

Open Data Institute / Report

Secondary use of health data in Europe

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Contents

4	About		
	About the ODI	4	
5	Executive summary		
	The importance of secondary use of health data	5	
	Our findings	6	
	Key themes and insights	7	
	How to use this report	7	
8	Chapter 1: The importance of secondary use of health data		
	1.1 The opportunity	8	
	1.2 The challenge	10	
	1.3 Data management and access in Europe	12	
13	Chapter 2: Policy vision for secondary use of health data		
	2.1 The ODI's theory of change	13	
	2.2 Insight tool: policy framework for secondary use of health data	14	
	2.3 Further considerations	16	
17	Chapter 3: EU policy for secondary use of health data		
	3.1 Insight tool: EU policy scorecard	17	
	3.2 Relevant EU-wide policy	19	
	3.3 Current strategic direction	20	
	3.4 Key aspects of EU policies and implementation	21	
22	Chapter 4: Country-level policy for secondary use of health data		
	4.1 Context: country-level legislation and regulation	22	
	4.2 Insight tool: country-level scorecards	23	
	4.3 Insight tool: country profiles	23	
24	Chapter 5: Discussion: 'What does good look like?'		
	5.1 Summary	24	
	5.2 Benchmarking	25	
	5.3 Analysis of country-level best-practice examples	26	
	5.3a Infrastructure	27	
	5.3b Capability	28	
	5.3c Innovation	29	
	5.3d Equity	30	
	5.3e Ethics	31	
	5.3f Engagement	32	
33	Chapter 6. Policy needs for secondary use of health data		
	6.1 Infrastructure	34	
	6.2 Capability	34	
	6.3 Innovation	34	
	6.5 Equity	34	
	6.4 Ethics	35	
	6.6 Engagement	35	
36	Annexes		
	Annex 1 – Detailed methodology	36	
	Annex 2 – Insight tool: policy framework	36	
	Annex 3 – Insight tool: EC-level and country level scorecards and profiles	36	

About

This report was researched and produced by the Open Data Institute (ODI) and published in September 2021. The lead author is Mark Boyd. The wider project team includes Mahad Alassow, Dr Milly Zimeta, and Dr Jeni Tennison. This report is independent work by the ODI that was commissioned by Roche.

If you want to provide feedback or get in touch, contact us at policy@theodi.org

About the ODI

ODI works to build a strong, fair and sustainable data economy by helping governments and businesses around the world get data to people who need it. It is independent, nonprofit and nonpartisan, founded in 2012 by Sir Tim Berners-Lee and Sir Nigel Shadbolt. From its headquarters in London and via its global network of startups, members and nodes, the ODI offers training, research and strategic advice for organisations looking to explore the possibilities of data.

Since its inception in 2013, the ODI startup programme has supported 33 startups spread across five 'cohorts'. Initially the programme focussed on businesses that placed open data at the core of their business model and had a triple-bottom-line impact socially, environmentally and economically. The evolution of the data-enabled economy sector demonstrated that most business models, whilst adopting an open-innovation approach, incorporated a blend of open and shared data. In response to this, we broadened the scope of the latest cohort to include a wide range of data-enabled startups.

As a whole, startups incubated by the ODI while in the programme have secured around £16m in sales and investments and directly employed more than 130 people.

Executive summary

Open and trusted health data systems can help Europe respond to the many urgent challenges facing its society and economy today. The global pandemic has already altered many of our societal and economic systems, and data has played a key role in enabling cross-border and cross-sector collaboration in public health responses. Even before the pandemic, there was an urgent need to optimise healthcare systems and manage limited resources more effectively, to meet the needs of growing, and often ageing, populations.

Now, there is a heightened need to develop early-diagnostic and health-surveillance systems, and more willingness to adopt digital healthcare solutions.

The importance of secondary use of health data

By reusing health data in different ways, we can increase the value of this data and help to enable these improvements. Clinical data, such as incidences of healthcare and clinical trials data, can be combined with data collected from other sources, such as sickness and insurance claims records, and from devices and wearable technologies. This data can then be anonymised and aggregated to generate new insights and optimise population health, improve patients' health and experiences, create more efficient healthcare systems, and foster innovation.

This secondary use of health data can enable a wide range of benefits across the entire healthcare system. These include opportunities to optimise service, reduce health inequalities by better allocating resources, and enhance personalised healthcare – for example, by comparing treatments for people with similar characteristics. It can also help innovation by extending research data to assess whether new therapies would work for a broader population.

To assess the policy context at European and country level, we drew on the [ODI manifesto's six areas for trusted and trustworthy data ecosystems](#) (infrastructure, capability, innovation, ethics, equity and engagement) to identify 22 key policy components needed to achieve such an ecosystem. For each component, we proposed a success indicator as a one-sentence statement explaining how it would operate if it was a fully functional policy area. Finally, we evaluated these in two ways:

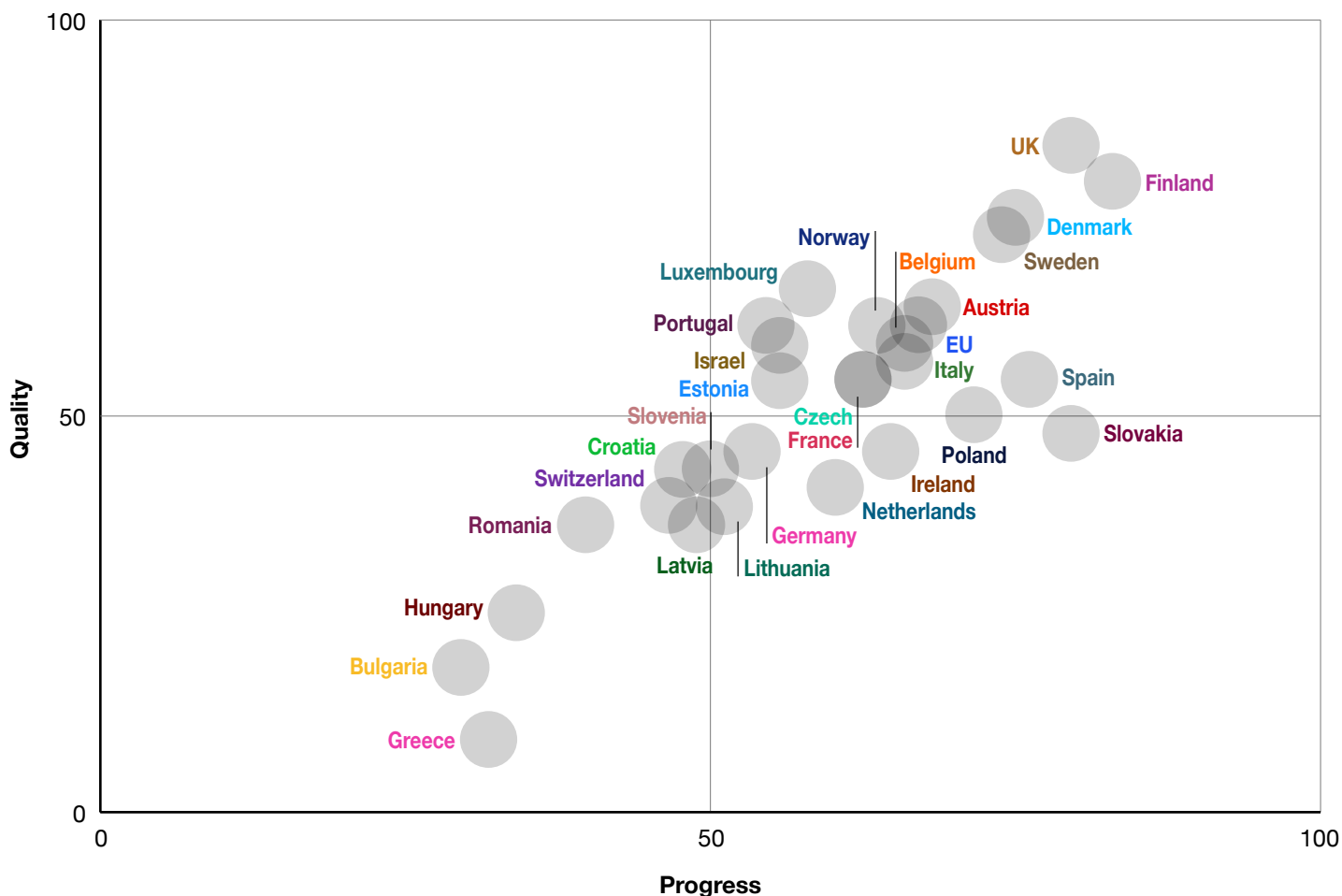
- **What is the quality of policy activity for this indicator?**
The evaluation range for activities is: having only limited aspects of the success indicator (low); aligned intent but missing key aspects (medium); fully comprehensive (high).
- **What progress is being made on implementation of policy for this indicator?**
The scoring range for the policy implementation stage is: not started (0); defined (1); planned (2); pilot initiatives (3); scaled-up implementations (4).

This approach allowed us to create a set of country rankings, and a library to demonstrate good practice or 'what does good look like?'. This also means country and regional policymakers and ministries of health can compare themselves with their peers and identify approaches they can adapt for their own context.

Our findings

Our research shows that policy work across countries in the European region can be ranked and organised in four groupings illustrated in Figure 1, below.

Figure 1: Secondary use of health data in Europe: country policy rankings



We clustered these countries in four broad groups above each quadrant line:

- Leaders:** where the quality of policy is stronger and the stage of implementation is more advanced. Sixteen countries and the European Commission fell into this category ([Austria](#), [Belgium](#), [Czech Republic](#), [Denmark](#), [Estonia](#), [European Commission](#), [Finland](#), [France](#), [Israel](#), [Italy](#), [Luxembourg](#), [Norway](#), [Portugal](#), [Spain](#), [Sweden](#), [UK](#)).
- Limited energy:** where the quality of policy is stronger but the stage of implementation is less advanced. No countries studied met these criteria.
- Limited vision:** where the quality of policy is weaker but the stage of implementation is more advanced. Six countries fell into this category ([Croatia](#), [Ireland](#), [Germany](#), [Netherlands](#), [Poland](#), [Slovakia](#)).
- Less prepared:** where the quality of policy is weaker and the stage of implementation is less advanced. Seven countries fell into this category ([Bulgaria](#), [Greece](#), [Hungary](#), [Latvia](#), [Romania](#), [Slovenia](#), [Switzerland](#)).

Key themes and insights

Overall, there are encouraging signs that European health data ecosystems are maturing to support secondary use of health data. However, many of the initiatives are still fragmented and significant work is needed to establish strong health-data ecosystems and infrastructure for reusing data. Though newer policy developments are looking to coordinate strategies across various stakeholders, initiatives and, importantly, member states.

However, one of the main challenges is the European General Data Protection Regulation (GDPR). While GDPR provides a strong foundation for secondary use of health data, governance tools are needed to enable data reuse. For example, codes of conduct, ethics committees, infrastructure for real-world data and real-world evidence, stronger data institutions, and clearer legal frameworks.

At both a country and a regional level, the lack of common open standards and data models is a key barrier to sharing data across borders. Much more work needs to be done to ensure public–patient participation in secondary use of health data.

How to use this report

This report is accompanied by a series of insight tools, including:

- a policy framework for 22 policy components for a trusted data ecosystem for secondary use of health data, along with a success indicator for each component
- a European-wide scorecard and profile against this framework, with policy challenges, policy achievements, and good practice highlights
- a set of 29 country scorecards and profiles against this framework, with policy challenges, policy achievements, and good-practice highlights.

We have created these tools using the ODI's [Theory of Change](#) for data value chains that lead to the best social and economic outcomes for everyone, and the [ODI's manifesto](#)¹ for an open, trustworthy data ecosystem. The project combines EU-level policy and country-level policy of 29 key states – 25 EU member states, and four non-EU countries (Israel, Norway, Switzerland, and the UK).

The report offers an overview of the current policy and implementation of secondary use of health data. However, it can only be a starting point: secondary use of health data is a key health policy issue in 2021 and beyond. The methodology for creating the insight tools, and how you can use them to help organisations and individuals participate in policy discussions, is available in the [Annexes section](#).

¹ ODI, n.d., '[Our manifesto](#)'.

Chapter 1: The importance of secondary use of health data

1.1 The opportunity

An open and trusted health-data ecosystem can help Europe respond to the many urgent challenges facing its society and the economy today. A data ecosystem consists of data infrastructure, and the people, communities and organisations who benefit from the value created by it.

