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THE VALUE OF INTERNATIONAL HEALTH DATA FLOWS FOR THE EU

A report prepared for Roche

15 NOVEMBER 2023

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EXECUTIVE SUMMARY

Frontier Economics was commissioned by Roche to conduct a study of the impact of the cross-border sharing of patient data between the European Union (EU) and non-EU locations which takes place in the healthcare sector.[1]

We focus on patient data sharing that involves private sector organisations. This may include, for example, where researchers located outside the EU access data originating from the EU that is shared by individuals, public sector organisations or other businesses (customers, suppliers, collaborators). We also focus on data sharing between EU and non-EU locations: for example, an organisation moving patient data from the EU to a secure non-EU location for storage or analysis.

The study involved:

- Desk research, which reviewed existing evidence on the role of the international sharing of health data;
- In-depth interviews with 12 stakeholders based in the EU and in the USA, including private and public sector organisations;
- A survey of 200 private sector organisations with international activities that operate in the EU healthcare sector;[2] and
- Modelling based on data gathered through our survey and secondary evidence.

Key findings

The purposes for and potential impacts of patient data sharing

Our desk research and interviews indicated that patient data can be shared for a wide range of purposes. We focused on modelling the impact of the international data sharing of patient data (hereafter, 'patient data sharing') aimed at:

- Enabling the cross-border delivery of data-intensive services including, for example, the development and delivery of more targeted treatments, which results from a better understanding of genetic variations of diseases across different populations using genomic data and integrating longitudinal datasets on patients health records;

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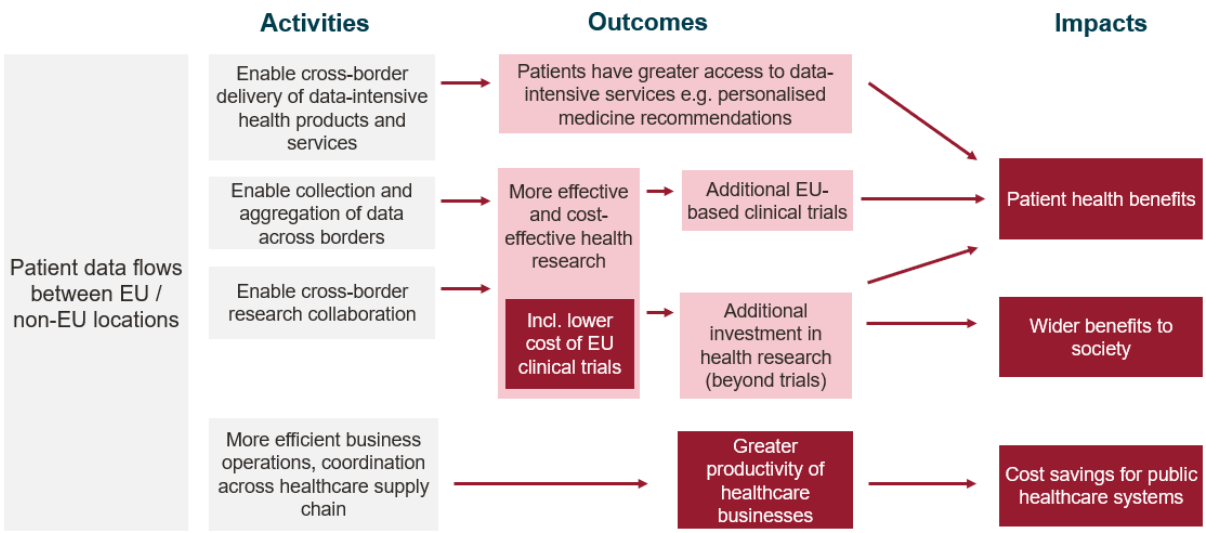
1 For the purposes of this study, we define 'patient data' to include information relating to patients' past and current health or illness, their treatment history, lifestyle choices and genetic or genomic data. This includes data on patients involved in clinical trials or on patients in other health-based research studies, and identifiable, pseudonymised and fully anonymised information.

2 We define 'international activities' as the exporting of products or services from the country where the organisations are headquartered or having affiliates outside the home country.

- Enhancing the effectiveness and efficiency of health research – for example, clinical trials – through access to data on a more diverse population, faster recruitment, and global collaboration; and
- Increasing the effectiveness of internal operations of healthcare organisations and enabling coordination across global healthcare supply chains.

These activities are likely to lead to benefits for patients, healthcare systems and wider society, as described in Figure 1.

Figure 1 Overview of impact channels quantified through this study



Source: Frontier Economics

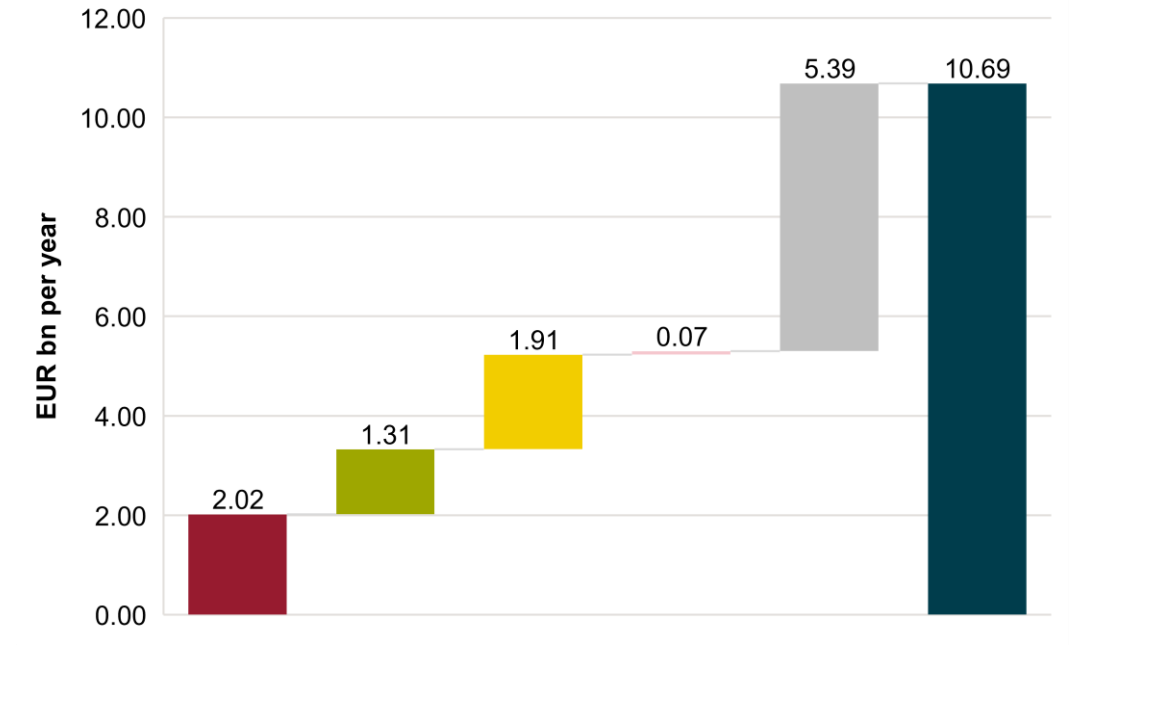
We tested and quantified the links between the activities, outcomes and ultimate impacts illustrated above through the data from our survey, combined with secondary evidence. This diagram does not attempt to reflect all possible ways in which patient data sharing can generate value. Therefore, our figures are a relatively conservative estimate of the total value of patient data sharing for the EU.

The current value of international patient data sharing for the EU

Figure 2 below summarises our main estimates of the current value of patient data sharing. Adding up the central estimates across all impact channels, **the total annual value of patient data sharing to the EU estimated in this report is €10.7 billion**. For context, this is larger than the research funding available through the health clusters of the Horizons Europe programme over the 2021-2027 period (€8.3 billion[3]).

[3] https://www.hrb.ie/funding/eu-funding-support/horizon-europe-information/horizon-europe-health-guide-for-researchers/1-understanding-horizon-europe/

Figure 2 Current value of EU to non-EU patient data sharing, by impact channel



Source: *Frontier Economics*

Note: *Includes central estimates for each impact channel.*

The impacts in the chart are all reported in euros to make them comparable and allow us to add them up to an overall impact figure. However, it is important to note that these figures reflect effects on researchers and patients that are not easily described through monetary values. For example, focusing on the impact on clinical trials:

- We estimate that patient data sharing enables the organisations that share this data to run approximately 14% more clinical trials than they would in the absence of patient data sharing.
- At EU level, this would imply that around 775 clinical trials every year are enabled by patient data sharing.
- Focusing on oncology trials only due to data availability, the treatments resulting from these trials are likely to lead to 64,000 quality-adjusted life years (QALYs) gained by cancer patients in the EU.

Besides the effects shown in Figure 2 above, we also estimate that patient data sharing could enable cost savings of **€4.9 billion per year** in EU hospitals. Indeed, patient data sharing between EU and non-EU locations involving private sector organisations can also have an impact on healthcare systems:

- Impacts on research determine what treatments are available and may also affect decisions taken in the public sector (for example, where research has implications for public health).
- Patient data sharing affects the ability to deliver personalised medicine, which often takes place through public primary and secondary care settings.
- The productivity benefits estimated above affect the availability, cost, quality and price of products/services supplied by private sector organisations to healthcare systems.
- Organisations within the healthcare system may themselves share data across borders, for example as part of pandemic preparedness or response activities.

We do not add these likely cost savings for EU hospitals to our overall €10.7 billion figure to avoid the risk of double-counting. This is because our estimate of the value of additional productivity of healthcare businesses (€5.4 billion) is likely to reflect in part the benefits of increased productivity for hospitals. Greater productivity means that the healthcare system and patients have access to improved products and services, and/or access to the same products and services at lower cost, and/or a greater choice of products and services. Therefore the value of the additional gross value added (GVA) generated by healthcare businesses reflects not only the benefits of patient data sharing to those businesses (ultimately, higher profits) but also, to some extent, the benefits to the healthcare system and ultimately to patients.

Due to the complexity of the channels through which patient data sharing generates value and limitations in the available data, there is significant uncertainty about the precise size of the impacts we modelled. In the main body of this report and in its technical annexes, we describe in detail our methodology and provide ranges for each of the estimates.

The impact of removing barriers on the value of international patient data sharing

Although the EU already realises significant benefits from patient data sharing, there are barriers that prevent healthcare businesses in the EU from using more data, with potential loss of associated benefits. Indeed, **50% of the companies in our survey that currently do not share patient data between EU and non-EU locations would start doing this, if the main**

barriers they are faced with were removed.[4] Almost all these companies are small or medium enterprises. The main barriers indicated by this group of companies include:

- Lack of interoperability between different data sources and lack of data standards;
- Complex and at times conflicting regulations (including variation between countries and organisations on the interpretation of General Data Protection Regulation (GDPR) requirements); and
- Lack of clarity over GDPR requirements – chiefly around what degree of anonymisation is sufficient and uncertainty around the requirements for data sharing between the EU and the USA.[5]

We estimate that the benefits of patient data sharing between EU and non-EU locations might increase by around **€5.4 billion per year** across the EU27 if the main current barriers to data sharing were removed.[6] This amounts to around 50% of our estimated current value of patient data flows between EU/non-EU geographies. As shown in the Figure 3, the estimated impact includes:

- €4.9 billion of additional value per year accrued as a result of new businesses starting to share patient data between EU/non-EU locations, which accounts for the majority of the value opportunity. These businesses already exist and use patient data in their business activities, but they would only start sharing it between EU/non-EU locations as a result of the removal of barriers to patient data sharing; and
- €0.45 billion of additional value per year realised as a result of businesses that already share patient data between EU/non-EU locations but that would undertake additional data sharing if key barriers to data sharing were removed.[7]

This value would be realised in addition to the current value of patient data flows between EU and non-EU geographies, which we estimate at €10.7 billion, as described in section 3 of this report. Therefore, if barriers to these flows were removed, we estimate that the value of patient data flows would increase to around €16.1 billion per year.

