record data systems are often insufficiently advanced to enable sharing of data beyond the clinical care setting.

³⁹ European Commission (2019), [Assessment of the EU Member States' rules on health data in the light of GDPR](#)

⁴⁰ European Commission (2021), [‘European “1+ Million Genomes” Initiative’](#), <https://ec.europa.eu/digital-single-market/en/european-1-million-genomes-initiative>

Through the ODI's work for the World Health Organization⁴¹, we have identified a range of data governance components that need to be addressed at the structural, legal and technical levels. Work packages within the Towards the European Health Data Space project are already prioritising some of these themes. Longer term, the European Health Data Space will need to help harmonise principles, share best practices, and provide or identify tooling to support stakeholders to mature their health data governance in the areas shown in Figure 2, below.

Figure 2: Key areas of health data governance that will need to mature with best practices and tooling



Increased collaboration and exchange: Across Europe, there are a wide range of initiatives in sub-sector domains that seek to encourage data sharing. The European Joint Programme on Rare Diseases⁴², for example, is a European health reference network aimed at improving clinical care and sharing data for research. There is a need for greater understanding of how learnings from these models can translate to whole-of-Europe policy and data ecosystem environments.

Role of health data in reducing inequalities: The economic and societal benefits of enabling personalised healthcare are rarely calculated and described in European health policy documents beyond broad statements that they are expected to create substantial benefits. A new European Partnership on Personalised Medicine⁴³ has been identified for establishment in 2023, and

⁴¹ The ODI (2021), Preread 3: Data governance maturity and best practices, https://cdn.who.int/media/docs/default-source/world-health-data-platform/events/health-data-governance-summit/preread-3-who-data-governance-summit_data-governance-of-health-data.pdf?sfvrsn=ffb4a33_1Q

⁴² EJP RD – European Joint Programme on Rare Diseases <http://www.ejprarediseases.org/>

⁴³ European Commission, n.d., 'General Information Preliminary title of the European Partnerships European Partnership for personalised medicine'

recognition of the value of personalised healthcare is being referenced in new health policies such as Europe's Beating Cancer Plan⁴⁴. This plan shows how there are expectations that the European Health Data Space and the 1+ Million Genomes initiative will solve current challenges in the use of data for personalised healthcare. There are few documents that describe how health data could be leveraged to reduce health inequalities. For example, when large datasets are pooled, it is possible to create meaningful analysis that addresses specific subpopulation needs.

In the current legislative agenda, the European Parliament has prioritised social fairness and prosperity and the mitigation of negative consequences of the Covid-19 crisis for vulnerable social groups⁴⁵. To align with these priorities, current health policy work could better describe the potential role of secondary use of health data in reducing health inequalities.

On a global level, Europe's GDPR legislative context is influencing data privacy legal contexts in other countries, including in low- and middle-income countries. Donors and philanthropy organisations based in Europe are requiring their partners in the Global South to adhere to health data regulatory environments that align with the GDPR. This can stall funding to agencies in the Global South who find themselves needing to build data governance systems that address GDPR requirements to receive funding, in addition to meeting the local regulatory context. These GDPR requirements may also impose western values on data privacy and regulation that do not necessarily align with local cultural values, such as those described in the CARE Framework, developed by First Nations and Indigenous Peoples networks. While the European Health Data Space is predominantly about governing health data in a European setting, the adoption of standards and legislation in Europe will have global influence. If health data is to be governed by the EHDS under new legislation, this cannot be considered in isolation from the rest of the world, as the European context affects global health research. Consideration should be given to how European health data governance could impact on geopolitical relationships, and in particular, on Europe's commitments to the Sustainable Development Goals and the ability of low- and middle-income countries to collect and use health data to benefit local communities.

Investment: Funding of health system transformation is often limited across EU member states. Member states may be able to access new funding through the European Recovery and Resilience Facility⁴⁶ to enable modernisation of data infrastructure, as has been proposed by the 1+ Million Genomes initiative⁴⁷. EMA is currently working on standardised tools for health technology assessment. There is currently limited standardisation in models for collecting data on social health insurance, which could be used to help drive greater planning and healthcare service optimisation.

⁴⁴ European Commission (2021), '[2021_01_25 Communication - Europe's Beating Cancer Plan v.24](#)'.

⁴⁵ European Commission (December 2020), 'Joint Declaration of the European Parliament, the Council of the European Union and the European Commission' <https://ec.europa.eu/info/sites/default/files/joint-declaration-legislative-priorities-2021.pdf>

⁴⁶ European Commission (2021), [Recovery and Resilience Facility | European Commission](#)

⁴⁷ European Commission (2021), '[European "1+ Million Genomes" Initiative](#)'

Forward look

Overall, there are encouraging signs at the European level that health data ecosystems are maturing to support secondary use of health data; however, many of the initiatives are still fragmented and there will be significant work required to establish robust health data ecosystems and infrastructure for data reuse. Newer policy developments are showing a greater focus on coordinating strategies across various stakeholders, initiatives and, importantly, member states.

However, one of the central challenges remains the disconnect between the European GDPR and opportunities to reuse health data in innovative ways. While the GDPR provides a strong foundation for secondary use of health data, **data governance tools are needed to enable data reuse within, and beyond, the European healthcare system. Examples include codes of conduct, ethics committees, infrastructure for real world data and real world evidence, stronger data institutions, and clearer legal frameworks.**

The challenge in recent years is that data governance gaps are well known, but there has been a lack of consensus building to encourage new agreements and create the necessary infrastructure beyond one-off pilot projects. Multiple reports and project summaries⁴⁸ have agreed that current approaches to data collection and sharing are fragmented, and that ethical frameworks are needed to oversee how data will be shared in future with appropriate protections for sensitive data. But action has not yet been taken to create the multistakeholder settings that encourage agents to resolve the roadblocks. We hope that the EHDS will facilitate a clear roadmap that creates mechanisms to co-operate to this end.

This white paper aims to share some initial research we have undertaken when mapping the secondary use of health data policy landscape in Europe. We are releasing it now to support European health data stakeholders to consider the current policy landscape when responding to the European Health Data Space consultation which closes on 26 July 2021.

We invite readers to [contact ODI](#) to discuss any feedback on this report and to share perspectives on how best to shape a trusted and trustworthy health data ecosystem for secondary use of health data in the European region.

Find out more about this [white paper, and the accompanying briefing event here.](#)

⁴⁸ Including: '[Why health is a special case for data governance](#)', '[A pharmaceutical strategy for Europe | Public Health](#)', '[An Application Programming Interfaces \(APIs\) framework for digital government](#)', '[Assessment of the EU Member States' rules on health data in the light of GDPR](#)', '[Proposal for a Data Analytics and Real-World Interrogation Network \(DARWIN\)](#)', '[2021.01.25 Communication - Europe's Beating Cancer Plan v.24](#)