The global Covid-19 pandemic has already altered many of our societal and economic systems, and data infrastructure has played a key role in enabling cross-border and cross-sector collaboration. Even before the pandemic, there was an urgent need to optimise healthcare systems and manage limited resources more effectively to meet the needs of growing, and often ageing, populations. Now there is a heightened need to develop early-diagnostic and health-surveillance systems, and more willingness to adopt digital healthcare solutions.

We define secondary use of health data² as:

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

Secondary use of health data plays a central role in enabling these improvements. It can increase the value of currently collected data from clinical settings, such as incidences of healthcare and clinical trials data, and data collected from other sources – such as sickness and insurance claims records – and from devices and wearable technologies. This data is often referred to as ‘real-world data’. We can then reuse this data, anonymised and aggregated, to improve people’s health and experiences, create more efficient healthcare systems, and foster innovation.

Secondary use of health data enables a wide range of benefits across the entire healthcare system. These include opportunities to optimise services, reduce health inequalities by better allocating resources, or use it to help enhance personalised healthcare – for example, by comparing treatments for people with similar characteristics. Secondary use of data can also help innovation by enhancing research data to assess whether new therapies would work for a broader population. Where we gain new insights from real-world data, this is often referred to as ‘real-world evidence’³. In this study, we analysed the infrastructure that supports real-world data collection and management, and enables decision-making based on this data.

How does a definition of secondary use of health data align with interpretations of the GDPR?

Our definition aims to reflect the EU’s General Data Protection Regulation (GDPR) definition of ‘secondary uses’, but in a health setting. Under GDPR, personal data about health includes all data about the health status of an individual. Using this personal data ‘for purposes other than those for which the data were initially collected’ is only allowed where the processing is compatible with the original purposes. Secondary use is generally allowed if it is necessary for carrying out a task in the public interest. Scientific research purposes may be permitted, where there is a lawful basis within a member state’s legislation⁴.

We show some secondary uses of health data and their potential benefits in Table 1.

² The European Federation of Pharmaceutical Industries and Associations (EFPIA) focuses on a definition of “secondary use of health data” that describes the secondary use of clinical health data, describing it as “the re-use of **clinical** trials data scientific research performed for health-related purposes other than the drug development program or other objective for which the clinical trial was performed”. (EFPIA (2019), ‘[Safeguards framework for secondary use of clinical trial data for scientific research](#)’.

³ ISPOR, n.d., ‘[Real-World Evidence](#)’.

⁴ EMA (2020), ‘[Electronic Health Record: Access, Share, Expand Project](#)’.

Table 1: Examples of secondary use of health data and their benefits

Uses	Optimise health systems	Improve the patient journey	Encourage patient-public participation	Expand innovation
Key benefits	<ul style="list-style-type: none"> • Reduce healthcare costs⁵ • Increase planning and more-efficient allocation of resources • Allow more equal prioritisation⁶ • Modernise reimbursement and pricing models⁷ • Enable insights for managing people’s health, early diagnosis, prevention and healthy living⁸ 	<ul style="list-style-type: none"> • Early, personalised and advanced diagnostics • Personalised care pathways and support for clinical decisions • Rapid access to personalised interventions • Remote monitoring and care through digital health apps and tools 	<ul style="list-style-type: none"> • Allow patients to contribute personal data • Use real-world data to discuss health • Enhance preventative care • Enable self-management of chronic illness 	<ul style="list-style-type: none"> • Enable new research • Expand development of medicine and technology⁹ • Facilitate predictive modelling • Reduce research risks • Allow new market entrants and encourage start-ups to collaborate with existing organisations • Strengthen assessment of health technologies

Healthcare systems around the world are changing. New approaches to using data are enabling new treatments and therapies, and healthcare professionals also use data to enable predictive modelling and design personalised care plans. As we have seen with the impacts of the Covid-19 pandemic, high-quality health data can also help governments and healthcare collaborative networks with population health management and in establishing early-warning systems.

With an ageing population, an increase in chronic illnesses, health impacts of climate change, and reduced available government spending in the wake of the pandemic, we urgently need to increase the efficiency of healthcare systems. Applying data insights can help optimise the allocation of healthcare spending, facilitate a more preventative-based model, encourage and enable self-management of chronic illness, and ensure fair prioritisation of health resources to those with the greatest health burden.

Secondary use of health data can also include predictive modelling and diagnosis, at an individual or population-wide level. Data can be drawn from a wide range of sources that were not previously used or available.

Letting healthcare innovators use health data for secondary purposes – that is, beyond primary care using the patient’s identifiable electronic health record – would help to progress science and innovation. This can help clinicians and others better understand the impact of healthcare interventions in real-world settings. It allows both:

- **broader analysis:** as they can use data from multiple interventions to guide clinical decisions, and
- **narrower analysis:** because they can filter data to assess real-world impacts on specific characteristics, such as age or co-morbidity.

Healthcare innovation can also expand further with real-world data, as people can create data flows that track and respond to patient needs in real-time. With the use of the Internet of Things, where digitally enabled devices can collect data, medical devices have evolved into more sophisticated tools that can help monitor and respond to patient health. In turn, these devices have given rise to new software that can help manage patient health automatically. Other data that could be used could include that sourced directly from patients, from government and institutional registries, and from patient healthcare records.

5 HIMSS, D’Amore, Mitchell (2020), ‘<https://www.himss.org/resources/electronic-health-record-data-governance-and-data-quality-real-world>’.

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

7 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](#)’.

8 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](#)’.

9 EMA (2020), ‘[GDPR and the secondary use of health data](#)’.

Where secondary use of health data is implemented in data ecosystems with trusted data flows, there is an opportunity to improve health outcomes for all of society. Recent examples from within the ODI's health portfolio demonstrate the potential:

- [Covid-19 symptom tracker apps](#) are able to collate health-surveillance data for early diagnostics, without exposing personal health data.
- [Data intermediaries](#)¹⁰ are able to protect the privacy of health data while also making anonymised, aggregated health data available for scientific research.
- Secondary use of health data can [open new markets in physical-activity businesses](#), which in turn generate greater preventative health opportunities for local populations.
- Competitors can share clinical-trial data on health challenges [such as antimicrobial resistance](#), while still protecting their commercial advantage.

1.2 The challenge

Introducing new data sources into the healthcare system, including clinical management as well as decisions on regulatory and reimbursement pathways, is reshaping the entire healthcare management system.

Across the health-data ecosystem, interoperability of data is one of the greatest challenges. In the EU, solutions must align with the four levels of interoperability (technical, syntactic, semantic, organisational), work across borders, and be drawn from a diverse range of health-system sections. This interoperability also needs to allow individual regions and countries to maintain autonomy in their health-policy decisions. For example, local values, culture, norms, and the organisation of healthcare as either central or regional, are all factors that need to be respected while ensuring interoperability across borders.

All stakeholders have specific needs, and face unique obstacles, in sharing data for health benefits. We discuss these in Table 2.

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¹⁰ Note that the draft [European Data Governance Act](#) defines 'data intermediaries' as 'providers of data-sharing services' that facilitate data-sharing between data holders and data users. The ODI defines the [broader category of 'data institutions'](#) of which data intermediaries are a subset as 'organisations that steward data on behalf of others, often towards public, educational or charitable aims', and whose functions can include granting data access, combining or linking data, or creating open datasets, among other functions.

Table 2: Secondary use of health data stakeholders and their needs

Stakeholder segment	Needs
Patients, people, carers, people interested in their own health and wellbeing, patient organisations	<ul style="list-style-type: none"> • Higher levels of data literacy • Understanding of the potential use and risks of sharing their data • New ways to give consent to their healthcare providers for making their data available • Trust – which must be built up by healthcare providers, business and governments to demonstrate they are responsible and are using health data solely for beneficial reasons
Healthcare professionals	<ul style="list-style-type: none"> • Ability to collect, store, use and share patient data securely • Inform higher-quality provision of care at both individual and population levels • In-house capability for good data management • Manage appropriate collecting and sharing of patient data with others
Healthcare regulators	<ul style="list-style-type: none"> • Oversee use of data to evaluate new therapies and healthcare interventions • Ability to use new data sources from outside clinical trials to augment decision-making and allow new evidence into regulatory processes • Capability to generate efficiency by harmonising regulatory pathways
Information regulators	<ul style="list-style-type: none"> • Capacity to ensure data systems are secure and uncorrupted • Monitor cyber-security threats • Ensure data governance that protects individual and group data rights
Competition regulators	<ul style="list-style-type: none"> • Uphold intellectual property and trade secrets of companies • Ensure organisations receive appropriate reimbursement for their innovations and participation in data-sharing systems • Foster a dynamic and innovative healthcare and health-technology market
Policy and lawmakers	<ul style="list-style-type: none"> • Greater access to data to inform decision-making • Interoperable data systems to share and link data, for example linking health data with environmental or industry data • Data institutions and structures to support leadership and collaboration in the data economy
Health system administrators, government and private health-insurance payers	<ul style="list-style-type: none"> • Ability to use data, as appropriate and within privacy guidelines, to move towards more efficient, value-based healthcare systems for reimbursement and in health-technology assessment • Reduce healthcare inequalities • Monitor and ensure that the value of new innovations is fairly distributed
Health ministers, health system leaders, diagnostic and preventative care professionals	<ul style="list-style-type: none"> • Ability to use health data to identify trends • Manage health surveillance • Create early-intervention alerts systems
Pharmaceutical and diagnostic industry, healthcare device inventors, and other stakeholders designing healthcare interventions	<ul style="list-style-type: none"> • Knowledge of where to find and access relevant data • Integration of data into their own systems • Ability to reuse the data in multiple ways to create new innovations and respond to patient-health needs • Ability to use data to build and test new products and services, and identify market gaps • Ability and support to use data to demonstrate reimbursement and to share the costs of healthcare innovation

1.3 Data management and access in Europe

Table 3 shows nine key types of data, and who controls which and at what operational level, in the European policy setting. We created this non-exhaustive list as an initial set of examples, drawing on the definition of secondary use of health data provided above (Section 1.1). When analysing the current policy environment for secondary use, it was helpful to identify the most common challenges that create barriers and obstacles to the access and reuse of these datasets.

Table 3: Key health datasets useful for secondary purposes

Dataset	Data controller	Level of management	Challenges observed to date	A good practice example of this dataset
Burden of Disease registries	Government authority	National, some regional blocs of countries	Lack of data-management standardisation	Comprehensive French health data systems
Biobank and genomic data	Government-funded independent initiative	National or regional blocs of countries, some Europe-wide	Pilot initiatives not fully implemented or scaled up	Austrian national node of a large European network for biobanks, the BBMRI -ERIC (BBMRI European Research Infrastructures Consortium)
Patient health records	Hospital networks, with access granted by patient giving specific consent	Local, regional, state, national or hospital networks	Poor interoperability	Belgium's series of data portals, including Brusafe, CoZo and Nexuzhealth are all linked together in a structured way
Medicine/ pharmaceutical registers	Government authority	National or regional blocs	Lack of data-management standardisation and limited resourcing	Portugal's adverse reactions database is integrated with the European framework
Patient-reported outcomes data	Hospitals, hospital networks Private companies	No clear coordination	Not used systematically or incorporated into healthcare reporting	Denmark's PRO system aims to be implemented across regions and municipalities
Scientific and clinical research data	Independent academic and research institutions	National, European or international level	Minimal numbers of datasets available Lack of legal and ethical framework for reuse	Estonia maintains an extensive list of open science health datasets
Public and private health-insurance claims data	Government authority Government payer authorities Private companies	National	Inconsistent data and lack of shared data models and interoperability	Lithuania's national compulsory health insurance system manages claims data
Employment sickness and social-security data	Government authority Government payer authorities Private companies	National	Varying in data quality, lack of shared data models	Statistics Norway regularly publishes up-to-date sickness absence data
Personal and health technologies data	Patient-accessible Often tech-managed or owned Often stored in tech companies' databases	International	Varying consent processes Lack of legal framework for collection and reuse	In Finland, citizens can add their health data from their apps and devices to their MyKanta portal