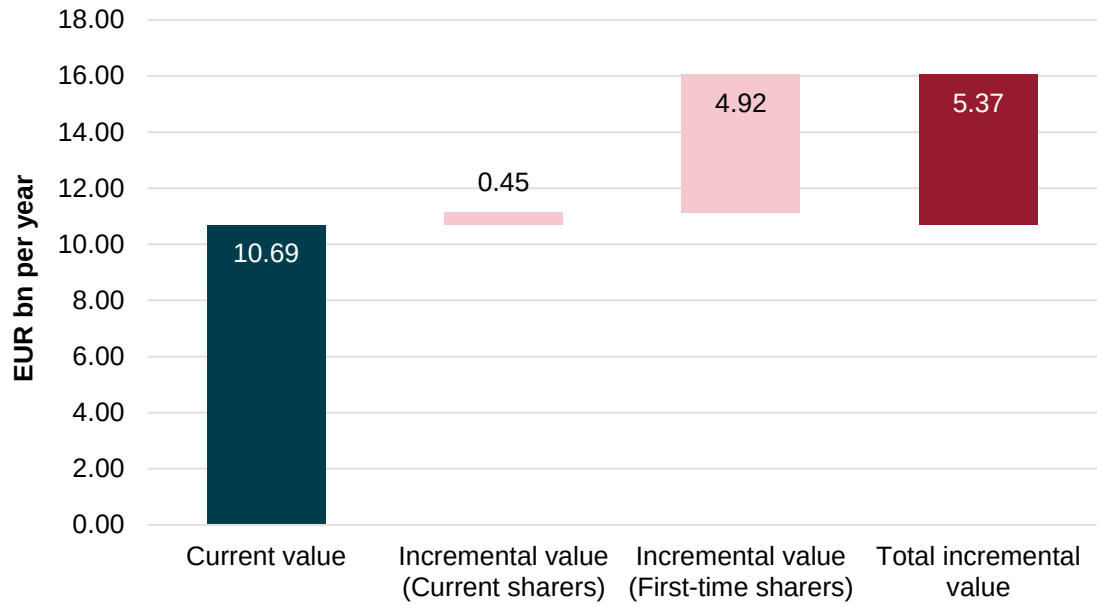
4 51 out of 102 companies that responded to our survey which work with patient data but currently do not share patient data between EU and non-EU locations would do so in the next five years if the key barriers they face with were removed.

5 Although in July 2023 the European Commission formally endorsed the 'EU-US Data Privacy Framework' (DPF), at the time of writing significant uncertainty remains due to lawsuits that may overturn the DPF,(similar to the Schrems II case which led to the previous arrangement for transatlantic data flows being invalidated by the Court of Justice of the European Union).

6 This figure relates to the expected annual impact up to five years after the barriers' removal.

7 Note that this estimate does not include all potential benefits that may originate from removing the barriers to data sharing that these organisations face. For example, the estimate does not include an estimate of the administrative costs that would be saved.

Figure 3 Incremental value of EU / non-EU patient data sharing



Source: Frontier Economics analysis of survey data and secondary sources

1 Introduction

1.1 Background

Globalisation has resulted in increased movement of people, goods and services across national borders. More recently, cross-border data access and usage has become an important part of these movements as data increasingly underpins practically all economic sectors and human activities in a digitised economy. In the health sector in particular, telecommunication and computing advancements have made it easier to collect and analyse health data from multiple international sources.

However, the movement of health data is limited by the speed of digitisation, regulatory restrictions and safety measures, which themselves are based on perceived risks. There are many legitimate reasons why the movement of health data should be limited. However, there is also a risk that regulations or the interpretation of those regulations may lead to unintended consequences – i.e. the loss or impairment of data flows that would otherwise generate significant benefits for EU businesses, citizens and society while posing no or limited risks to their security, privacy and wellbeing.

It is also worth noting that the use of health data may also be limited by restrictions on within-country data sharing, which, however, are beyond the scope of this study.

1.2 Objectives of this study

This study provides new evidence on the role of international data flows in healthcare and on the value that they generate for patients, businesses, healthcare systems and wider society.

We focus on patient data, which may include information relating to patients' past and current health or illness, their treatment history, lifestyle choices and genetic or genomic data. This includes data on patients involved in clinical trials or on patients in other health-based research studies, and identifiable, pseudonymised and fully anonymised information.

The study aimed to produce estimates of:

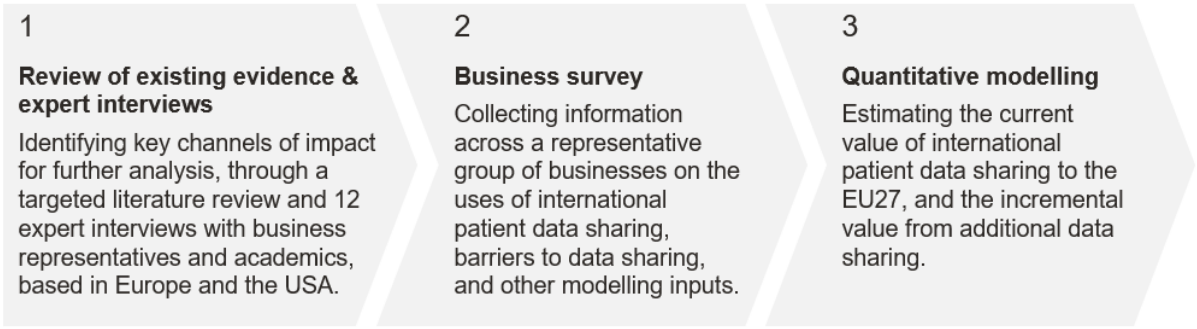
- The current value of international sharing of patient data between EU and non-EU locations; and
- The potential value that could be unlocked by removing some of the current barriers to the international sharing of patient data.

We focus on patient data and EU to non-EU data flows involving private sector organisations because these are the types of flows that are affected most by current restrictions to data sharing in healthcare and are a live policy topic.

We define EU/non-EU patient data sharing as including: cases when a company's EU site shares health data with or accesses data from a non-EU site or company, or vice versa. This also includes moving patient data to a secure non-EU location for storage or analysis and sharing and accessing data from collaborators, providers or customers located outside the EU through a secure environment. In this report, we use "international patient data sharing" and "cross-border flows of patient data" interchangeably.

1.3 Our approach

We delivered the study across three phases of work.



We first reviewed **existing evidence** on the benefits from international patient data sharing and the existing restrictions to cross-border sharing that constrain the data-based activities of EU businesses. Drawing on this evidence collected, we held 12 **interviews** with experts based in Europe and the USA who work in healthcare businesses, policy and academia. These interviews explored and tested the key benefits from and barriers to international patient data flows and the resulting economic impacts. Based on our evidence collection and expert interviews, we developed a conceptual framework that describes the key channels through which patient data flows between EU/non-EU geographies generate value for EU27 patients, health businesses and hospitals.

The second phase of the project entailed **survey fieldwork** with 200 healthcare businesses that operate in the EU with activities abroad. Our survey results presented up-to-date information on the key uses of international patient data flows and the materiality of barriers to international patient data sharing on business activities. They also generated key inputs for our quantitative value modelling in phase 3.

In the third and final phase of the project, we undertook **quantitative modelling**. This combined inputs from the business survey with key parameters from the literature to generate a series of estimates of the value of international patient data flows across our key impact channels.

Our findings and policy implications are based on evidence gathered through the full range of sources used in this study, across the existing literature, our expert interviews, descriptive statistics on responses to the business survey and our modelling outputs.

Further detail on our interviews and our survey is provided in Annex A .

1.4 Structure of this report

The remainder of this report is structured as follows.

- Section 2 describes existing evidence and expert views on the purpose and benefits of international patient data flows, as well as current barriers to international patient data flows collected from our evidence review and expert interviews.
- Section 3 describes our business survey and our modelling estimates for the current value of EU to non-EU patient data flows.
- Section 4 describes survey results on the key barriers to EU to non-EU patient data flows, followed by our modelling estimates for the incremental value opportunity from removing those barriers.
- Section 5 concludes and provides a discussion of policy implications.

2 The role of international flows of health data

Globalisation has resulted in increased movement of people, goods and services across national borders. More recently, cross-border data access and usage has become an important part of these movements as data underpins practically all economic sectors and human activities in a digitised economy. In the health sector in particular, telecommunication and computing advancements have made it easier to collect and analyse health data from multiple international sources.

International flows of health data involve different types of health data which are used for different purposes that generate a range of benefits to the stakeholders.

2.1 Types of health data in international health flows

International health data flows include cross-border data flows between organisations within the healthcare sector (public, private and third sector) and between organisations and individual patients. Health data, in this context, predominantly takes the form of digital data, given the ease and convenience of the digital transfer of data. This information is either captured directly through digital technologies or converted into a digital format from physical records. This data can be of different types and involve various actors across the data value chain.

In the context of international health data flows, it is helpful to categorise health data based on the level of sensitivity associated with it, as this is the primary criterion used to regulate its flow. This results in broadly two types of health data:

- **Patient data**: This includes all health data associated with individual patients. Patient data is classified as personal or non-personal. Where patients can be identified or re-identified either directly or in combination with other datasets,[8] the data is considered as 'personal data'. Examples of personal health data include real-world data such as electronic health records (EHRs) and electronic medical records (EMRs),[9] observational study data, pseudonymised clinical trial data[10] and genetic data.[11] On the other hand, patient health data is non-personal when identification of the individual data subject is not possible in

8 Personal data has been defined as 'data processing for the purposes of provision of health and social care by health and care providers to the patient concerned'. Source: Study on Health Data, Digital Health and Artificial Intelligence in Healthcare, prepared for the European Commission.

9 EMRs are a digital version of the paper charts in the clinician's office. They tend to be specific to health providers. EHRs focus on the total health of the patient – going beyond standard clinical data collected in the provider's office and inclusive of a broader view on a patient's care. EHRs are designed to reach beyond the health organisation that originally collects and compiles the information

10 This refers to key-coded data that is usually used in scientific research, such as clinical data that separates out direct identifiers from the data.

11 Although there is ambiguity around determining when genetic or genomic data is 'personal data' under regulations such as the General Data Protection Regulation (GDPR). Source: PHG Foundation/University of Cambridge (2020) The GDPR and genomic data

any way. For example, data related to the health of patients which has been aggregated or fully anonymised.

- **Non-patient data:** This includes health data that is not associated with individual patients or aggregated from multiple patients. For example, information on administrative aspects of a health provider, such as technical data on the functioning of tools and equipment used for healthcare services, would fall into this category.

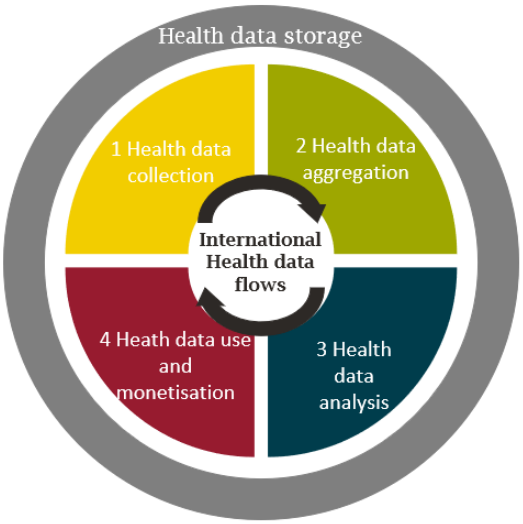
It is important to note that, based on the ease of re-identification of individual patients, patient health data can fall anywhere in a continuum with non-anonymised personal health records at one end of the spectrum and aggregated patient health data at the other end.

2.2 Data value chain in the context of international health data flows

In this study we are interested in the value of health data generated by bringing together individual data points. This is because health data can generate more value to the patient and other patients, health sector businesses, health providers and health systems when brought together in significant quantities and used in combination with other relevant health and non-health data from the same individual, from other patients or from other non-patient sources.

Additional value is extracted from health data through collection of raw patient or health-provider data (see stage 1 in Figure 4), aggregation of health data (stage 2), analysis of health data (stage 3) and use and monetisation of health data (stage 4). At this point, the use and monetisation of health data can itself generate more raw data which then forms a cycle of value creation from health data (Figure 4 below). Throughout this value-creation cycle, data can be stored in cloud or physical locations, or both.

Figure 4 International health data value-creation cycle



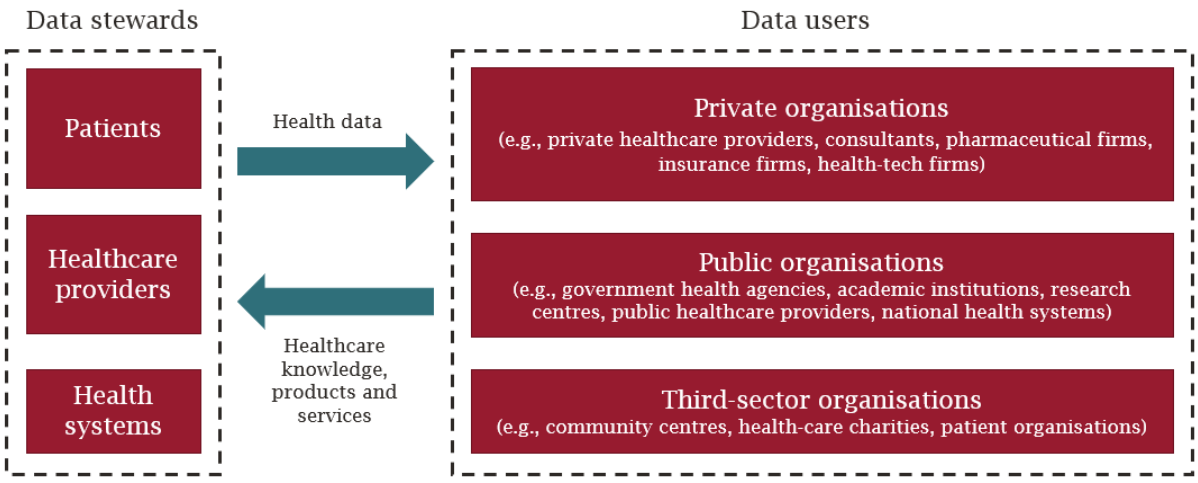
Source: Adapted from Frontier Economics (2021) – The value of cross-border data flows to Europe: Risks and opportunities

Cross-border health data flows can take place at any stage of the value-creation cycle. For example, the collection of clinical trial data for a global clinical study can involve health data flowing from different geographies to be aggregated in Germany, where the research takes place and, consequently, the data is analysed and used within Germany only. Similarly, data can be collected and stored in the EU in one form but can flow across borders to the USA in another form for the data to be analysed there due to the availability of the required computing speed and scientific capabilities. In the case of rare diseases, collaborations between research centres – such as Cancer Core Europe – is crucial, as the number of patients that a single centre can have access to is relatively low and makes it challenging to obtain statistical power that is high enough to reach meaningful results.[12]

2.3 Stakeholders in the international health data flows ecosystem

Health data that flows across borders originates primarily from three sources – patients, healthcare providers and national health systems which own the raw data (data stewards). Value from this data is then extracted by public, private and third sectors (data users) which use the health data to create knowledge, products and services, with cross-border data flows taking place at one or more of the stages across the value-creation cycle. The benefits from the use and monetisation of health data from across borders ultimately accrues to patients, national health systems and healthcare businesses through new healthcare knowledge, products and services (see Figure 5).

Figure 5 Stakeholders of international health data flow ecosystem



Source: Frontier Economics

When it comes to categorising stakeholders into different roles, it is important to note that these roles are dynamic and dependent on specific contexts. In some cases, the data steward

12 Pastorino et al (2019). Benefits and challenges of big data in health care. An overview of European initiatives

and the data user can be the same entity. For example, a hospital may own a mobile application which requires it to manually enter its data or data is collected through equipment across a period of time. In other cases, several parties will be involved, such as a third-party healthcare provider (data user) who generates laboratory results for patients (data steward) or shares those results with the hospital (data user) for providing care to its patients.

2.4 Key use cases of cross-border health data flows

International health data flows can be used for two broad purposes:

- **Primary use cases**: These include use cases where international health data flows relate to the direct provision of healthcare or are used in the process of making decisions to provide efficient and appropriate care directly to patients; and
- **Secondary use cases**: These relate to the processing of health data for purposes other than the initial purposes for which the data was collected.

For example, data collected for the purpose of running a clinical trial would relate to primary data use. On the other hand, real-world data being used in clinical studies is more often secondary use, as the data was not originally collected for the purpose of the study, as stated by the European Federation of Pharmaceutical Industries and Associations.[13]

2.4.1 Primary use of international health data flows

Recent developments in medical research and treatments as well as digital technologies have enabled healthcare providers to provide better and more efficient care to patients using their health data. Based on interviews carried out for the purposes of this study and desk research, we identified two key areas of medical advancements that use international health data flows to deliver healthcare to patients: personalised medicine and telehealth.

Personalised medicine

Personalised (or precision) medicine recognises that complex diseases such as cancer take different forms based on the biological make-up of individual patients. It makes use of different available types of patient data, such as genomic, clinical, diagnostics and lifestyle data, to tailor medical treatment based on the individual characteristics of patients and nature of their diseases. Such a targeted treatment approach, which is more patient-centric compared to the current one-size-fits-all approach, requires easier access to patients' longitudinal data to provide them with a tailor-made treatment plan.

Health data integration and making use of different data sources are at the core of personalised medicine. This is because the foundation of personalised medicine is built on the

13 https://www.efpia.eu/media/413227/position-paper-safeguards-framework-for-secondary-use-of-clinical-trial-data-for-scientific-research-september-2019.pdf

understanding of genetic variations of diseases across different populations using genomic data and integrating it with dense, longitudinal datasets on patients' health records kept by healthcare providers to help study the natural history of these diseases.[14] Larger, cross-country datasets and greater variation in genomic data from across populations enables richer development of personalised medicine products. This is particularly true for rare diseases which, by their very nature, impact a minority of the world population.

These cross-country datasets also improve the delivery of personalised medicine services, by enabling the analysis of local data samples against databases of relevant information collected from all over the world.

Telehealth

Telecommunication advancements and digitalisation of healthcare have led to widespread use of digitally enabled and data-intensive healthcare products and services. These technologies help to provide care for patients remotely in an accessible, efficient and cost-effective manner. For example, telehealth has created the opportunity to provide remote care to patients through video or phone appointments between a patient and their healthcare practitioner.

Cross-border flows of health data are an important part of telehealth services. Providing remote care through technology-enabled healthcare services can include instances where the patient and healthcare practitioner are physically located in different geographies across borders. Such consultations require health data to flow across borders as the underlying technology often requires the cloud-based integration of supplier-side technologies such as laboratory testing equipment and patient-side technologies such as health-related Internet of Things devices used by the patients. Even if the patient and healthcare practitioner are located within national boundaries, it might still involve health data flowing across borders as the underlying technological platform (e.g. a cloud server) which is collecting, storing and transferring the data is hosted in another geography. Additionally, cross-border access to healthcare data analysis solutions can enable the analysis of local data samples against databases of relevant information collected from all over the world. This improves the reliability and accuracy of diagnosis and treatment recommendations.

2.4.2 Secondary use of international health data flows

Clinical trials

Clinical trials are a type of medical research that studies new tests and treatments and evaluates their effects on human health outcomes. Individuals volunteer to take part in clinical trials to test medical interventions including medical drugs, surgical procedures, medical devices and preventive care.[15]

14 Abul-Husn and Kenny (2020). Personalised medicine and the power of electronic health records

15 WHO - Clinical trials overview

Clinical trials are crucial in advancing medical research. They often involve the collection and analysis of vast amounts of health data across different population groups to make the findings robust and applicable across diverse patient populations. As such, cross-border flows of health data have become an important source of data and collaborations for sharing medical knowledge and new technologies for conducting clinical trials.

For example, the clinical trials of the first Covid-19 vaccine (Pfizer/BioNTech) included trial sites located in Argentina, Brazil, Germany, Turkey, South Africa and the USA.[16] A recent study estimated that each additional month of delay in the approval of the Covid-19 vaccine caused by not being able to share personal data between the EU and other countries could have caused €70 billion of damage to the EU economy.[17]

We discussed the sharing of patient data across borders with five stakeholders involved in conducting clinical trials and the supply chain.[18] Based on our interviews and our desk research, some of the key reasons for using cross-border health data in clinical trials are:

- **Diverse patient populations**: One of the primary advantages of cross-border health data flows in clinical trials is access to diverse patient populations. Different regions and countries have varying genetic backgrounds, lifestyles and healthcare systems. By collecting data from diverse sources, researchers can ensure that their findings are more representative of the global population. This diversity can help with identifying treatment responses, side effects or disease trends that may not be apparent within a single region.

- **Faster recruitment**: Recruiting participants for clinical trials can be a time-consuming and challenging process. Cross-border data sharing allows researchers to tap into larger patient pools, expediting recruitment. This not only speeds up the trial process but also enhances the statistical power of the study, leading to more robust results.

- **Global collaboration**: Cross-border health data sharing fosters international collaboration among researchers, institutions and pharmaceutical companies. This collaboration leads to the pooling of resources, expertise and data, which can result in more comprehensive and impactful clinical trials. Researchers from different parts of the world can work together to tackle complex medical challenges, from rare diseases to global health crises.

Global healthcare supply chains

The healthcare delivery supply chain is global and consists of multiple actors. It involves sourcing different resources required by healthcare departments from vendors and distributors who meet the requirements as well as from other stakeholders such as manufacturers,

16 https://www.pfizer.com/science/coronavirus/vaccine/about-our-landmark-trial

17 Analysis Group (2021). The importance of cross-border data flows.

18 Clinical trial supply refers to the process of providing the necessary materials, equipment and medication to conduct a clinical trial. It is a critical component of the drug development process as it ensures that the trial is conducted safely and efficiently.

insurance companies and regulatory agencies. This supply chain is a network of systems, components and processes spread across countries that work together to ensure that medicines and other healthcare supplies are manufactured, distributed and provided to patients.

Cross-border health data flows are integral to a global healthcare supply chain in order to optimise costs, logistics, risk mitigation and responsiveness to demand. Business software applications, from sourcing and managing inventory to managing financial and logistical responses, are increasingly data driven.[19] As such, supply chain operators rely on data transfers and cross-border access to the health industry's cloud infrastructure to streamline processes. Health data needs to flow across borders to reach the right actors and for them to take the right decisions at the right time.

Internal operations of healthcare providers

Like every other industry, healthcare organisations produce data through their internal operations. This includes data such as patients' medical history (diagnosis- and prescription-related data), medical and clinical data (such as data from imaging and laboratory examinations) as well as non-patient data (such as laboratory equipment testing data and hospital administration data). This data is used by healthcare providers to improve patient service quality and make their internal operations more efficient and cost-effective, among other uses. Healthcare providers make use of health data from diverse sources, including international ones, for a variety of reasons including:

- **Better financial decision-making**: Access to health data from different regions and countries can give healthcare providers global insights into healthcare trends, disease prevalence and treatment outcomes. By analysing this data, providers can make informed decisions regarding patient care protocols, resource allocation and strategic planning. Providers can implement strategies to reduce wastage, streamline administrative processes and control healthcare expenditures, while maintaining or improving the quality of care.

- **Benchmarking and performance evaluation**: Healthcare organisations can use cross-border health data to benchmark their performance against international standards and best practices. Comparative analysis can highlight areas where improvements are needed, leading to better internal management. They can use these insights for targeted interventions to enhance their overall quality of care and operational efficiency.

- **Better understanding of population health**: Cross-border health data can support healthcare organisations in predictive analytics and risk assessment. By analysing data from different regions, providers can identify factors that contribute to disease prevalence and patient risks. This information allows them to develop targeted preventive strategies,

19 Global Data Alliance (2021). Cross-border data transfers and supply chain management

early intervention programmes and population health management initiatives to reduce healthcare costs and improve patient outcomes.

2.5 Key benefits of international health data flows

International health data flows advance healthcare provision to patients, directly or indirectly, by facilitating better analysis of health challenges and developing solutions which are novel and/or more efficient. This in turn promotes public health in general.

Based on the stakeholder landscape discussed in section 2.3, the benefits of cross-border health data flows are ultimately expected to accrue to the data stewards, i.e. patients, healthcare organisations, and healthcare providers and health systems.