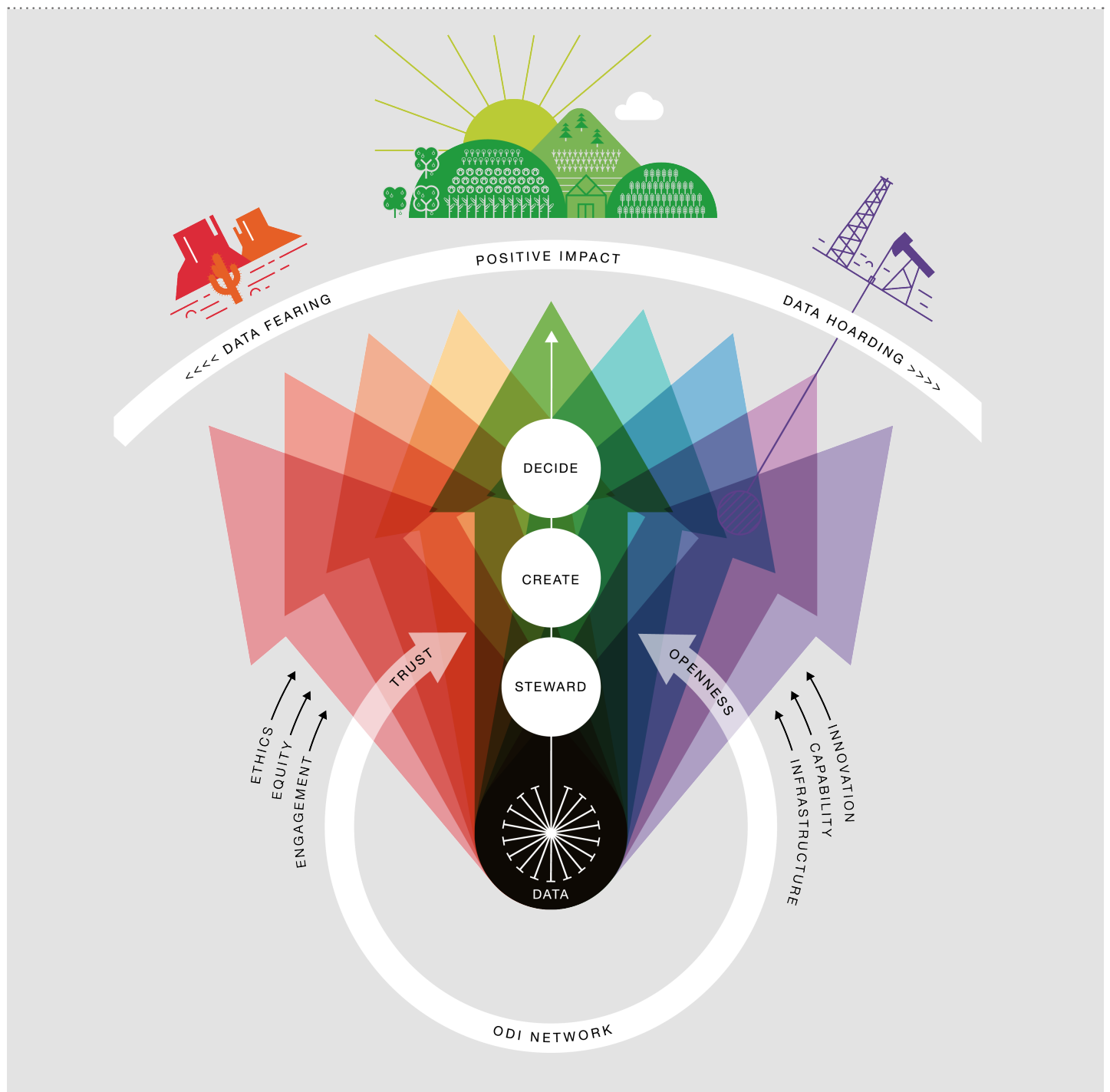
At a European level, it is necessary to analyse the legal framework and investment in coordinated data infrastructure covering these key datasets. At a country level, understanding current access and maturity of data infrastructure helps clarify whether good-quality, comparative data is available for reuse.

Chapter 2: Policy vision for secondary use of health data

2.1 The ODI's theory of change

The [ODI's theory of change](#)¹¹ looks at how we can foster an open and trusted data ecosystem by focusing on multiple elements, so that the use of data has a positive impact – as illustrated in Figure 2.

Figure 2: The ODI's theory of change for open and trusted data ecosystems



¹¹ ODI, (2018), 'Theory of Change'.

The ODI believes an open and trusted data ecosystem with the following key areas:

- **Infrastructure:** Sectors and societies must invest in and protect the data infrastructure they rely on. Open data is the foundation of this emerging vital infrastructure.
- **Capability:** Everyone must have the opportunity to understand how data can, and is, being used. We need data literacy for all, as well as data-science skills, and experience using data to help solve problems.
- **Innovation:** Data must inspire and stimulate innovation. It can help businesses, governments, individuals and communities create products and services, leading to economic growth and increased productivity.
- **Equity:** Everyone must benefit fairly from data. Access to data and information promotes fair competition and informed markets, and helps people as consumers, creators and citizens.
- **Ethics:** People and organisations must use data ethically. The choices made about what data is collected and how it is used should not be unjust, discriminatory or deceptive.
- **Engagement:** Everyone must be able to take part in making data work for all. Organisations and communities should collaborate on how they use and access data to help solve problems.

This model for data ecosystems can be applied to any jurisdiction, sector or domain. Here, we've used it alongside our analysis of country-level policy environments for secondary use of health data in the European region, to examine good practice.

2.2 Insight tool: policy framework for secondary use of health data

It's challenging to find an agreed industry or government-led framework that describes an effective health-data ecosystem that supports secondary use of health data. Some work was done in 2007 to move towards a common understanding¹² but, like the challenge itself, many efforts since then have worked on specific aspects rather than on the whole. Examples include secondary use of health data for scientific studies¹³, and interoperability of electronic health-record systems¹⁴. Where secondary use of health data is addressed directly, it is usually described at country level, to document the legal framework necessary to make secondary use possible, rather than at an industry-wide view¹⁵.

To assess the European policy context at the pan-European and country level, we drew on the ODI's six areas for open and trusted data ecosystems (infrastructure, capability, innovation, ethics, equity and engagement)¹⁶ to identify 22 key policy components needed for an open and trusted ecosystem for secondary use of health data.

For each of the framework components, we propose a one-sentence statement (called a success indicator) explaining how that component would operate if it was a fully functional policy tool, able to achieve goals – ie “what does good look like for this component?”. This is shown in Table 4. We provide a more-detailed discussion of the methodology and creation of this framework in the [Annexes](#).

¹² PubMed (2007), 'Toward a National Framework for the Secondary Use of Health Data: An American Medical Informatics Association White Paper'.

¹³ PubMed (2020), 'The increasing need for a new Italian legislation to facilitate execution of observational studies assuring ethics and the highest standards of scientific and methodological quality. Editorial'.

¹⁴ European Commission (2021), 'Electronic health records | Shaping Europe's digital future'.

¹⁵ Sitra (2019), 'A Finnish model for the secure and effective use of data. Innovating and promoting the secondary use of social and health data'.

¹⁶ ODI, n.d., 'Our manifesto'.

Table 4: Policy framework for secondary use of health data: what does good look like?

Policy framework component	Alignment with ODI manifesto area	Success indicator
Burden of Disease registries	Infrastructure	National illness and disease registries have been established with >75% of relevant patient population data recorded
Biobank and genomic data centralisation	Infrastructure	Established biobank and genomics databases centralise all structured diagnostic results
Patient health records	Infrastructure	Interoperable formats and standards for electronic health records are adopted, and records can be shared securely across borders
Medicine/ pharmaceutical registers	Infrastructure	National registers are maintained, including adverse drug-reaction registers
Patient-reported outcomes data	Infrastructure	Interoperable formats and standards are created for patient-reported outcomes
Science/clinical data	Infrastructure	Data from scientific studies, observational studies and clinical trials are available, and can be shared
Insurance-claims data	Infrastructure	National registers on social health-insurance claims are maintained and published regularly
Employment sickness and social-security data	Infrastructure	National registers on illness and sickness, including social-security financing and costs of illness on workplace participation, are maintained and published regularly
Personal and health-technologies data	Infrastructure	National systems for standardising, collecting and reusing personal-health data from wearables, fitness trackers, remote patient monitoring and software as a medical service are described, with people participating
Real-world data infrastructure	Infrastructure	All real-world data is captured in consistent standardised formats with advanced data-curation systems that enable exploration, cleaning and enrichment
Real-world evidence decision-making	Infrastructure	Health-technology assessment (HTA) bodies, regulators and policymakers have established a clear framework for using real-world evidence in decision-making
Adoption of open standards	Infrastructure	Health-data policies confirm the importance of using open standards for health datasets, and ministries of health are committed to adopting them
Legal framework for sharing of secondary use of data	Infrastructure	A legal framework is articulated that protects personal data so de-identified data can benefit society
Evaluation framework for health technologies	Capability	A strong, ethical, and community-inclusive health-technology assessment process is adopted across Europe and in each member state
Investment in EHR systems	Innovation	Training is resourced and incentives are available to healthcare institutions and data ecosystem stakeholders to encourage adoption of standard and data sharing, including use of EHRs

Policy framework component	Alignment with ODI manifesto area	Success indicator
Secondary use of health data policy is a national priority	Innovation	Specific policy is developed that recognises the value of secondary use of health data and all stakeholders are encouraged to participate in ecosystem networks, with strategic investment available to foster best practices
Equity considerations addressed	Equity	Policies recognise the uneven distribution of health resources and want secondary use of health data to address this
Privacy regulation	Equity	There is rigorous privacy regulation that allows appropriate industry access and use of high-quality healthcare data within agreed privacy constraints
High level of trust in data-informed healthcare	Ethics	We can see a high degree of willingness by the public to consent to reuse of their health data for research and personalised healthcare goals
Ethical/accountability framework for secondary use of health data	Ethics	Clear reporting, methods of redress and consequences are defined and resourced
Sustainable and trustworthy data institutions ¹⁷	Engagement	Strategic investment in data institutions that can oversee data infrastructure and report on implementation and capabilities
Public/patient participation	Engagement	Investment to support participation of citizens and healthcare communities in decision-making

For each component, we identified current policy work, institutional support, and strategic initiatives. We then evaluated these activities using two measures:

- **What is the quality of policy activity for this indicator?** The scoring range for these quality evaluations is: having only limited aspects of the success indicator (low / 0); aligned intent but missing key aspects (medium / 2); or fully comprehensive (high / 4).
- **What progress is being made on implementation of policy for this indicator?** The scoring range for policy-implementation stages is: not started (0); defined (1); planned (2); pilot initiatives (3); scaled-up implementations (4).

2.3 Further considerations

As with any such analysis, the approach we've taken has limitations that we highlight here to aid with the interpretation of the results:

- The implementation scores evaluate the extent to which policy-makers have invested in implementation of the policy, but do not evaluate the effectiveness of that implementation, or its impact. So, for example, policy activity might be evaluated against the framework as high quality – which means there are comprehensive policy statements on the topic – and as having scaled-up implementation, but the nature of that implementation might still be flawed.

- The policy indicators are not evenly distributed across the ODI's manifesto areas for open and trustworthy data ecosystems: for example, the Infrastructure policy area has 13 indicators while the Ethics policy area has only two, so jurisdictions that have invested in data infrastructure policy while neglecting data ethics policy might still score highly overall. One option for mitigating this imbalance would have been to weight scores across each manifesto area: however, this may have led to a different kind of skew or imbalance in the results, since not all the tools or interventions needed to support open and trustworthy data ecosystems are policy tools.
- The policy indicators evaluate the readiness of the policy environment in the jurisdiction, but do not evaluate other key considerations for implementation and impact – such as the economic, political, and social environment. We have provided some of this context in the country profiles (see Annexes), which include data on country GDP, population size, GDP per capita, and Gini co-efficient for in-country inequalities. The extent and distribution of positive impact from policies to do with secondary use of health data will depend on these and other factors.

¹⁷ Note that the draft [European Data Governance Act](#) defines 'data intermediaries' as 'providers of data-sharing services' that facilitate data-sharing between data holders and data users. The ODI defines the broader category of 'data institutions' of which data intermediaries are a subset as 'organisations that steward data on behalf of others, often towards public, educational or charitable aims', and whose functions can include granting data access, combining or linking data, or creating open datasets, among other functions

Chapter 3: EU policy for secondary use of health data

Overall, Europe presents an exciting policy base for creating secondary use of health data. In the last two years, in line with the European Strategy for Data¹⁸, a health-data policy environment that encourages secondary use has begun to emerge. Policies and strategies increasingly take a joined-up approach. The four biggest challenges that remain are:

- Differing interpretations of GDPR and lack of clarity on how to enable secondary use of health data while maintaining Europe's strong data privacy.
- Fragmentation of initiatives and approaches across Europe hindering member states' ability to support each other or 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 use secondary health data to reduce health inequalities.

3.1 Insight tool: EU policy scorecard

Table 5 shows a summary table of the current analysis of the European policy environment, assessed using the policy framework (for the full scorecard and profile, please see the [Annexes](#)). While secondary use of health data is increasingly identified as an opportunity in health, the digital economy, and data strategies, implementation is fairly new. Many strategies are only just starting to identify work programmes. We expect many changes as European policy advances over the coming years.

Table 5: Summary table: EU policy scorecard

Framework indicator	Indicator evaluation	Stage of implementation
Burden of Disease registries	Low Med High	4/4
Biobank and genomic data centralisation	Low Med High	4/4
Patient health records	Low Med High	3/4
Medicine/pharmaceutical registers	Low Med High	4/4
Patient-reported outcomes data	Low Med High	1/4
Open science/open clinical data	Low Med High	2/4
Insurance-claims data	Low Med High	4/4
Employment-sickness and social-security data	Low Med High	4/4
Personal and health-technologies data	Low Med High	1/4
Real-world data infrastructure	Low Med High	3/4
Real-world evidence decision-making	Low Med High	4/4
Adoption of open standards	Low Med High	2/4
Legal framework for sharing of secondary use of data	Low Med High	2/4
Evaluation framework for health technologies	Low Med High	2/4
Investment-in electronic-health-record systems	Low Med High	2/4
Policy for secondary use of health data is a recognised priority	Low Med High	2/4
Equity considerations addressed	Low Med High	1/4
Privacy regulation	Low Med High	4/4
High level of trust in data-informed healthcare	Low Med High	4/4
Ethical/accountability framework for secondary use of health data	Low Med High	4/4
Sustainable and trustworthy data institutions	Low Med High	2/4
Public/patient participation	Low Med High	3/4

3.2 Relevant EU-wide policy

There are two main policy areas that affect policy for secondary use of health data, as shown in Table 6. 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.

Table 6: Key European policy areas

European vision for a data-enabled future	Digital transformation of healthcare
<ul style="list-style-type: none"> • GDPR¹⁹ • European Strategy for Data²⁰ <ul style="list-style-type: none"> • Data Governance Act²¹ • White Paper on Artificial Intelligence²² • Final Report and Action Plan from the Commission Expert Group on FAIR Data²³ • Europe’s Digital Decade²⁴ 	<ul style="list-style-type: none"> • Communication on enabling digital transformation of health and care²⁵ <ul style="list-style-type: none"> • Commission Recommendation on a European Electronic Health Record exchange format²⁶ • 1+ Million Genomes initiative²⁷ • European Reference Networks²⁸ • Electronic Exchange of Social Security Information²⁹ • Integrating Healthcare Enterprise³⁰ • eHealth Network³¹ • One Health Action Plan Against AMR³²

In many instances, these two categories of work are operating independently of each other. The strategies that relate to ‘Europe’s vision for a data-enabled future’ often refer to other policies within that grouping. But the 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. Implementation of electronic health records by EU member states often led to a lack of interoperability and data fragmentation across borders, and limitations in being able to collect and compare Covid-19 data, to assess infection rates and healthcare access in different regions.

There is a third, emerging, group of policy work that could create a bridge between these two currently disconnected areas. The following initiatives represent an opportunity for a new collaborative approach, drawing on the secondary use of health data. In fact, ensuring capacity for secondary-use purposes could be what encourages policy action, as it is a common element needed to achieve many of the wider policy goals discussed in the documents. This will involve multiple stakeholders from the digital, healthcare, and privacy domains. The key policies and initiatives behind this joined-up approach are:

- European Health Data Space³³
- Pharmaceutical Strategy for Europe³⁴
- European Medicine Authority Regulatory Science to 2025³⁵
- Europe’s Beating Cancer Plan³⁶.

It is encouraging that, in contrast to earlier healthcare modernisation policies, these more recent files are able to identify the other, current, related bodies of work that support the acceleration of data and digitally enabled healthcare systems.

These documents, as shown in Figure 3, 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?

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

20 European Commission (2021), [‘A European Strategy for Data. Shaping Europe’s Digital Future’](#).

21 European Commission (2021), [‘European data governance’](#).

22 European Commission (2020), [‘White Paper On Artificial Intelligence – A European approach to excellence and trust’](#).

23 European Commission (2018), [‘Turning FAIR into Reality’](#).

24 European Commission (2021), [‘Europe’s Digital Decade: Commission sets the course towards a digitally empowered Europe by 2030’](#).

25 European Commission (2019), [‘Communication on enabling the digital transformation of health and care in the Digital Single Market’](#).

26 European Commission (2019), [‘Recommendation on a European Electronic Health Record exchange format’](#).

27 European Commission (2021), [‘European “1+ Million Genomes” Initiative’](#).

28 European Commission, n.d., [‘European Reference Networks’](#).

29 European Commission, n.d., [‘Digitalisation in social security coordination – Employment, Social Affairs & Inclusion’](#).

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

31 European Commission, n.d., [‘eHealth Network | Public Health’](#).

32 European Commission (2017), [‘A European One Health Action Plan against Antimicrobial Resistance \(AMR\)’](#).

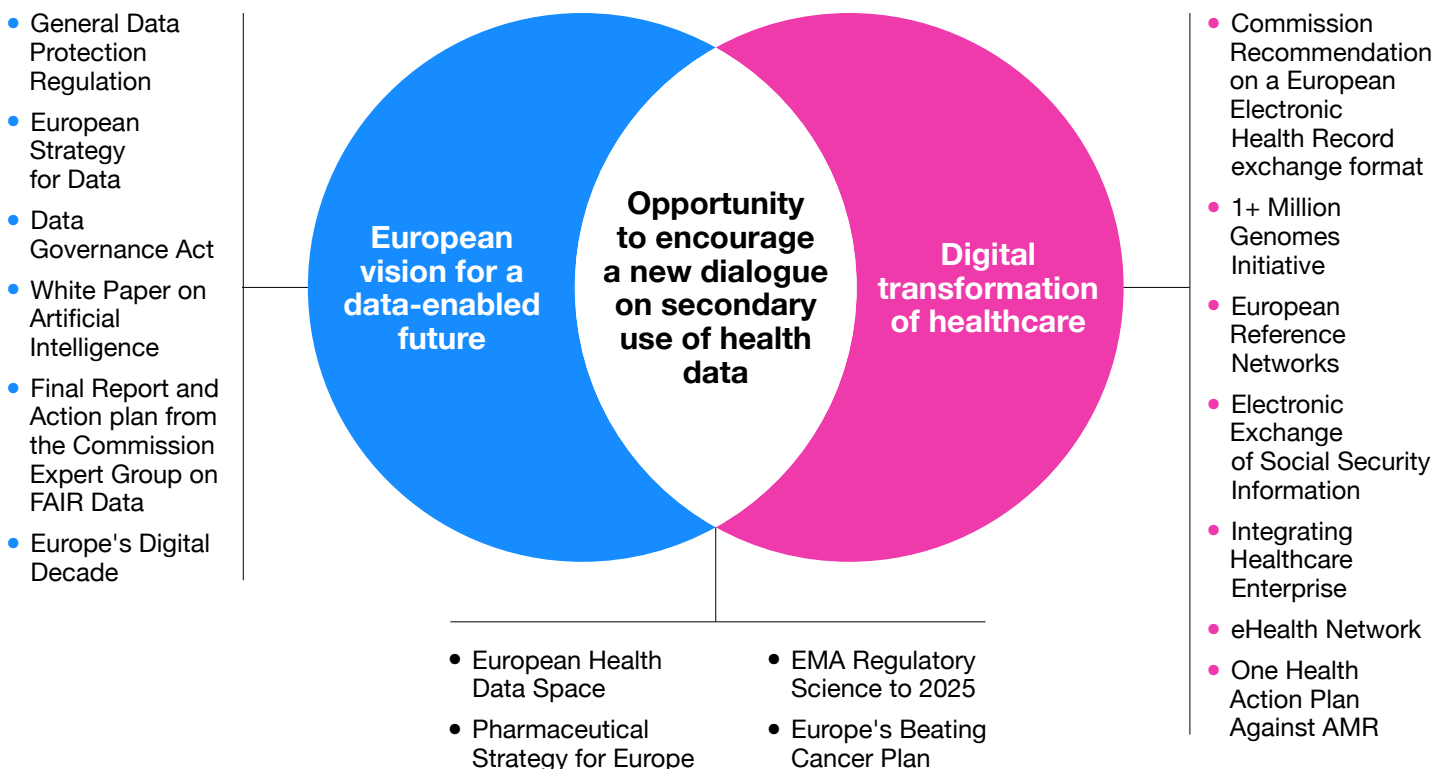
33 European Commission, n.d., [‘European Health Data Space | Public Health’](#).

34 European Commission (2020), [‘A pharmaceutical strategy for Europe | Public Health’](#).

35 European Medicines Agency (2020), [‘EMA Regulatory Science to 2025’](#).

36 European Commission (2021) [‘Europe’s Beating Cancer Plan v.24’](#),

Figure 3: Thematic analysis of relevant European health-data policies



3.3 Current strategic direction

The European Commission has significant potential to create a cohesive ecosystem that enables the secondary use of health data. This will mean supporting member states must implement standardised, interoperable, and collaborative health-data strategies. The commission’s **European Strategy for Data** aims to create a consciously ethical approach, including strict data protection 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 fundamental change of the ‘big data’ revolution – that has enabled large-scale and rapid collection of detailed data, and new kinds of advanced data analysis or digital products and services – also brings challenges. Much of the legislation and regulation of 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 they are anticipating future needs, risks, and opportunities. Similarly, new potential uses of health data – including the secondary uses of health data, and personalised healthcare – are not always easily navigated within existing policies for health data.

There is much hope 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 Space³⁷ will aim to:

- promote safe exchange of patients’ data (including when they travel abroad) and citizens’ control over their health data
- support research on treatments, medicines, medical devices and outcomes
- encourage 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, governed by common rules, procedures and technical standards to ensure health data can be accessed within and between member states, with full respect for the fundamental rights of individuals’³⁸.

The **Joint Action Towards the European Health Data Space**³⁹ (TEHDS) is the initial step to create this network. Ideally, this network will take a multi-stakeholder approach that encourages participation by industry (including pharmaceutical companies), regulators, healthcare providers,

37 EUR-Lex (2016), ‘EU eGovernment Action Plan 2016-2020 Accelerating the digital transformation of government’.

38 European Commission (2019), ‘Assessment of the EU Member States’ rules on health data in the light of GDPR’.

39 TEHDAS (2020), ‘Joint Action Towards the European Health Data Space’.

health surveillance and data-system operators, patient advocacy and consumer groups, emerging health tech start-ups, privacy and digital rights advocates, and researchers. Drawing on examples for digital government frameworks⁴⁰, this network could identify key uses and priorities of work, 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. Current work by TEHDS includes a summary document outlining why health data needs separate regulation to cover its use, to address the fragmentation challenges in interpreting GDPR when applied to health data.

The work of the **European Medicines 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 AI⁴¹ and, through its Heads of Medicines Agencies (HMA)/ EMA Big Data Steering Group⁴², has outlined how these guidelines could help inform the work of an ethics committee to oversee secondary use of healthcare data, and help in creating 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)⁴³ and has supported pilot models that test the use of real-world data infrastructure in 'pharma-covigilance' and for detecting drug-safety issues.
- It has identified the need to create standardised tools for health-technology assessment for use across Europe.

3.4 Key aspects of EU policies and implementation

We identified the following common themes as risks and blockers in the current policy environment, that may affect the development of open and trusted 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 Europe-wide policy documents, and research papers aimed at understanding the secondary use of health data policy context, have agreed:

- there needs to be shared agreement on data-consent mechanisms, codes of conduct for using and sharing data, common data models and data standards
- that common infrastructure needs to be built
- that greater multi-stakeholder collaboration should be made easier

As this work begins, through the Joint Action Towards the European Health Data Space, stakeholders will need to provide their opinions and implementation practices. This means industry stakeholders and member states will need to agree on various models and ways forward. One of the challenges, and part of the reason for the cycle of recommendations in recent years, is that there are not many examples of implementation and not many people expressing an opinion on the specific elements proposed. For example, open standards are proposed, but which ones 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.

Increased collaboration and exchange: Data sharing is still fairly minimal across Europe, outside specific initiatives. The ambitious 1+ Million Genomes initiative⁴⁴, signed by 23 countries 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 the greatest challenge was using existing datasets consistently and with patients' consent. Electronic health-record data systems are often not advanced enough to be shared beyond the clinical care setting.