2.5.1 Benefits to patients

The key benefit of these flows to patients is the improved patient care received from healthcare providers, usually represented in patients' quality-adjusted life years (QALYs).[20] As a summary measure of health outcomes for economic evaluation, this incorporates the impact of improvement in healthcare on both the quantity and quality of life. The improved quality of care results from receiving efficient and targeted healthcare (e.g. through personalised medicine), irrespective of where the patients are physically located (e.g. through telehealth), and from getting access to novel drugs and treatments as a result of improved medical research and development of new healthcare technologies (e.g. for rare diseases).

2.5.2 Benefits to healthcare organisations and healthcare systems

International health data flows also benefit healthcare organisations[21] as a result of:

- Improved ability to provide innovative products and services to patients and healthcare organisations – for example, the ability to deliver personalised medicine products and services. These improve the quality of healthcare and effectiveness of treatment, reducing patient re-admission rates and the length of time patients stay in hospital, thereby saving hospital costs;

- Improved productivity of research and innovation activities such as clinical trials and observational studies and an increased number of studies in areas such as rare diseases.[22] This leads to the development of more robust clinical guidelines and protocols, ultimately improving the effectiveness of treatment, reducing patient re-admission and

20 A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to one year of life in perfect health.

21 Broadly defined – from hospitals to providers of diagnostic solutions, digital applications used by individuals or healthcare providers, and others.

22 It is estimated that around 300 million people are living with a rare disease around the world and up to one in seven people in G20 countries are affected by a rare disease. See Bellgard, M.I., Snelling, T. & McGree, J.M (2019). RD-RAP: beyond rare disease patient registries, devising a comprehensive data and analytic framework.

therefore hospital costs. This can come about from more robust scientific studies based on representative samples from the global population and lower costs to collect or access the data;

- Increased productivity of healthcare organisations' operations through economies of scale in data use,[23] sharing fixed costs across a larger base and specialisation of operational activities;

- Increased resilience and efficiency of healthcare supply chains. This is achieved by using real-time data for predictive analytics, such as accurately forecasting demand to ensure that the right quantities of supplies are available when and where they are needed, for optimising the allocation of resources including personnel and equipment based on patient needs, and for identifying potential disruptions in the supply chain such as geopolitical tensions, natural disasters or pandemics, etc.;

- Improved cost efficiencies generated through specialised and integrated management and information systems as well as economies of scale from data use to deliver healthcare, for example from pooling resources such as transportation and warehousing to ensure that critical supplies are distributed efficiently; and

- Effective preparation for preventing communicable diseases from spreading across borders and better public health monitoring. Crises such as pandemics require rapid decision-making which is supported through cross-border data sharing. Health systems can quickly identify affected areas, assess their supply needs and coordinate relief efforts more effectively. It also helps to streamline emergency response efforts across countries, ensuring a more coordinated and efficient response to global health crises.

2.6 Key barriers to international health data flows

Cross-border sharing and processing of data by public, private and third-sector stakeholders in the healthcare ecosystem can be challenging as barriers can limit the free movement of data. Some of these barriers originate from valid considerations around data security, privacy and protection of individuals' fundamental rights which are enforced through regulations across different jurisdictions. However, in some cases, pursuing these objectives has unintended negative consequences such as compliance burden and reduced data interoperability, which can lead to an unnecessary loss of health, wellbeing, and economic and financial benefits to individuals and society.

While barriers to the efficient flow of health data across borders can arise as a result of both regulatory and non-regulatory issues (such as data infrastructure and technological differences), we focus on regulatory barriers in this study. The main overarching regulatory

[23] For example, patient registries is the tool most commonly used to manage rare disease patient data – attempts are made to address these concerns by collecting data on therapy effectiveness, clinical endpoints, clinical trial recruitment, clinical decision-making, patient-reported outcomes, cost-effectiveness, natural disease progression and other variables

barrier to cross-border data flows that we identified, based on the interviews conducted as part of this study, was the **interpretation or implementation of GDPR** and the need for clear **adequacy decisions (ADs)** with minimal uncertainty over the final decision and its implications. GDPR creates barriers in the efficient flow of health data because under the GDPR regulation:

- Personal data may not be transferred outside the EU unless there are provisions in place to guarantee that individuals have equivalent rights and protections to those enjoyed in the EU. Those countries which are considered to have a regime equivalent to that in the EU need an AD. To date, only 15 countries have full ADs,[24] including the recently EU-backed 'EU-US Data Privacy Framework' (DPF). However, there is still uncertainty around the implementation of the DPF as two lawsuits have been filed with the EU Court of Justice[25] seeking to overturn this framework.

- Data exchange between the EU and third countries which do not have a full AD are based on standards contractual clauses (SCCs) or binding corporate rules (BCRs) approved by the European Commission. Companies willing to use SCCs or BCDs need to verify, on a case-by-case basis, whether legal protections concerning government access to personal data meet EU standards.[26] These are complex and lengthy and include specific provisions concerning laws and practices related to access by third-country authorities which cannot be altered (e.g. dispute resolution in European courts). [27]

Moreover, our in-depth interviews identified a **lack of clarity in the interpretation and implementation of GDPR and conflicting regulations across European countries**, which pose further challenges to the flow of data to other jurisdictions and even within the EU. These include the following.

Differences in implementation and enforcement of GDPR

Rights under GDPR depend on the choice of legal basis.[28] Organisations must have a valid and legal reason to process personal data and must inform data subjects what their legal basis is for processing their data. Due to multiple legal bases (including consent mechanisms) and

24 European Commission Adequacy Decisions

25 Latombe and Schrems legal challenges, summarised here.

26 This was an outcome of the Schrems II decision of the Court of Justice of the European Union, which initially ruled that provisions of US data protection laws (e.g. the Health Insurance Portability and Accountability Act) were not equivalent to those in the EU, therefore invalidating the EU-US Privacy Shield Framework. Since then, a new framework has been endorsed by the European Commission, recognising that the level of protection for personal data transferred under this new framework is essentially equivalent.

27 European Commission (2022). Study supporting the Impact Assessment of policy options for an EU initiative on a European Health Data Space

28 There are seven main legal bases under the GDPR: 'consent', 'contractual obligations', 'legal obligations', 'vital interests', 'public interest' or 'legitimate interest' or SCCs/BCRs.

derogations used across European countries,[29] different legal bases apply to different datasets collected and held in different countries. In these cases, organisations have to go through derogation processes to be able to use this data. However, European countries can set their own derogations under the GDPR, which makes it challenging to create a common approach for processing personal data that is legally compliant across all countries.

Lawful bases under GDPR for the cross-border transfer of personal data are limited with respect to secondary research and in most cases are not viable.[30] For example, consent is often not viable because data subjects may not be in direct contact with researchers (e.g. biobanks) and there may be statutory conflicts that prevent other countries (e.g. USA) from signing the required contracts under the GDPR.[31] This restricts collaboration with public research centres including public universities and public hospitals. Additionally, it is difficult to use pre-GDPR data for retrospective studies as it is not clear whether consent was collected or explained in accordance with GDPR principles.

Differences in interpretations of GDPR concepts

Some concepts like 'personal data', 'anonymisation', 'pseudonymisation', 'broad consent', 'further processing', 'scientific research' and 'genetic data' are ambiguous or are open to interpretation across EU member states and across different organisations. For example, GDPR only differentiates between personal and non-personal data, but the strict separation of these categories can be technically and economically inefficient for companies. Moreover, it reduces the value of data for research purposes.[32] In reality, anonymisation is complex and burdensome, and data often lies in between the personal and non-personal categories as defined by GDPR.[33]

On top of that, there are new risks of **conflicting enforcement** between GDPR, the Data Governance Act and Data Act.[34] The new acts are aimed at regulating transfers of non-personal data but address laws that involve personal data and are already covered by GDPR. The existence of both GDPR and these acts could lead to parallel and inconsistent regimes.

Beyond the interpretation or implementation of GDPR, other regulatory barriers include:

- Lack **of standardisation** for the approval, certification, data protection, liability and reimbursement of digitally enabled products and services (e.g. e-mobile health, wellbeing

29 Abboud et al (2021). Case studies on barriers to cross-border sharing of health data for secondary use. Towards European Health Data Space THEDAS Join Action, EC.

30 Peloquin et al (2020). Disruptive and avoidable: GDPR challenges to secondary research used of data. European Journal of Human Genetics. 28:697-705.

31 Allea, EASAC & FEAM (2021). International sharing of personal heath data for research.

32 Van Veen (2018). Observational health research in Europe: understanding the GDPR and underlying debate. European Journal of Cancer. 104:70-80.

33 Finck & Pallas (2020). The who must not be identified. Distinguishing personal from non-personal data under the GDPR. International Data Privacy Law, 10(1).

34 DIGITALEUROPE (2022). Data transfers in the Data Strategy: Understanding myth and reality.

apps, AI-powered services, etc.).[35] The EU directive on the applications of patients' rights in cross-border healthcare (Directive 2011/24/EU) is becoming outdated and it does not cover new models of data interoperability. For example, under the current directive, reimbursement is subject to national law and is dependent on national, regional and local healthcare systems, which are highly fragmented. In most countries, digital health technologies that deliver cross-border services are not reimbursed.[36]

- **High level of regulatory fragmentation** across countries.[37] Multiple and overlapping pieces of legislation, rules, directives, code of conduct, guidelines, transfer mechanisms, data-sharing agreements and certification schemes, which vary across countries, add to the complexity and contribute further to different interpretations of the law.

These regulatory barriers also interact with other operational, economic and behavioural issues, including:

- Higher level of **fragmentation of national health systems** due to a lack of mutual recognition of open standards, protocols, cybersecurity principles, data integration principles, taxonomies and ontologies).[38] Some codes of conduct exist (e.g. health network) but these are voluntary and may not have binding requirements for digital infrastructure and information technology.

- **Lack of interoperability of different health data systems** relating to some or all of the following:[39] lack of foundational inter-connectivity such that secure data communication is not possible; lack of common format or syntax of data exchanged; lack of common underlying models or codification of the data; and other organisational differences in governance, policy, social and legal processes which inhibit the secure and timely communication of data both within and between organisations, entities and individuals. This restricts the potential to collect, preserve, use, reuse and integrate health data from diverse sources.

- **Public distrust** towards sharing personal data coupled with limited knowledge of rights on own data. As a result, obtaining informed patient consent for cross-border data sharing can be challenging, adding to language barriers, differing cultural norms and varying consent processes in different countries.

35 European Commission (2021). Study on health data, digital health and artificial intelligence in healthcare

36 Ibid.

37 DIGITALEUROPE (2022). A digital health decade. Driving innovation in Europe.

38 ODI (2021). Secondary use of health data in Europe

39 Healthcare Information and Management Systems Society, 2023.

3 The current impact of international patient data flows

Headline Results

- We estimate selected benefits to the EU that result from international flows of patient data between the EU and non-EU geographies. We estimate that these benefits are worth between **€6.8 billion and €18.5 billion per year**, with a central estimate of €10.7 billion per year. For context, this is larger than the research funding available through the health clusters of the Horizons Europe programme over the 2021-2027 period (€8.3 billion).
- This impact results from the sum of the following outcomes that are enabled by sharing patient data internationally under current practices and regulatory frameworks, compared to a situation where businesses are unable to share patient data internationally:
  - Patient data sharing enables additional health research investment which generates annual benefits to EU society valued at around **€0.7 billion to €2.7 billion**.
  - EU businesses undertake more clinical trials in the EU (14% more than would take place without international patient data sharing). We estimate that these additional clinical trials have improved the expected cancer lifetime **health** of annually diagnosed new cancer patients by **48,000 to 80,000 QALY** every year. The monetary value of this health gain is around **€1.1 billion to €6.3 billion.**
  - An additional 9% of cancer patients are reached by personalised medicine services, which we conservatively estimate have improved the **health** of annual newly diagnosed cancer patients by **1,700 to 15,000 QALY** per year. The monetary value of this health gain is around **€70 million** per year.
  - Clinical trials in the EU are less costly – international sharing of patient data generates around **€1.0 billion to €1.6 billion** in **cost savings** per year for organisations involved in clinical trials.
  - Patient data sharing leads to increased productivity, with gains to EU health businesses and EU healthcare systems of around **€4.0 billion to €6.7 billion** per year.

Our headline results are presented as ranges to reflect the uncertainty in estimates related to whether our business survey results are representative of the broader EU business population and a range of possible values for secondary evidence parameters.