Quality: Across Europe, there is a wide range of initiatives in sub-sector domains that seek to encourage data sharing. The European Joint Programme on Rare Diseases⁴⁵, 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 for how lessons from these models can translate into policy for the whole of Europe and data-ecosystem environments.

Global data flows: 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 Medicine⁴⁶ has been identified for establishment in 2023, and recognition of the value of personalised healthcare is referred to in new health policies such as Europe's Beating Cancer Plan⁴⁷. This plan shows 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.

Investment: Funding of health-system transformation is often limited across EU member states. Member states may be able to access new funding for modernising data infrastructure through the European Recovery and Resilience Facility⁴⁸, as has been proposed by the 1+ Million Genomes initiative⁴⁹. 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 further optimise planning and healthcare service.

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

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

42 EMA (2020), '[Big data](#)'.

43 EMA (2020), '[2.2. Proposal for a Data Analytics and Real-World Interrogation Network \(DARWIN\)](#)'.

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

45 [EJP RD – European Joint Programme on Rare Diseases](#)

46 European Commission, n.d., '[General Information Preliminary title of the European Partnerships European Partnership for personalised medicine](#)'.

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

48 European Commission (2021), '[Recovery and Resilience Facility | European Commission](#)'.

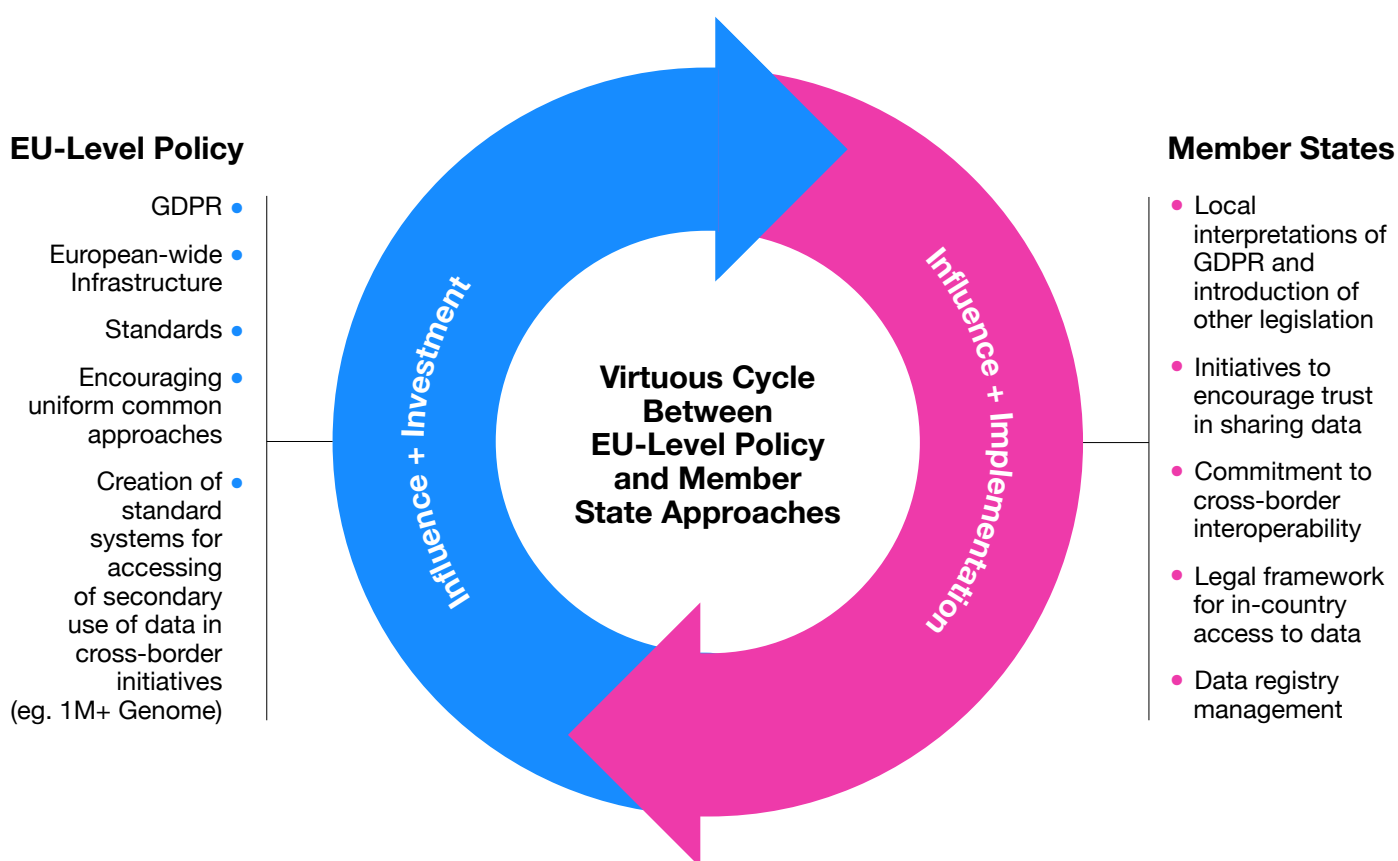
49 European Commission (2021), '[European "1+ Million Genomes" Initiative](#)'.

Chapter 4: Country-level policy for secondary use of health data

4.1 Context: country-level legislation and regulation

The EU and member-state policy cycle encourages a flow of influence and investment between the Europe-wide policy environment and local decisions. Under the Treaty on the Functioning of the European Union⁵⁰, the EU may set broad policy directives, strategies or legislation. This is then enacted on a member-state level, where investment may also be provided to build collaborative demonstration projects. In turn, the lessons from these initiatives influence future Europe-wide policy. This cycle of influence, investment and implementation is shown in Figure 4.

Figure 4: Virtuous cycle between EU-level policy and member-state policy



⁵⁰ EUR-Lex (2012), '[Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union](#)'.

Countries in scope⁵¹ for this study were:

Austria	Greece	Poland
Belgium	Hungary	Portugal
Bulgaria	Ireland	Romania
Croatia	Israel	Slovakia
Czech Republic	Italy	Slovenia
Denmark	Latvia	Spain
Estonia	Lithuania	Sweden
Finland	Luxembourg	Switzerland
France	Netherlands	UK
Germany	Norway	

4.2 Insight tool: country-level scorecards

The country-level scorecards are available in the [Annexes](#). As with the European Commission-level scorecard, for each framework component on the country-level scorecards, we identified current policy work, institutional support, and strategic initiatives. We then evaluated these activities for two measures:

- What is the quality of policy activity for this indicator?** The scoring range for these quality evaluations is: having only limited aspects of the success indicator (low / 0); aligned intent but missing key aspects (medium / 2); or fully comprehensive (high / 4).
- What progress is being made on implementation of policy for this indicator?** The scoring range for policy-implementation stages is: not started (0); defined (1); planned (2); pilot initiatives (3); scaled-up implementations (4).

These country-level scorecards are subject to the same considerations discussed around the EC-level scorecard in section 2.3 of this report.

4.3 Insight tool: country profiles

The country profiles are available in the [Annexes](#). Country profiles provide brief overviews of the current policy environment for secondary use of health data including:

- Key data:** a snapshot of the countries population size, GDP, GDP per capita, % GDP spend on healthcare, and Gini coefficient for in-country inequality.
- Chart:** a visualisation of the performance of each country against the ODI manifesto areas
- Overview:** a summary that outlines health-strategy incorporation of secondary use of health data, along with how country-level patient data-privacy legislation is managed.
- Policy challenges:** a summary of key policy challenges facing further implementation of secondary use of health data.
- Policy achievements:** a summary of where each country excels and shows leadership in policy.
- Good-practice highlights:** a bullet-pointed description of the good practices within different ODI manifesto areas.

Creating accurate country profiles was challenging for a number of reasons:

- Centralised v distributed:** Some countries have centralised health systems. In others, responsibility is devolved to autonomous regions, or they are reforming to a centralised or decentralised system. In all cases, this increases the number of different systems being used, such as electronic health-record collection and decision-making on sharing and reuse of data, which makes it hard to summarise a single policy picture across an entire country.
- Implementation tells a different story:** During validation of some country profiles, it became evident that while policy documents suggested infrastructure and data systems were in place, stakeholder experience suggested that it was not actually as advanced. For example, some policy documents noted a robust health-data registries network, but in practice data was not maintained.
- Languages locked in:** While this research was conducted in English, we translated documents using online translation tools. If key strategy and policy documents were available only as PDFs, this was more difficult and we may have missed some policy initiatives and detail.

⁵¹ Several countries included in this study are outside the EU and include Israel, Norway, Switzerland, and the UK, but share a location in the European region and their long-term relationships with healthcare systems within the European Union.

Chapter 5: Discussion: ‘What does good look like?’

5.1 Summary

Analysis that spans both European Commission-level policymaking and individual country-level policymaking can encourage and support Europe-wide leadership on secondary use of health data policy by drawing on, and demonstrating, country-level success.

We can use cross-country comparisons to identify where other countries in the region have been able to advance, allowing and encouraging sharing of best practices across Europe. Common challenges – such as fragmentation in data collection and lack of consistency in data-model definitions – can be more easily identified, and regional approaches proposed.

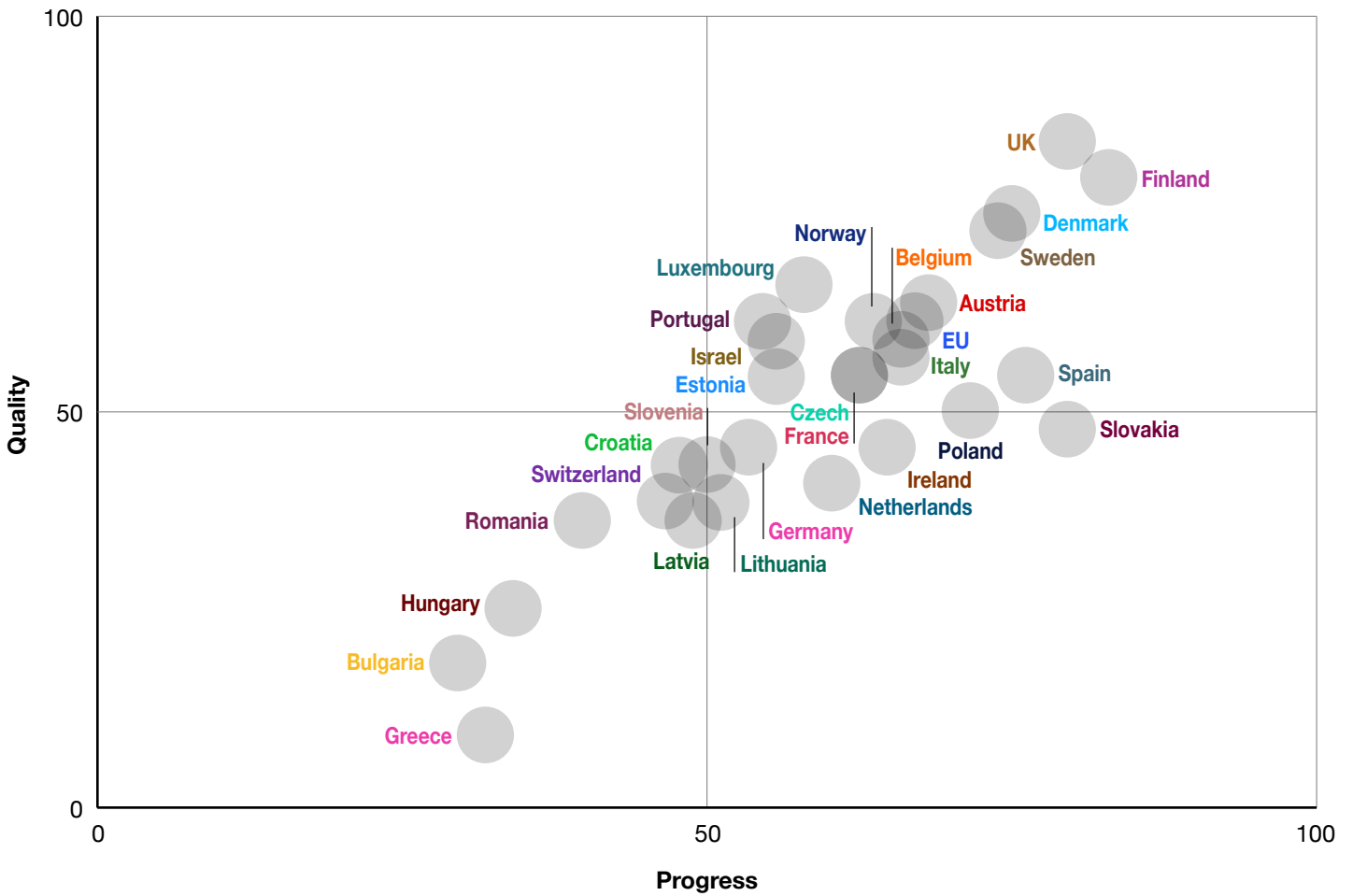
Several common themes emerged in the level of maturity of secondary use of health data in current country-level policy:

- **Levels of investment differ:** Only some countries are investing in managing their data infrastructure.
 - **Policy vision related to secondary use of health data is limited or incomplete:** Some countries have secondary use of health data policies and guides, or personalised healthcare strategies that address this. Others have only documented wider goals or have broad ‘e-health’ policies that focus solely on electronic health-record infrastructure.
 - **Data infrastructure collection and quality varies:** While most countries have some data registries available, they vary – some are updated regularly while others were last published in 2016 or earlier.
-

5.2 Benchmarking

Our research shows that policy work across countries in the European region can be ranked and organised in four groupings illustrated in Figure 1, below.

Figure 1: Secondary use of health data in Europe: country policy rankings



We clustered these countries in four broad groups above each quadrant line; the groupings and their main characteristics are described in Table 7, below.

Table 7: Secondary use of health data: country policy groupings

Group	Characteristics	
Leaders	<ul style="list-style-type: none"> Recognise the value of secondary use of health data for innovation, personalised healthcare, improved diagnostics Working towards improving health-data infrastructure and ecosystems for reusing data Incorporating use of real-world data and real-world evidence into health systems 	Austria Belgium Czech Republic Denmark Estonia European Commission Finland France Israel Italy Luxembourg Norway Portugal Spain Sweden UK
Limited energy	<ul style="list-style-type: none"> Have recognised the value of secondary use of health data Implementation lagging, as strategic vision is yet to be enacted 	No countries
Limited vision	<ul style="list-style-type: none"> Often do not explicitly mention the value of secondary use of health data or have fragmented practices where strategies are not fully implemented Limited vision in using data infrastructure beyond interoperable electronic health records Some momentum on implementing health strategies that have some data relevance 	Croatia Ireland Germany Netherlands Poland Slovakia
Less prepared	<ul style="list-style-type: none"> Do not explicitly describe the value of secondary use of health data Are not focused on progressing digital health or national health strategies 	Bulgaria Greece Hungary Latvia Romania Slovenia Switzerland

Leaders exhibited some common features:

- Opportunities for secondary use of health data to enable personalised healthcare, improved diagnostics, and preventative healthcare are explicitly mentioned ([UK](#), [Finland](#)), but also some of those in the Limited Vision category, including [Ireland](#) and [Netherlands](#)).
- Pilot projects are being implemented to introduce real-world data infrastructure ([Estonia](#) and [Spain](#)).
- There is a focus on multi-stakeholder involvement, including establishment of data institutions that enable a range of organisations to participate in the emerging data infrastructure ([Israel](#), [France](#)).
- There is a link to ethical frameworks, such as establishment of ethics committees for approving secondary-use requests ([UK](#), [Sweden](#)).

- There is a legal framework to enable secondary use that recognises GDPR rights, but looks to provide greater clarity on appropriate secondary-use cases ([Finland](#)).

5.3 Analysis of country-level best-practice examples

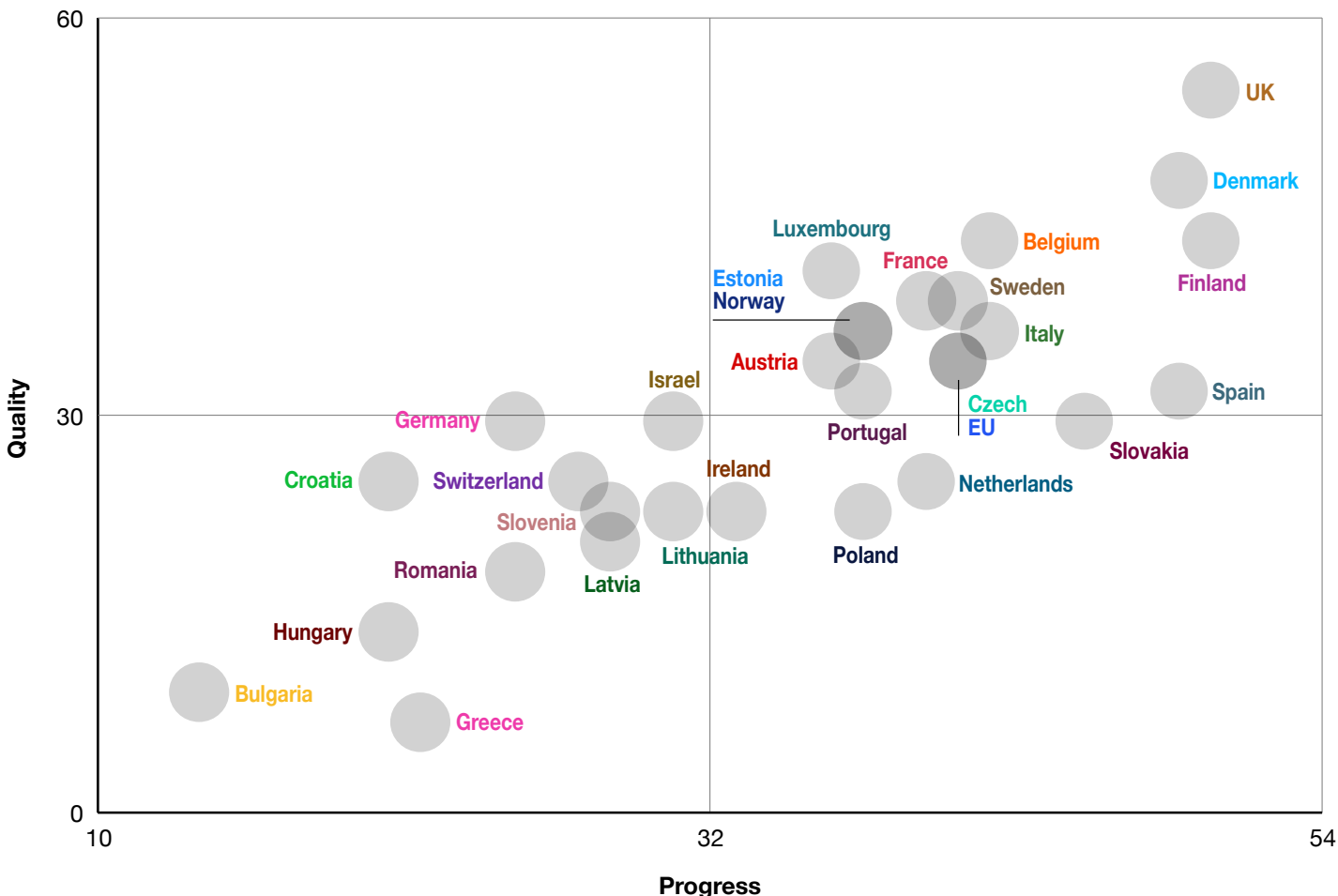
While a summary of each country's overall progress helps identify European-wide trends and opportunities, it can also hide areas where each country may have further work to do. The scoring model calculates country progress based on two scores: alignment with success indicators, and implementation progress. All countries have the opportunity to improve the way secondary use of health data is positioned in their digital-health strategies and in their level of progress.

Looking in more detail at where each country can improve the openness and trustworthiness of its individual ecosystem for secondary use of health data, can allow more strategic action and help motivate countries to address gaps and obstacles.

5.3a Infrastructure

From the 22 policy components of the policy framework, we identified 13 that aligned with the ODI manifesto area of Infrastructure. These include individual datasets, real-world data and evidence infrastructure, and the adoption of open health-data standards. Figure 5 benchmarks the country-level policy environment for these components.

Figure 5: Secondary use of health data: country policy benchmarking – Infrastructure



The [UK](#), [Belgium](#), and [Denmark](#) have invested in health-data infrastructure to enable secondary use of high-quality, comparable health datasets, and the incorporation of new infrastructure to support real-world data and real-world evidence, including for reimbursement and optimisation of health systems.

The [UK](#), for example, has aligned health-data registries and regularly reports on data collected in a consistent, standardised format.

[Belgium](#)'s electronic health-record system is designed so that decentralised, regional-based health provision does not hinder sharing health data. Multiple health-data portals, even multiple portals within one health region, all draw on interoperable data models, so data is linked in a structured way. Sustainable and trustworthy data institutions ensure they maintain data standards.

[Denmark](#) also has a strong health-data system, with health-data registries regularly collected and reported. Denmark is a leader in implementing real-world data and real-world evidence infrastructures, drawing on WHO SNOMED ICD-10 coding to ensure consistency. It has established [Danishhealthdata.com](#) for researchers and organisations to request health data.

5.3b Capability

From the 22 policy components of the policy framework, we identified one indicator that aligned with the ODI manifesto area of Capability. This focused on measuring whether there was an evaluation framework for health technologies in place. Figure 6 benchmarks the country-level policy environment for this component.

Figure 6: Secondary use of health data: country policy benchmarking – Capability



A strong, ethical and community-inclusive health-technology assessment system provides a country with the capabilities to manage secondary use of health data.

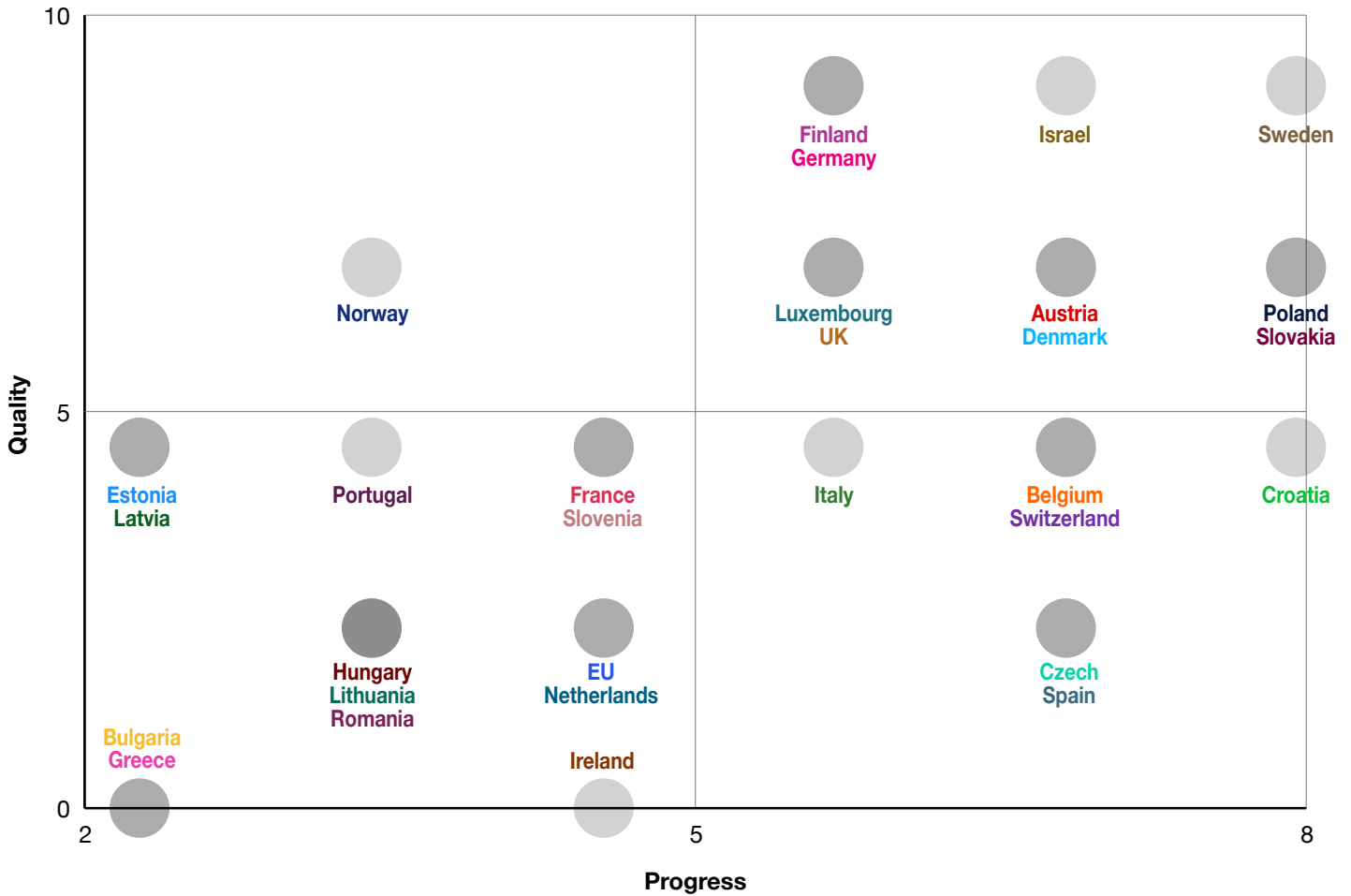
The [Czech Republic](#)'s SUKL acts as the national health-technology assessment agency and provides a strong evaluation framework for secondary use of health data when reviewing new health therapies and technologies.