3.1 The impact channels that we investigated

We were interested in investigating the impact of patient data sharing on healthcare businesses, patients and healthcare systems. Our modelling focuses on the value of patient data – as opposed to personal data – as it best matches the full scope of health data that is affected by key barriers to international data sharing.

Our research, described in section 3, identified the following key types of impact:

1. **EU patient benefits** from access to new, improved treatments (resulting from additional clinical trials and access to personalised medicine);

2. **Benefits to EU healthcare systems and EU healthcare businesses** from improved productivity in the healthcare sector; and

3. **Wider benefits to EU society** from additional EU health research (beyond the clinical trials reflected under channel 1. above).

There may be additional benefits to non-EU patients, health systems and businesses but our methodology does not estimate these benefits.

We then identified the specific channels that could be modelled within the scope of our study, given the data we would be able to collect from primary and secondary sources. The channels that we identified were:

- Greater efficiency and effectiveness of EU-based clinical trials, thereby reducing the cost and/or increasing the incentive to undertake clinical trials and therefore affecting the number of EU-based clinical trials;

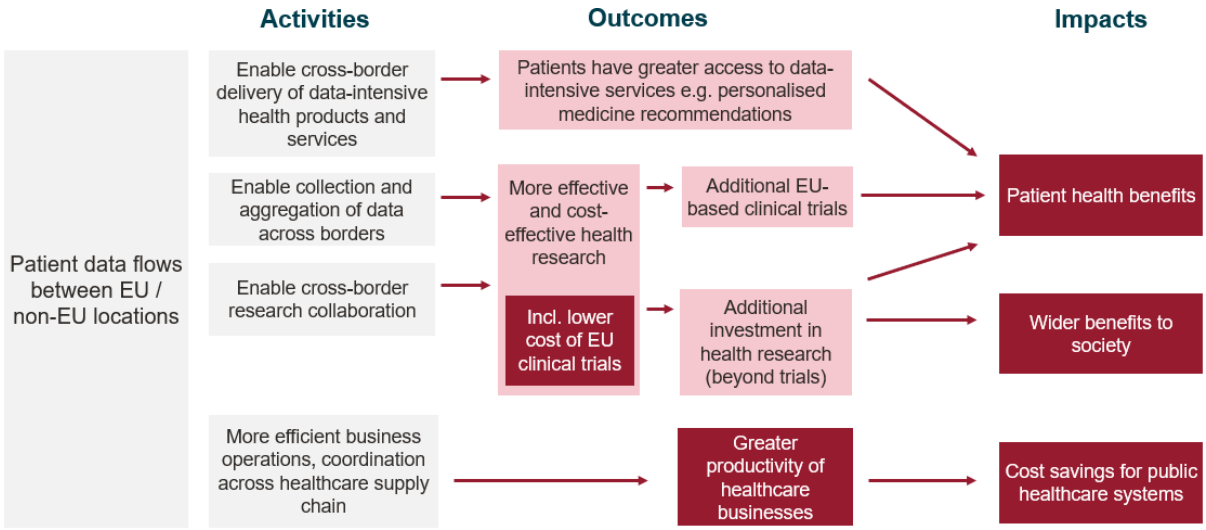
- Greater efficiency and effectiveness of other research activities beyond clinical trials (e.g. observational studies), increasing the amount of investment in EU-based health research, with associated economic benefits;

- Additional delivery of personalised medicine treatments to EU patients by businesses that specialise in personalised medicine; and

- More efficient and effective data-intensive activities for EU healthcare businesses, from data collection through to processing and analysis, leading to higher business gross value added (GVA) through increased volume or quality of production.

As part of our modelling methodology, we estimated the extent to which these specific channels materialised in terms of better outcomes for patients, businesses and hospitals, compared to what would have happened if no patient data sharing between EU and non-EU locations took place. The diagram in Figure 6 below summarises the impact channels modelled in our study.

Figure 6 Impacts of patient data flows modelled in this report



Source: Frontier Economics

It is worth noting that if the EU-based activities enabled by patient data flows between EU and non-EU locations do not take place, they may instead be diverted or replaced by non-EU-based activities. If this is the case, the resulting outcomes and impacts may still (at least partly) materialise, to the benefit of EU patients, businesses and hospitals. However, it is challenging to assess the magnitude of this diversion to non-EU-based activities. This analysis is beyond the scope of this study but it could be a useful area for exploration through further research.

3.2 Our approach to estimation

We estimate the current value of cross-border patient data flows between EU and non-EU locations in their current state (or 'as is'). To generate these estimates, we:

- Rely on the results from a bespoke survey of 200 private sector organisations to understand if they share patient data between EU and non-EU locations, and the outcomes enabled by this data sharing; and
- Combine results from the survey with existing secondary evidence and informed but conservative assumptions to estimate impacts on patients and to scale up results from our survey sample to the EU as a whole.

3.2.1 The survey

To quantify the impacts described above, we carried out a survey of 200 private sector organisations active in the healthcare sector in at least one of eight EU member states.[40] We selected this set of countries as they reflect a range of EU geographies. It was not possible to survey organisations in all 27 EU member states within the scope of our study because we were collecting responses from a very specific set of organisations (i.e. organisations that share patient data across borders). Annex A provides further detail on the data collection process.

We specifically targeted organisations with international activities (e.g. organisations with offices in more than one country and/or organisations that sell their products/services abroad). Responses were gathered through computer-assisted telephone interviews with C-level executives and directors, as well as personnel working directly or indirectly with health data (i.e. data protection officers, data compliance officers, managers with responsibilities for data-related business functions, etc.).

The characteristics of firms in our sample were compared with the overall population of businesses in the EU healthcare sector (using European Commission/Eurostat data[41]) to check the representativeness of the sample. This was particularly important for checking that we are able to generalise the results from our survey to the broader EU business population.

We found that the composition of our sample reflected the broader business population in terms of firm size. The majority of firms (91%) in our sample were classified as small or medium-sized enterprises (SMEs), while 9% were large companies. This is very similar to the broader population of healthcare businesses in the EU.[42] However, our sample differed somewhat from the population of EU healthcare businesses in terms of sub-sector mix. Our survey responses over-represented health companies that specialise in research and development (R&D) (which accounted for 17% of our sample, compared to 5% of all healthcare businesses in the EU), while under-representing businesses in the 'human health activities' sub-sector (58% of our sample compared to 79% of all healthcare businesses in the EU).[43]

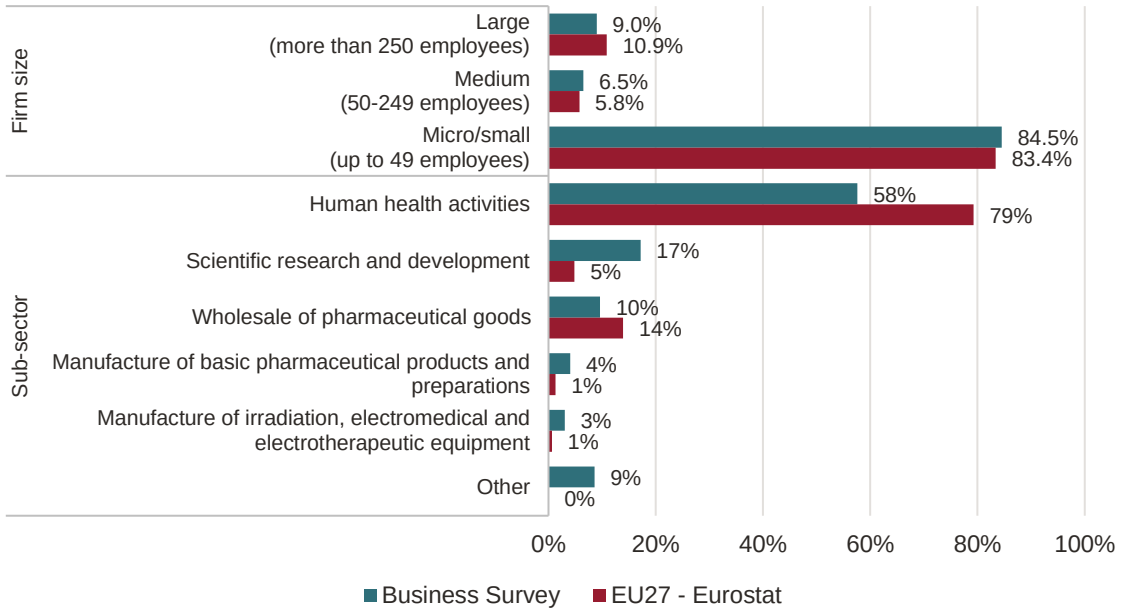
40 Our chosen eight EU countries were France, Germany, Italy, Spain, Sweden, Austria, Netherlands and Belgium. We defined the healthcare sector as including the following industry codes (NACE codes): manufacture of basic pharmaceutical products and pharmaceutical preparations; manufacture of irradiation, electromedical and electrotherapeutic equipment; wholesale of pharmaceutical goods; scientific research and development (related to health); human health activities.

41 EC/Eurostat - Annual enterprise statistics by size class

42 In line with the typical definitions used by Eurostat and other statistical agencies, we classified companies by size based on the number of employees. Companies were categorised as small/micro (with 49 or fewer employees), medium (between 50 and 249 employees) and large (more than 249 employees).

43 Medical consultation and treatment in the field of general and specialised medicine by general practitioners or medical specialists and surgeons.

Figure 7 Distribution of companies by firm size and healthcare sub-sectors



Source: *Business survey and Eurostat*
Note: *Business survey results based on a sample of 200 companies.*

To account for this, our results are weighted to ensure that they reflect the underlying EU business population as closely as possible. In order to account for the under-/over-representation of certain sub-sectors in our sample, we adjusted the survey results (i.e. percentage change in outcomes) using sub-sector weights.[44]

Respondents were asked whether their organisations shared patient data between EU and non-EU locations and about barriers to sharing patient data and how patient data sharing contributed to their research, their ability to reach customers and patients, and other outcomes.

3.3 Modelling the value of the impact channels

To assess the outcomes enabled by international patient data sharing (e.g. whether and to what extent international data sharing enables more clinical trials to take place), we gathered information from our survey on:

- The current extent of patient data sharing between EU and non-EU locations; and
- Respondents' assessments of the impact of patient data sharing – specifically, what would happen if that sharing had to be stopped due to factors outside of their control.

[44] Calculated as the inverse of the probability of being sampled or the ratio between the proportion of companies in each sub-sector in Europe and the proportion of companies in each sub-sector in our sample.

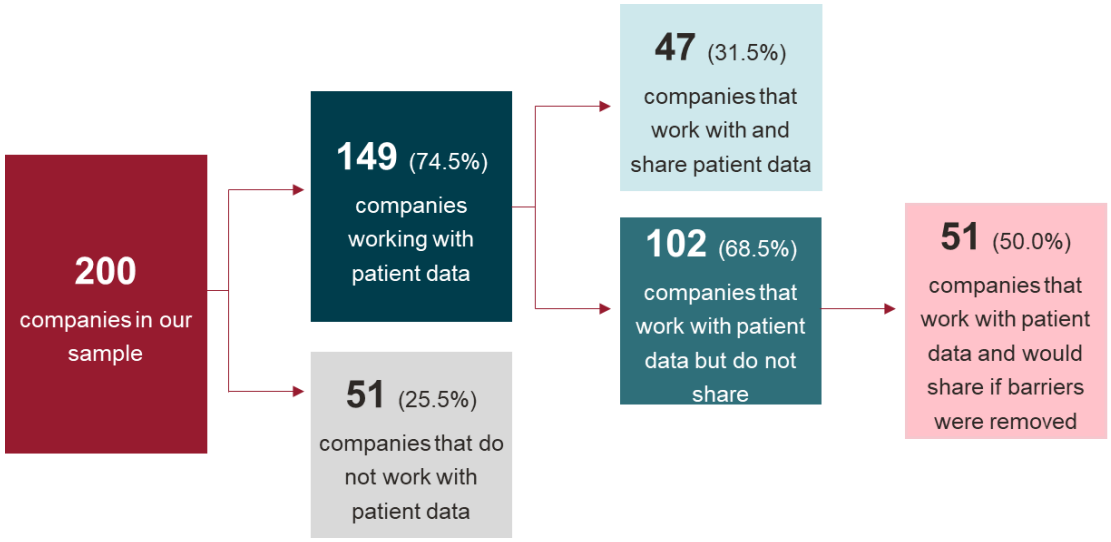
We then combined these results with secondary evidence to generate estimates of the value of patient data sharing in monetary terms. This included:

- Generalising our findings from the sample of the businesses we interviewed to the broader relevant EU27 population (of businesses or patients as relevant); and
- Where relevant, linking intermediate outcomes measured through our survey to ultimate impacts on EU patients, hospitals and broader society.

3.3.1 The extent of patient data sharing

We collected responses from 47 companies that currently share patient data between EU and non-EU locations. This is **one-third of the 149 companies in our sample that work with patient data** (which in turn account for around three-quarters of the 200 total responses to our survey). Of the remaining 102 companies that work with patient data but do not currently share this data across borders, 51 (50%) said they would start sharing data if current barriers were removed. We discuss this finding and its implications in greater detail in section 4.

Figure 8 Distribution of firms based on data sharing status



Source: Business survey

Respondents share data between their EU and non-EU sites and with their collaborators, suppliers or customers located outside the EU through a secure environment. This includes transferring or exchanging patient data to secure non-EU location for storage, processing or analysis.

Based on this data, **we estimate that around 16,000 healthcare companies in the EU currently share patient data between EU and non-EU geographies**. We were unable to determine the non-EU country partners for these EU businesses that share patient data

internationally, but it is clear from a review of existing evidence that the USA is a critical partner country for EU/non-EU data sharing generally, and particularly in the context of healthcare.

The USA is a key export market for EU businesses. It is the largest trade partner for the EU in services, with transatlantic trade continuing to increase over time; the EU27 exported €509 billion in goods to the USA in 2022,[45] a record high figure for EU exports to the USA. The USA is also a particularly large importer of pharmaceuticals and medical goods, accounting for 20% of global imports of pharmaceutical goods in 2019.[46]

Data sharing with US businesses is particularly important as part of production activities of EU-based multi-national enterprises. Frontier Economics (2022)[47] estimated that 59% of EU businesses that shared non-personal data internationally were sharing data with the USA, and the Analysis Group (2021)[48] stated that, at the time of the Schrems II decision, 5,300 EU businesses were relying on the EU-US Privacy Shield framework to transfer data from the EU to the USA.

Our sample of 47 companies that currently share patient data is a relatively small sample from which to draw implications for the EU as a whole. Therefore, as detailed in the following sections, we cross-checked our survey findings against secondary data wherever possible, we make conservative assumptions when scaling the results up to EU level, and present results in ranges, rather than point estimates, to reflect the underlying uncertainty in our estimates.

The relatively small size of our sample is due to the difficulty of identifying and reaching companies that share patient data. To the best of our knowledge, there is no way of understanding at scale whether a particular organisation works with and shares patient data without directly asking someone in that organisation. Adding to this difficulty, there are only a small number of people within each organisation who can speak about the organisation's approach to international data flows (typically this will be senior members of the organisation with overall management responsibilities and/or a specific responsibility for data governance).

Therefore, collecting responses from organisations that share patient data is very time consuming (relative, for example, to a situation where one may want to collect responses from the population of all manufacturing firms in Europe, which can be identified ex ante from existing data). It involves initially reaching a larger number of organisations, from which those that share patient data are selected, and for each of those organisations, reaching specific members of staff who know whether the company shares data internationally. Annex A provides further detail on how we approached the primary data collection and tackled these challenges.

45 Eurostat extra-EU trade by partner

46 S&P Global (2020)

47 Frontier Economics (2022), P20

48 https://about.fb.com/wp-content/uploads/2021/06/The-Importance-of-Cross-Border-Data-Flows.pdf

3.3.2 Gathering data from respondents on the impact of patient data sharing

To assess the impact of patient data sharing, we asked respondents who currently share patient data between EU and non-EU locations to compare two states of the world:

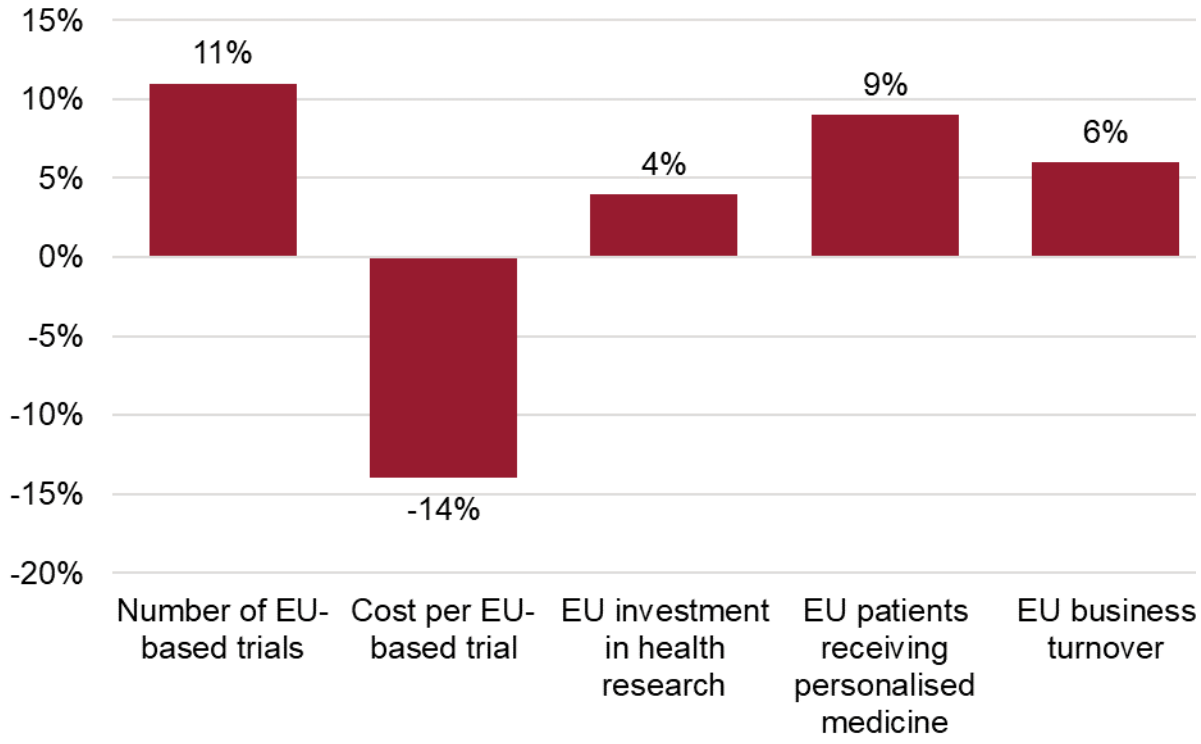
1. The current 'factual' state where businesses use patient data and share it between EU/non-EU locations, with associated benefits to EU businesses, patients and hospitals; and
2. A hypothetical 'counterfactual' state where there is a hypothetical ban on EU/non-EU international patient data flows, with follow-on impacts to EU businesses, patients and hospitals.

Clearly, such a ban is not realistic, but setting this scenario was useful to help respondents assess the role of international data flows. The key difference across these states of the world is whether patient data is shared between EU/non-EU locations. Therefore, assessing the difference in healthcare business, patient and healthcare system outcomes (in value terms) between the 'factual' and 'counterfactual' states is equivalent to assessing the value of current levels of EU/non-EU patient data sharing.

We chose to present respondents with a hypothetical scenario because we expected that they would not be able to answer more direct questions (e.g. 'how many more patients can receive personalised medicine treatments thanks to international data sharing?' or 'what is the value of international data sharing to your organisation?'). Therefore we provided them with a counterfactual scenario to make the questions more concrete and easier to answer. We implemented a process of 'cognitive testing' to test this approach through ten in-depth interviews prior to launching the survey fieldwork to ensure that respondents understood and felt they could answer our questions. The final version of our questionnaire was adapted based on the feedback received during this process.

Figure 9 below shows the average impact of data flows on the outcomes that we asked respondents to assess.

Figure 9 Weighted survey respondents' assessment of the impact of patient data sharing on their activities



Source: Frontier Economics analysis of business survey data
Note: Sample size: 47 companies.

3.3.3 Valuing the impact of data sharing

Scaling up our results to EU level

To keep the scope of our primary data collection manageable, as it is very challenging to identify and engage with organisations that share patient data across borders, we collected responses from businesses located in eight EU countries: Austria, Belgium, France, Germany, Italy, Netherlands, Spain and Sweden.

As we are interested in the impact of patient data sharing on the EU as a whole, we scale up our results to all relevant populations in the EU27. We recognise that this approach has limitations, as we do not have data from all EU member states in our sample and, specifically, we do not have data on countries in some of the eastern regions of the EU, such as the Balkans, Bulgaria, Hungary, Poland, Romania and the Baltic region (largely including countries that joined the EU in 2004). Our sample does, however, include wide variation along a number of key characteristics, including:

- Use of digital technologies, which is likely to be related to the extent of patient data use and sharing. For example, the lowest country in our sample in terms of enterprise adoption of cloud computing is France (sixth lowest in the EU27), while the highest is Sweden;[49]

- General economic outcomes – for example, the lowest country in our sample in terms of gross domestic product (GDP) per capita is Portugal (eighth lowest in the EU27), while the highest (seventh highest) is the Netherlands.[50]

However, it is also the case that several of the countries excluded from our sample tend to have worse health outcomes in terms of some metrics: for example, Bulgaria, Romania, Hungary, Latvia, Slovakia, Lithuania, Poland, Croatia, Czechia and Estonia are all at the bottom of the table in terms of female life expectancy at birth, and the picture for male life expectancy is very similar.[51] Therefore, in Annex B we present sensitivity checks where we show how our results would change with different assumptions about the impact of patient data sharing on countries that joined the EU in 2004.

Estimating ultimate impacts on patients and wider society

In some cases, the effects we assessed through the survey are intermediate outcomes which are linked to further ultimate impacts. For example, survey respondents assessed that patient data sharing leads to additional clinical trials, but we are ultimately interested in the benefits of those trials for EU patients. Therefore, we calculate these as the product of i) our estimates of the number of additional clinical trials that are undertaken due to patient data sharing, and ii) an average estimate of the increase in QALYs linked to additional clinical trials.

In the next sections, we provide more detail on each of the impact channels described above.

3.4 Impact on patients through additional clinical trials

Our in-depth interviews and literature review identified that EU/non-EU patient data flows can be critical for businesses which undertake clinical trials in the EU. Our research identified several channels of impact. For example:

- They enable cross-country trials which are cost efficient and which, in turn, have larger, more varied samples, improving research quality and probability of success across a range of countries;

- They increase access to non-EU markets by enabling overseas regulatory certification of trial results in non-EU markets through the transfer of patient data to the relevant authority; and

49 As of 2021, latest year available. Source: Eurostat

50 GDP per capita in euros at current prices, 2022 Source: Eurostat.

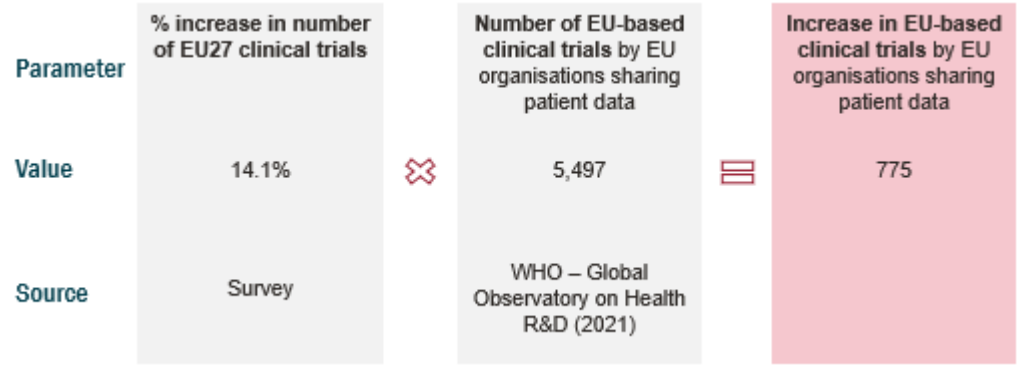
51 As of 2021, latest year available on Eurostat. Source: Eurostat

- They are necessary to deliver larger-scale and/or decentralised trials, which accrue cost efficiencies.