[Austria](#) has built a comprehensive health-technology assessment guide and participates in the EUnetHTA collaborative network, regularly reporting on decisions made.

5.3c Innovation

From the 22 policy components of the policy framework, we identified two indicators that aligned with the ODI manifesto area of Innovation. In this case, we focused on assessing if country-level health policies recognised the opportunity of secondary use of health data (for example, by explicitly mentioning secondary use in national policies). We also analysed the investment that was being made in electronic health-record systems as a foundation for enabling future innovation. Figure 7 benchmarks the country-level policy environment for this component.

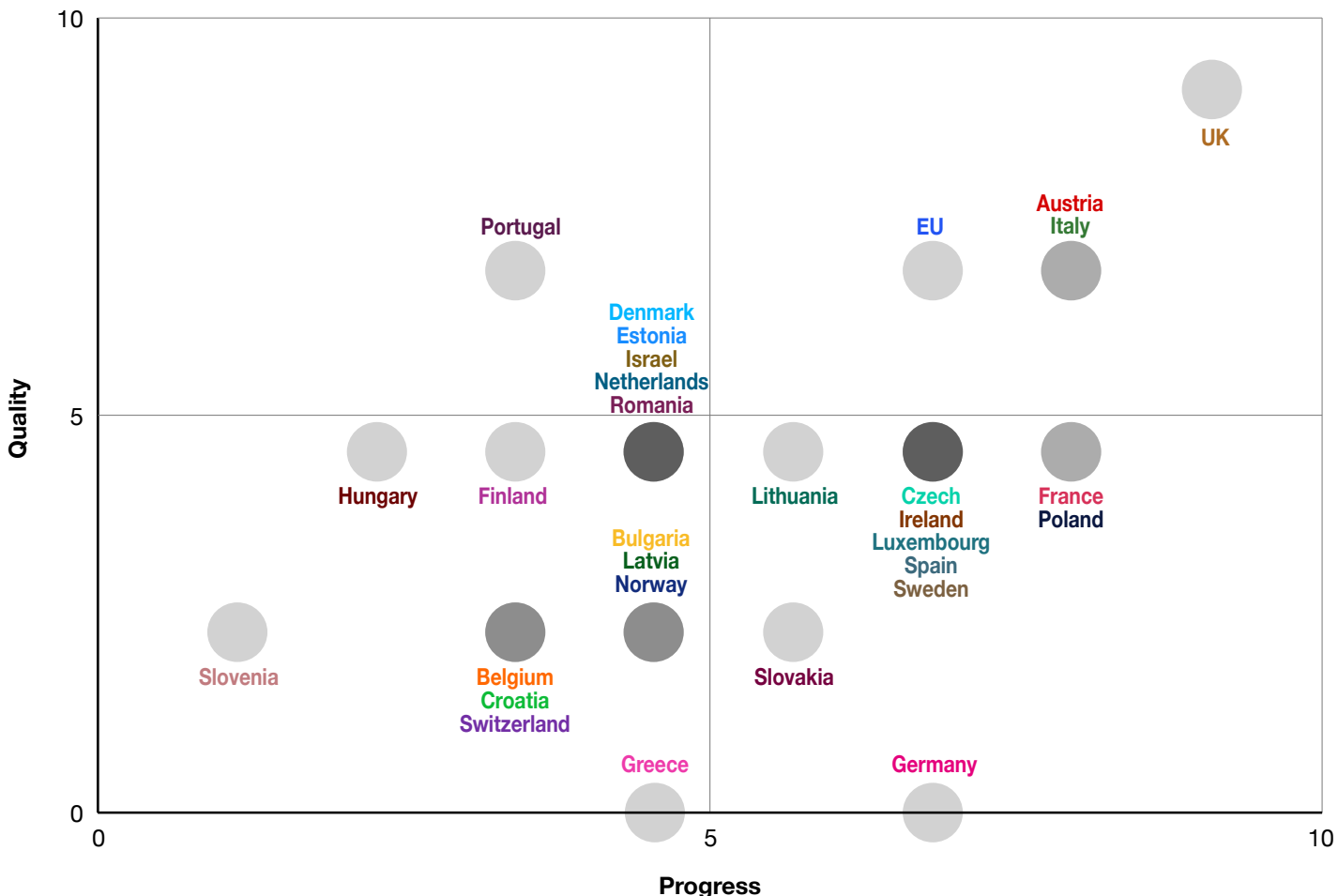
Figure 7: Secondary use of health data: country policy benchmarking – Innovation



5.3d Equity

From the 22 policy components of the policy framework, we identified two indicators that aligned with the ODI manifesto area of Equity. This focused on privacy regulation, and whether opportunities for secondary use of health data were identified to help reduce health inequalities. Figure 8 benchmarks the country-level policy environment for this component.

Figure 8: Secondary use of health data: country policy benchmarking – Equity



Equity is measured by strength of privacy regulation, and how clear strategies are in creating the potential to use secondary use of health data to reduce inequalities in access to healthcare, or in reducing inequalities in health outcomes of marginalised populations. Most countries analysed have developed strong data-privacy regulations, aligned with GDPR. However, making use of data to prioritise strategies that address health inequity is often not discussed when describing secondary use of health data, or it is discussed in passing in broader strategies.

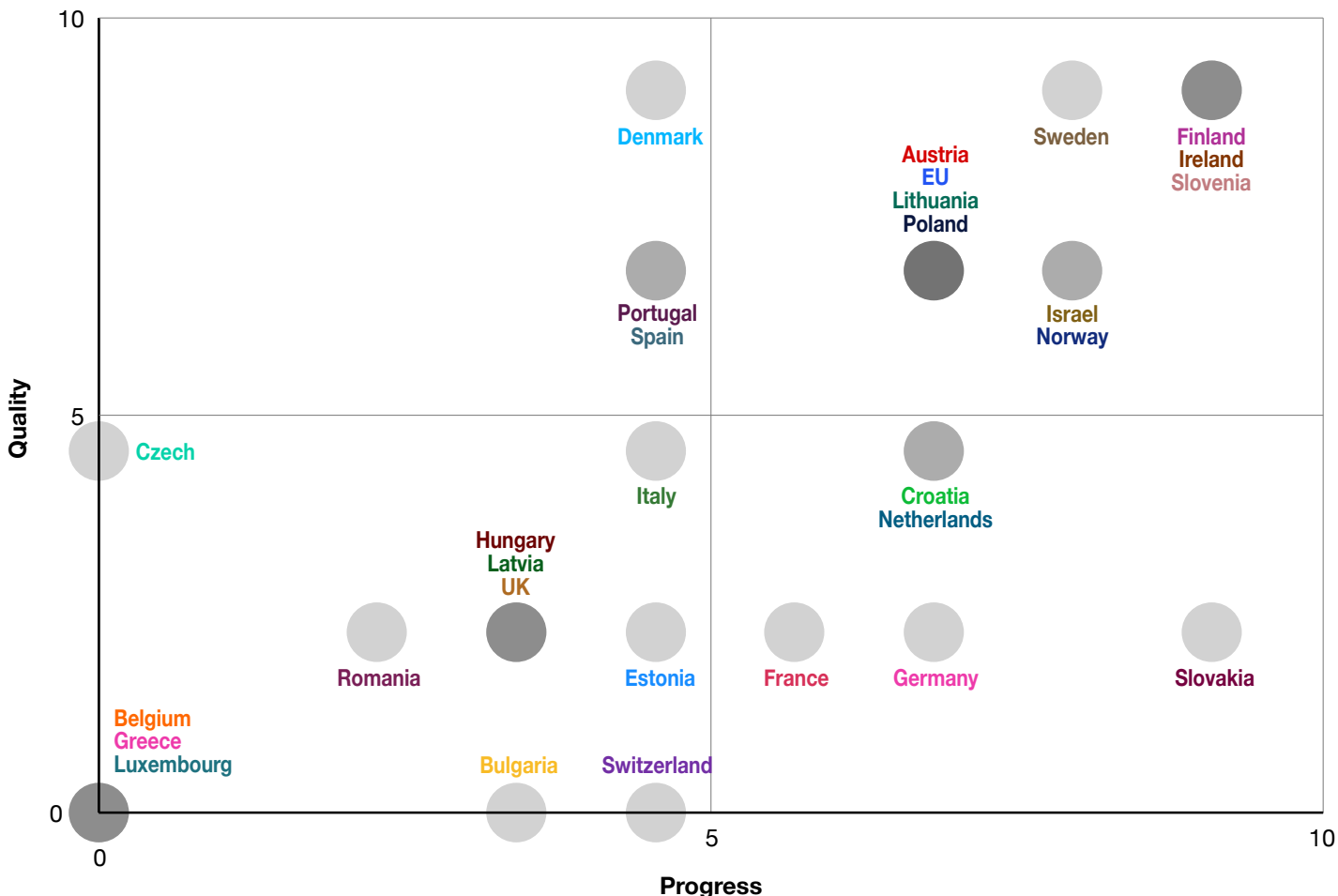
The UK’s National Health Service’ (NHS) strategies include using secondary health data to measure progress towards reducing health disparities. This includes publishing a health-equity dashboard⁵² drawn from health-registry data and available to local governments across the country.

52 Public Health England (n.d.), ‘Health Inequalities Dashboard’.

5.3e Ethics

From the 22 policy elements of the policy framework, we identified two indicators that aligned with the ODI manifesto area of Ethics. These focused on the level of trust in healthcare systems, and the ethical and accountability framework in place for secondary use of health data. Figure 9, below, benchmarks the country-level policy environment for these components.

Figure 9: Secondary use of health data: country policy benchmarking – Ethics



A successful ecosystem for secondary use of health data requires the trust of people and patients. Initiatives that build trust in sharing data – and ethical and accountability frameworks that ensure consent and provide redress – are essential.