3.4.1 Number of clinical trials

Our survey asked businesses involved in clinical trials to estimate the impact of a hypothetical ban on EU/non-EU patient data sharing on their annual investment in health research in the five-year period after the ban came into effect. Figure presents the results.

Figure 10 Summary of calculations – impact on number of clinical trials



Source: Frontier Economics

We received responses from 14 businesses that share patient data between EU/non-EU and that are currently involved in running clinical trials in the EU. On average, respondents indicated that the hypothetical ban would reduce the number of clinical trials they undertake by 14%. Therefore, conversely, this would imply that businesses are able to carry out 14% more EU-based clinical trials 'as is' due to their current use of EU/non-EU patient data flows.

3.4.2 QALY gains from oncology trials

In the previous section, we presented the findings from our sample of businesses that conduct clinical trials and showed that the number of clinical trials is expected to be 14% higher, on average, as a result of EU/non-EU patient data flows.

To understand the impact of this on patients, we need an estimate of how an increase in clinical trials can affect health outcomes. The best source of evidence that we were able to identify was an academic study which estimates the health benefits of 23 successful US oncology clinical trials (Unger, LeBlanc & Blanke, 2017).[52] Therefore, our modelling focuses on the QALY gains for EU cancer patients, as this study's results relate to benefits for cancer

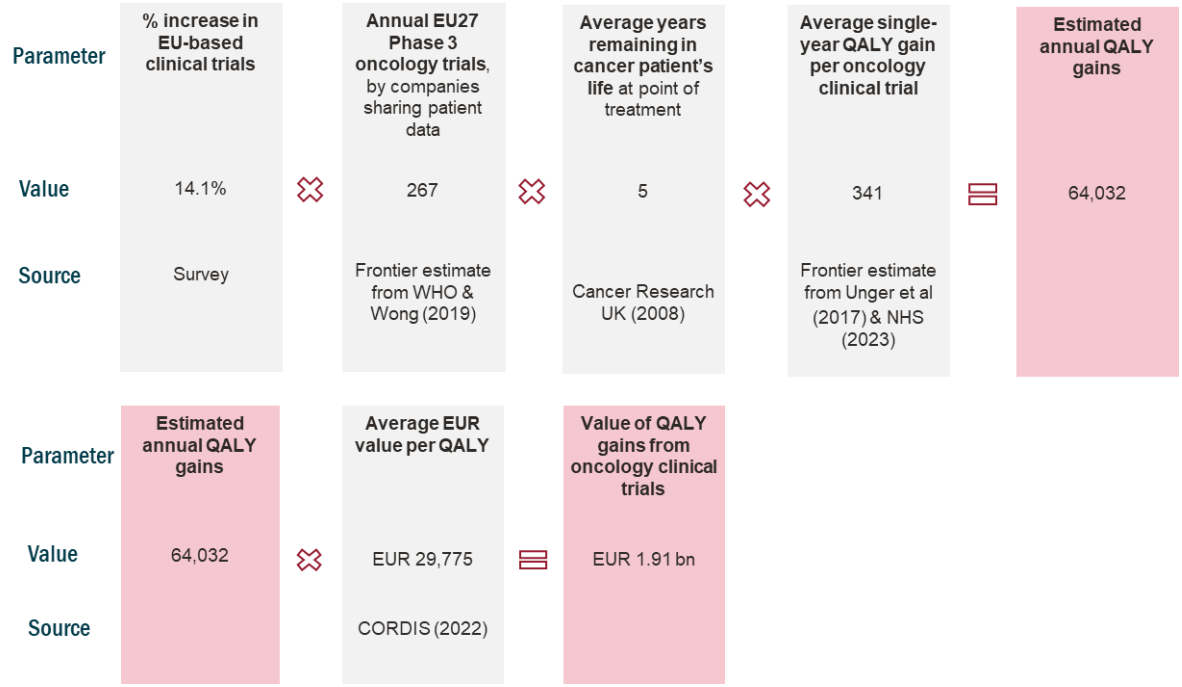
[52] Unger, J.M., LeBlanc, M., & Blanke, C.D. (2017). The effect of positive SWOG treatment trials on survival of patients with cancer in the US population. JAMA oncology, 3(10): 1345-1351.

patients only. In any case, the number of annual new EU cancer patients is significant, and therefore our modelling relates to a significant number of EU patients.

We adjust the Unger et al (2017) results to account for the success rate in oncology trials[53] and differences in the relative size of the EU and US cancer populations. We also condense the study's results down to the estimated lifetime benefit of personalised medicine for a single cohort of newly diagnosed cancer patients in a given year. We do this by multiplying an estimated benefit of 341 life years saved across the full population of annual newly diagnosed cancer patients for a single year of treatment, by the average number of years remaining in a cancer patient's life at point of diagnosis (five years). Our full modelling method is described in Annex B.

Figure 11 presents our results.

Figure 11 Summary of calculations – impact on QALY from cancer trials



Source: Frontier Economics

Our central estimate of the EU/non-EU patient data flow increase of EU lifetime patient health, by enabling the delivery of additional EU-based clinical trials, is 64,000 QALY[54] on an annual

[53] This is because not all oncology clinical trials are successful, whereas the Unger at al study focuses only on successful trials.

[54] 64,000 is calculated as the multiplication of the inputs in Figure 9. Two of these inputs include the average number of years that a patient has cancer (5), and the average QALY gain per year of taking a treatment from a successful clinical trial, across all patients taking the treatment (341).

basis for **newly diagnosed EU cancer patients**, with a range between **48,000 QALY to 80,000 QALY**.[55]

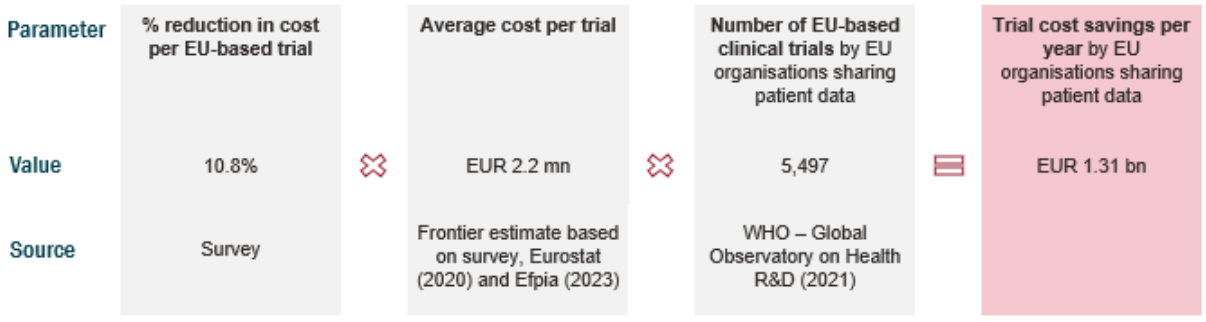
Applying estimates from CORDIS on the euro value per QALY, we converted our QALY estimates to value terms. We estimate that EU/non-EU patient data flows increase EU patient health by **€1.1 billion to €6.3 billion** for **newly diagnosed EU cancer patients,** with our central estimate being €1.9 billion.[56]

There is significant uncertainty over the size of our figures for the patient benefits of EU/non-EU patient data sharing, as our survey results for clinical trials are generated from a particularly small sample of businesses. Nonetheless, even our lower-bound estimate for EU/non-EU data flows that enable the delivery of clinical trials generates large health benefits for EU patients.

3.4.3 Cost of clinical trials

We asked the same businesses involved in conducting clinical trials about what the impact would be on their cost per clinical trial in the five-year period after the ban came into effect. Figure 12 presents the results. Our sample of clinical trial businesses that share patient data between EU/non-EU responded that the hypothetical ban would increase their cost per trial by 11%, on average, as a central estimate. Therefore, conversely, these businesses are experiencing reduced cost per trials of 11% 'as is' due to their current use of EU/non-EU patient data flows.

Figure 12 Summary of calculations – impact on cost of clinical trials



Source: Frontier Economics and various

55 Our range is based on adjusting the survey result by +/-25% to reflect uncertainty about whether our sample result is representative of the effect for the broader population of EU businesses.

56 Our range is based on our above adjustments to our QALY results and an additional range of estimates for the value of a QALY, from €22,000 to €79,000.

We applied our 11% cost-saving parameter to secondary evidence on the annual EU spending on clinical trials, adjusted to reflect only those trials performed by businesses with international activities that share patient data between EU/non-EU geographies.[57] We estimate that EU/non-EU patient data flows generate economic value of **€1.0 billion to €1.6 billion per year** to the EU27 through reduced clinical trial costs, with a 'central' estimate of €1.3 billion per year.[58]

We present this figure as a range to reflect the uncertainty about whether our survey results represent the impacts from the broader population of firms across the EU27.

Our survey results also find that EU businesses would deliver 14% more clinical trials as a result of patient data sharing between EU/non-EU geographies. These trials would incur costs of production, but these additional costs are not netted off in our trial cost-saving figures.

3.5 The impact of personalised medicine on patient health

Our in-depth interviews and literature review identified that EU/non-EU patient data flows can enable the development and delivery of personalised medicine. The development of personalised medicine products relies on large, granular genomic datasets for research purposes and on the delivery of personalised medicine services which match individual patient genomic data to the genomic data and health outcomes of a large, broader cohort of patients.

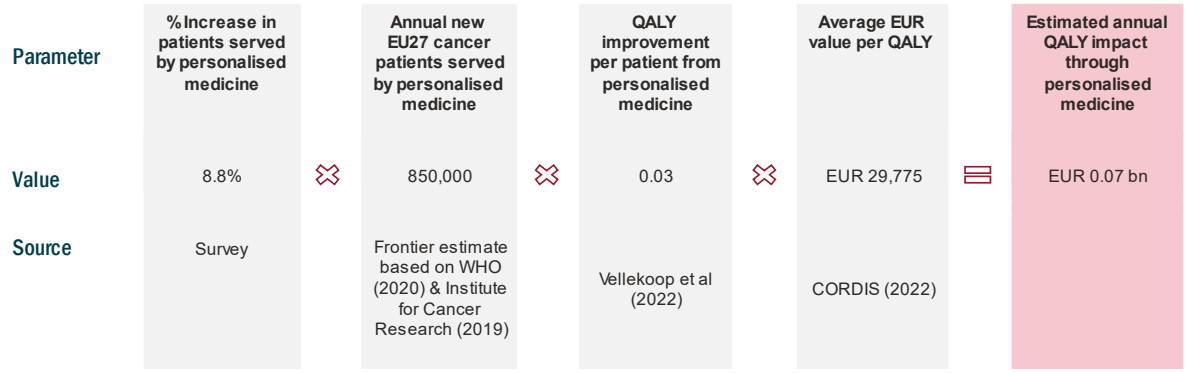
Through our business survey, we gathered evidence on the number of current EU-based patients receiving personalised medicine who might not be served as a result of the hypothetical ban on EU/non-EU patient data sharing. As the number of participants in our sample who responded to this question was particularly low, we use the percentage reduction in sales due to the hypothetical ban for businesses engaged in personalised medicine activities as a proxy for this effect. This is a reasonable proxy as the volume of sales would be strongly associated with the number of patients served.

Figure 3 presents our approach to estimating the QALY gains associated with access to personalised medicine.

[57] For simplicity, we use one average cost per trial. However, trial costs are likely to vary substantially. It is possible that international patient data sharing is more likely to take place in larger trials and therefore possible that our cost per trial figure underestimates the baseline average cost of trials that benefit from international patient data sharing.

[58] Our range is based on adjusting the survey result by +/-25% to reflect uncertainty about whether our sample result is representative of the effect for the broader population of EU businesses.

Figure 13 Summary of calculations – impact on QALY from personalised medicine



Source: *Frontier Economics*

Note: *% increase in patients served by personalised medicine service proxied by % increase in turnover by personalised medicine companies.*

Our sample of companies that provide personalised medicine and share patient data between EU and non-EU countries indicates that the hypothetical ban on such sharing would reduce sales by 8.75%, on average. Therefore, conversely, these businesses are expected to be serving 8.75% of the current new cancer patients who receive personalised medicine 'as is' due to their EU to non-EU patient data flows.