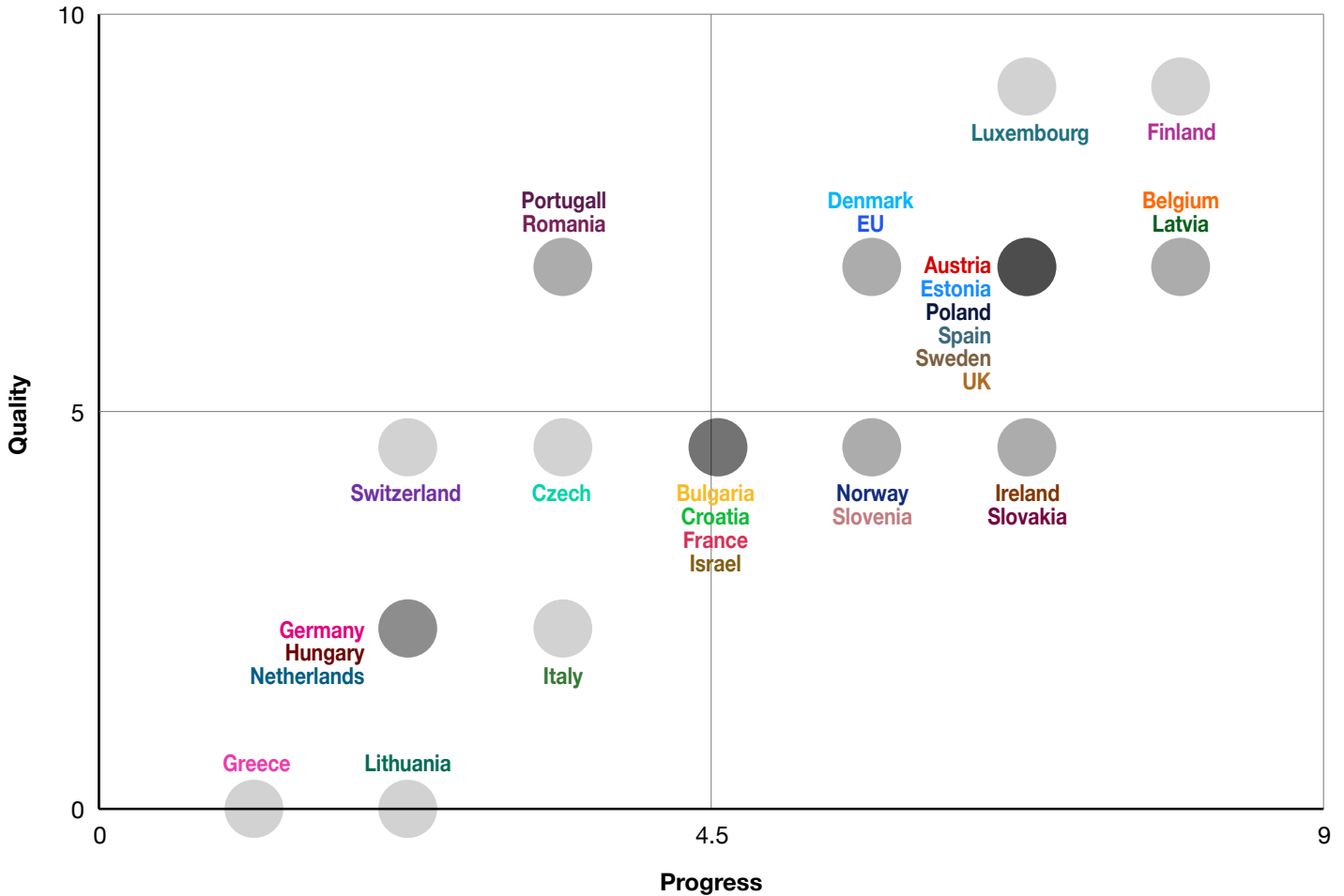
In [Sweden](#), under the life-sciences roadmap, which includes strategic goals for secondary use of health data, they have established a Committee for Technological Innovation and Ethics, to oversee use of data for personalised medicine. [Israel](#) has instituted clear approval processes for secondary use of health data, and has established a legal framework for ensuring the data is de-identified prior to reuse.

[Lithuania](#) has established ‘sandbox’ environments that isolate health data for use in developing AI tools. This enforces data-management standards, but there is still work to be done to overcome fragmentation in data-collection systems. Lithuania’s challenge in overcoming data fragmentation has not prevented it moving towards an ethical and accountability framework for secondary use of health data, showing that countries can still progress towards open-data ecosystems while addressing shortcomings.

5.3f Engagement

From the 22 policy components of the policy framework from Chapter 3, we identified two indicators that aligned with the ODI-manifesto area of Engagement. This focused on investment and initiatives to ensure public and patient participation in data ecosystems, and sustainable and trustworthy data institutions. Figure 10 benchmarks the country-level policy environment for these components.

Figure 10: Secondary use of health data: country policy benchmarking – Engagement



Enabling patient and public participation in how health data is used is essential for open and trusted data ecosystems. There are few structures evident where patients are involved in the emerging infrastructure and institutions that govern secondary use of health data.

Finland has an admirable infrastructure, with initiatives such as FinnGen, and the work of Sitra, enabling greater community and patient involvement in decision-making. However, initiatives still suffer from being unconnected, and it can be difficult to see how patients can participate as a group and individually across all secondary use of health data initiatives.

Chapter 6. Policy needs for secondary use of health data

An open, trusted data ecosystem for secondary use of health data enables the use and sharing of data, encourages the adoption of personalised healthcare, and increases efficiency and innovation in the health system.

Many of these ecosystem elements are needed at a pan-European level, but will be informed by implementations and policy decisions at a country level. Table 8 provides an overview of the work needed at the Europe-wide level to foster a this data ecosystem for secondary use of health data.

Decision-making will need examples and agreements at the country level to highlight demonstrations of how these elements work locally, to inform collaborative policy action. Therefore, there is the opportunity at country level to influence European policy, by clarifying implementation frameworks for each of the following areas.

Table 8: Policy needs for secondary use of health data in Europe

ODI manifesto area	Policy needed
Infrastructure	<ul style="list-style-type: none"> • A common data language and infrastructure
Capability	<ul style="list-style-type: none"> • Improved data skills for all stakeholders
Innovation	<ul style="list-style-type: none"> • Common health-technology assessment instruments • Agreement on governance, use of patient-reported outcomes and wearables, and other consumer health data
Equity	<ul style="list-style-type: none"> • Opportunities for secondary use of health data to improve health access and care-planning for population groups prioritised
Ethics	<ul style="list-style-type: none"> • Standardised models of consent and privacy for sharing data • Clearer harmonisation of GDPR to define processes for data-privacy methodologies • Established ethics processes
Engagement	<ul style="list-style-type: none"> • Ability for a wide range of entities to participate in health-data networks, including commercial stakeholders such as new health start-ups and pharmaceutical companies • Involvement of patient advocacy groups

6.1 Infrastructure

Policy needed:

- A common data language and infrastructure

A commitment to data governance is needed across Europe's healthcare-data ecosystem. Newer health-policy documents, such as the Europe's Beating Cancer Plan, recognise the need to establish centralised data registries that use common data models for all of Europe. Approaches to generating open standards for health-data models are urgently needed.

Before developing common data models, it is essential to study the work already undertaken. This is crucial for health where, under the various pilots and initiatives (including the European Health Reference Networks and eHealth Digital Services Infrastructure), a lot of work has already been done but is at risk of duplication, or of adopting new standards and models that are not aligned with previous work.

The cross-sector nature of data relevant to personalised healthcare also brings both opportunities and challenges. Key datasets for personalised healthcare might have origins or uses beyond the traditional healthcare sector, and the interdependencies or data flows across sectors can influence policy norms. The cross-sector nature of the ecosystem for health data can mean policymakers for legislation and regulation of the secondary uses of health data must consider frameworks and norms beyond the health domain. But it is also an opportunity for policymakers in health to draw on, or learn from, good practice in other domains and sectors, and to be influenced by the wider benefits of a trusted ecosystem for health data beyond the health domain.

6.2 Capability

Policy needed:

- Improved data skills for all stakeholders

The ODI's [Data Skills Framework](#)⁵³ describes the range of skills needed by various stakeholders in an open-data ecosystem. Skills in managing data ecosystems, beyond technical data skills, are required by multiple stakeholders: policy, healthcare practitioners, researchers, regulators, and consumer-advocacy groups.

6.3 Innovation

Policy needed:

- Common health-technology assessment instruments
- Agreement on governance and use of patient-reported outcomes, wearables and other consumer health data

The work by EMA on health-technology assessment will be essential to building new models of reimbursement, and to financing for new treatments and approaches built on secondary use of health data.

At present, there are limited European examples of patient-reported health outcomes and wearable and other sensor-based technology health data being collected and used as part of an ecosystem for secondary use of the health data. Again, new models of governance, data collection, and appropriate reuse infrastructure will support innovation, drawing on these emerging health datasets.

6.5 Equity

Policy needed:

- Opportunities for secondary use of health data to improve health access and care-planning for population groups need to be prioritised

One of the greatest benefits of secondary use of health data is that it can enable new treatments and solutions that meet the needs of smaller population groups. Traditional healthcare systems often build evidence by screening out any characteristics that may reduce wider application of proposed clinical solutions.

Secondary use of health data allows data from previous clinical studies, observational studies and electronic health records to be analysed by sub-population characteristics. This could mean early diagnosis and screening, and personalised healthcare solutions, can be created to suit each patient individually. This is often a data-quality question. Ensuring representative data collection, correcting for bias in data and research design, and enabling use and analysis, would improve data quality. This would enable a focus on secondary-use purposes that reduce inequitable distribution of health and health-resource allocation.

This is recognised as one of the benefits of secondary use of health data when working on solutions targeting rare diseases. But it is not often applied to personalised healthcare or diagnosis opportunities for marginalised groups that continue to face health inequalities in access and treatment outcomes. Secondary use of health data can be used for improved health-service planning to target concentrated areas of disadvantage. It can also be used to create new reimbursement structures and clinical-care cost calculations, where care is provided for patients with a history of inequitable healthcare access and health outcomes.

53 ODI (2020), 'Data Skills Framework'.

6.4 Ethics

Policy needed:

- Standardised models of consent for sharing data
- Clearer harmonisation of GDPR to define processes for data-privacy methodologies
- Established ethics processes

Greater clarification is needed to harmonise and support the GDPR implementations that enable secondary use of health data. GDPR ensures all European citizens and residents have the right to privacy, and access to their data. Health data is recognised as highly sensitive, needing additional safeguards to protect citizens. Because secondary use of health data can make use of anonymised, aggregated data at a population-wide level to advance scientific research, several Recitals, such as Recital 157, aim to provide greater clarity on when sensitive personal data can be used for health research.

However, individual EU member states may interpret these in different ways. Some accept the findings of Recital 157 (such as [Austria](#)) and some do not (such as [Finland](#)). To clarify some areas of legislation, individual member states have enacted national data-privacy legislation that reflects key characteristics of GDPR but also strengthens or defines other areas such as secondary use of health data.

In [France](#), for example, legislative guidelines limit recognition of anonymised health data and its use for future research. Finland has introduced new legislation to enable secondary use of health data. In the [Netherlands](#), strict interpretations of GDPR have limited the health data for use in AI. In [Germany](#), laws allow data to be used for scientific research, but private industry is specifically excluded.

Greater clarity is needed at a Europe-wide level on appropriate interpretation of GDPR and its implementation for reuse of anonymised health data for research, diagnostic, and personalised healthcare purposes.

The European Data Governance Act proposes new models for data altruism, meaning citizens agreeing to share their data for research or social good. There is a proposal for a new, dynamic consent-mechanism model that would allow citizens to consent for multiple purposes at the same time. At present, GDPR requirements and interpretations across Europe rarely grant approval to data access for research purposes. The establishment of an ethics committee, with patient and consumer participation, would help create the infrastructure needed. The recognition by EMA and other bodies of the ethics guidelines for trustworthy AI could also be used as a basis for secondary use of health data.

6.6 Engagement

Policy needed:

- Ability for a wide range of entities to participate in health-data networks, including commercial stakeholders such as new health start-ups and pharmaceutical companies
- Involvement of patient-advocacy groups

There must be support for a multi-stakeholder network to participate in a data ecosystem that supports secondary-use purposes. At present, commercial entities are sometimes reluctant to participate in healthcare networks that encourage the secondary use of health data for innovation, diagnostics, and personalised healthcare. However, recent reviews of the separation between non-commercial and industry use have recognised that the lines are often blurred⁵⁴. Industry collaborates with academia and government to help finance and create healthcare solutions for social good. Industry stakeholders need to be invited to participate in new structures, including the European Health Data Space.

Trust in healthcare systems and appropriate secondary use of health data also needs a participating patient network. Data is also often collected by individuals through wearable and other technologies, and people need to participate in discussions on consent to secondary use. Patient-advocacy groups need to be part of open health-data ecosystems.

⁵⁴ DG Health and Food Safety,(2021), '[Assessment of the EU Member States' rules on health data in the light of GDPR](#)'.

Annexes

Annex 1 – Detailed methodology

[An overview of the methodology](#) we used to create the policy framework.

Annex 2 – Insight tool: policy framework

[The policy framework of 22 success indicators](#) for adoption of secondary use of health data alongside ODI manifesto areas for an open, trustworthy data ecosystem.

Annex 3 – Insight tool: EC-level and country level scorecards and profiles

Detailed summaries of the policy environment for the EC and 29 countries, organised by the 22 success indicators of the policy framework for secondary use of health data:

[Austria country profile and country scorecard](#)

[Belgium country profile and country scorecard](#)

[Bulgaria country profile and country scorecard](#)

[Croatia country profile and country scorecard](#)

(NB Croatia's country data has been sourced from the CIA World Fact Book)

[Czech Republic country profile and country scorecard](#)

[Denmark country profile and country scorecard](#)

[Estonia country profile and country scorecard](#)

[EU region profile and region scorecard](#)

[Finland country profile and country scorecard](#)

[France country profile and country scorecard](#)

[Germany country profile and country scorecard](#)

[Greece country profile and country scorecard](#)

[Hungary country profile and country scorecard](#)

[Ireland country profile and country scorecard](#)

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