We combined our survey results with information from secondary sources to estimate the total number of EU27 patients currently served by personalised medicine based on proxies of intensity of demand[59] and likely uptake of personalised medicine among cancer patients. Again, we only focus on benefits to cancer patients because cancer therapy is a field in which personalised medicine has been pioneering and systematic evidence on the benefits to patients is available.

Based on information provided by the WHO-Global Cancer Observatory[60] and Institute for Cancer Research,[61] and converting the Europe-level WHO figure to an EU27 figure,[62] we found that around 74,000 newly diagnosed EU27 cancer patients per year would no longer receive personalised medicine due to the hypothetical ban. We translate this result in terms of QALY gains based on existing evidence on the benefits of personalised medicine for cancer

59 We adjusted the total EU27 population by the percentage of self-perceived longstanding illness and the percentage of hospital discharges associated with treatment of chronic diseases – both from Eurostat – to estimate the population that is likely to demand treatment.

60 WHO - Globacan 2020 Report

61 Institute for Cancer Research

62 We estimated that in 2023 the EU27 population (448 billion) was approximately 60% of the Europe population (742 billion underlying source is United Nations statistics).

patients, which indicates that these treatments may result in lifetime QALY gains of between 0.03 and 0.16 ,[63] depending on the type of cancer treated and the stage of the illness.

Overall, we estimate that, by allowing patients to access personalised medicine, EU/non-EU patient data flows increase EU patient health by 1,700 to 15,000 QALY for diagnosed EU cancer patients, with our central estimate being 2,200 QALY. As in the previous section, applying estimates from CORDIS on the euro value per QALY, we calculate that the current value of EU/non-EU patient data sharing from the delivery of **personalised medicine** is between **€40 million and €1.2 billion** for annual newly diagnosed cancer patients, with our central estimate at €70 million.[64]

This range is not symmetric because the upper-bound estimate also includes the 75th percentile value of QALY gains (0.16) from personalised medicine treatment, compared to the 50th percentile figure used in the central estimate and lower bound. The upper-bound monetary value of QALY (€79,000) is also considerably higher than the central estimate value (€29,775).

More generally, it is not surprising that we estimated a wide range for the potential impact through personalised medicine treatments. First, there is significant heterogeneity in the QALY effect of personalised medicine, depending on the type of cancer type and the stage of the illness (disease classification), purpose of intervention (e.g. disease and/or genetic marker screening, gaining information on prognosis, identifying patients with adverse drug reaction, identifying non-responders to treatment) and the type of treatment (i.e. pharmaceutical, non-pharmaceutical or a combination of both, gene therapy). Second, as personalised medicine as a field is still developing, even if some treatments are already used regularly, we would expect greater uncertainty over the size of its potential health benefits.

We also consider that our central estimate of €70 million is conservative and likely to increase in the future:

- We focus on benefits to newly diagnosed cancer patients using data relating to the figure for 2020, but the evidence suggests that the prevalence of cancer in the EU27 is increasing over time.[65]
- As with other innovative products and services, personalised medicine treatments are still in their infancy. Their full benefits may take decades to materialise as the treatment

63 Vellekoop H., Versteegh M., Huygens S., Corro Ramos I., Szilberhorn L., Zelei T., Nagy B., Tsiachristas A., Koleva-Kolarova R., Wordsworth S., Rutten-van Mölken M.; HEcoPerMed consortium (2022). The net benefit of personalized medicine: A systematic literature review and regression analysis. Value Health, Aug 25(8):1428-1438.

64 Our range was constructed by varying three parameters: adjusting the 8.75% survey result by +/-25% to reflect uncertainty about whether our survey result is representative of the effect experienced by the broader population; using the 0.03 and 0.16 QALY parameters for the lower and upper bounds respectively; and using a range of €22,000 to €79,000 for the euro value of a QALY. Annex B.5 provides further detail on our methodology.

65 According to the European Cancer Information System, the number of people being diagnosed with cancer by 2040 in EU and European Free Trade Association (EFTA) countries is estimated to increase by 21%.

matures and becomes used more widely. Our chosen central QALY effect parameter is 0.03, which is at the lower end of results.

3.6 The impact of patient data sharing on EU productivity

Our in-depth interviews and literature review identified that EU/non-EU patient data flows can be critical for the operations of many healthcare businesses. Ideally, to understand the overall economic impact of this data sharing, we need to assess whether it leads to improved productivity. Estimating productivity impacts allows us to understand the net effect of data sharing on the healthcare sector rather than the specific effect on individual businesses (which could be measured, for example, through sales), in line with best practice in economic evaluation and appraisal.

Improved productivity gains from patient data sharing undertaken by healthcare businesses could result from:

- Patient data sharing that allows businesses to provide better products or services for the same cost;
- Patient data sharing that allows businesses to provide the same products or services at lower cost; and
- Enabling businesses to provide products and services in more geographical locations, increasing competition and choice for their customers (healthcare systems, consumers or other businesses).

In the case of the healthcare sector, we also need to consider that if the impact of data sharing is producing better products for the same cost, this would mean that an increase in productivity could also mean an increase in costs for the public healthcare system. As described later in this chapter (section 3.8), we also investigated the impact of data sharing directly on public healthcare costs for secondary care (hospitals), and our findings are mixed.

On the one hand, survey respondents indicated that patient data sharing reduces costs per patient admitted to care and reduces the risk of re-admission (which in turn would also lead to lower costs). On the other hand, while many survey respondents expected patient data sharing to improve the operational efficiency of hospitals, a slightly higher number of respondents indicated a potential decrease in operational efficiency. Therefore, for our main estimates, we assume that hospital costs do not change as a result of patient data sharing. However, we also assess what the likely decrease in cost per patient could be worth.

In economic impact studies, productivity is often measured as output per worker, GVA per worker or total factor productivity. While, ideally, we would have asked our survey respondents to tell us about how patient data sharing affects these metrics, in practice most respondents would not have been able to do that. This is because businesses typically do not track these measures. Therefore, we asked survey respondents to report impacts on their turnover and employment. This enables us to measure turnover per employee as a rough proxy for

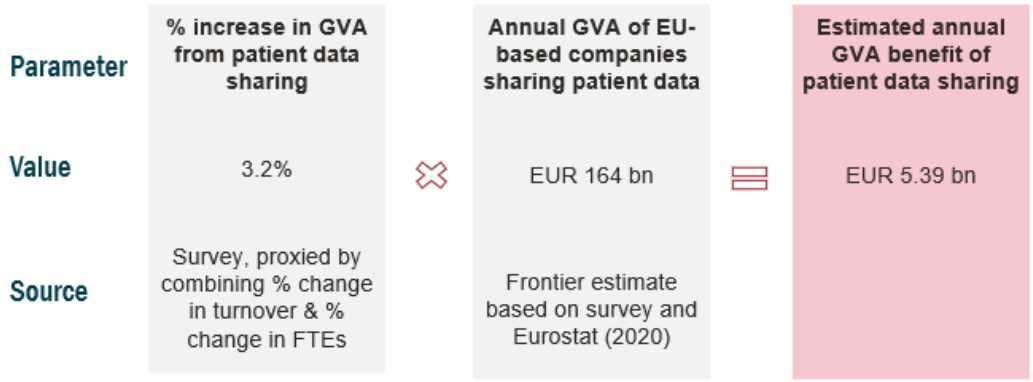
productivity. We then multiply the impact on turnover per employee by the baseline GVA of the EU health sector to obtain an estimate of the impact on the EU of greater productivity enabled by patient data sharing.

Our survey asked businesses to estimate the impact of a hypothetical ban on EU/non-EU patient data sharing on their annual turnover from sales of health products and services and the annual number of full-time equivalent employees (FTEs), in the five-year period after the ban came into effect. On average, respondents who share patient data between EU/non-EU locations responded that the hypothetical ban would reduce their annual sales by 6.1% on average and would reduce their number of FTEs by 2.8% on average. On that basis, the hypothetical ban would reduce turnover per employee by 3.2% on average.[66] Therefore, these businesses experience approximately 3.2% higher annual revenue from sales than would be expected otherwise as a result of EU/non-EU patient data flows.[67] We use this parameter as a proxy for the % increase in business productivity due to international patient data flows.

Figure 4 below shows our calculations using this estimated productivity impact.

We then multiply this percentage change to the total production value of the relevant business population (all healthcare businesses in the EU27 which have international activities and share patient data between EU and non-EU locations), measured as GVA. As a result, we estimate that EU/non-EU patient data sharing increases EU-based business **GVA** by **€4.0 billion to €6.7 billion per year**, with a central estimate of €5.4 billion per year.[68]

Figure 14 Summary of calculations – impact on business productivity



Source: Frontier Economics

66 Calculated as a reduction of (((1+6.1%)/(1+2.8%)) – 1).

67 On average, across our survey respondents, a ban on patient data sharing would lead to a 3.2% decrease in turnover per business. This means that if their GVA is worth EUR 200 today, without patient data sharing they would only sell (1-0.032)*200= EUR 193.6. We interpret this finding as implying that patient data sharing leads to an increase in sales from EUR 193.6 to EUR 200, i.e. a 6.4/200=3.2% increase in sales.

68 Our range is based on adjusting the survey result by +/-25% to reflect uncertainty about whether our sample result is representative of the effect for the broader population of EU businesses.

Note: Annex B provides further detail on our estimation of the number of healthcare businesses in the EU that have international activities and share patient data between EU and non-EU locations, and on their baseline sales.

As for other aspects of this study, we report our estimates of the impact of patient data sharing on GVA as a range from €4.0 billion to € 6.7 billion per year, to reflect the uncertainty about whether survey results represent the impacts from the broader population of firms across the EU27.

3.7 Impact on the amount of health research investment in the EU

As described in section 2 of this report, our in-depth interviews and literature review identified that EU/non-EU patient data flows can help to reduce the cost and increase the effectiveness of health research. For example, international data flows enable patient data from different countries to be combined, increasing the size of datasets being analysed and enabling analysis of more diverse populations. They also enable greater international collaboration as part of international research studies increasing the rate of knowledge transfer and improving the quality of research.

Our hypothesis was that these effects would increase health businesses' incentives to invest in health research, which depends on the expected benefit from that investment, net of cost. Our survey was used to test whether international patient data flows lead to greater business investment in health research and, if so, by how much. To test our hypothesis we asked businesses to estimate the impact of a hypothetical ban on EU/non-EU patient data sharing on their annual investment in health research in the five-year period after the ban came into effect. We asked respondents to exclude clinical trials from their responses as we investigate the impact of patient data sharing on trials separately (section 3.4). Figure 5 presents the results.

We obtained 45 responses from businesses that currently share data between the EU and non-EU locations and currently invest in health research. These respondents indicated that, on average, a hypothetical ban would reduce their annual investment in health research by 3.6%. Therefore, conversely, 3.6% of these businesses' current EU-based investment is due to EU/non-EU patient data flows.[69]

To assess what this means for EU businesses and society, we estimate the total euro amount of additional investment attributable to patient data flows. We obtain this by multiplying the percentage increase (3.6%) from the survey by an estimate of the total annual investment in health research undertaken by businesses that share patient data between the EU and non-EU locations, based on information provided by Eurostat.[70]

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69 Four businesses reported that their EU-based investment would actually increase as a result of a ban on international patient data flows. It is worth noting that an increase in investment in that case could be the result of a greater cost of doing business in the EU rather than increased incentives to invest. Our figures above relate to the net impact of EU/non-EU patient data sharing, i.e. the 3.6% parameter is the net result of responses from both businesses increasing and decreasing investment as a result of EU/non-EU patient data flows.

70 EC/Eurostat - Annual enterprise statistics by size class

Our estimates suggest that EU/non-EU patient data sharing by EU businesses is associated with an increase of €0.61 billion per year.

However, this figure includes additional investment in EU-based oncology clinical trials, which we separately included in our modelling of health benefits from additional EU-based clinical trials. We therefore remove the proportion of EU27 annual investment in oncology trials (16%) from our €0.61 billion figure to avoid double-counting their research benefits. Annex B.7 provides details on our calculation.

Having removed additional investment related to oncology clinical trials, we estimate the remaining increased investment in health research to be €0.52 billion per year, with a range of **€0.4 billion to €0.7 billion per year**.[71]

The following step in our calculations assesses the ultimate societal impact of this additional investment.

The benefits of additional health research reliant on international patient data flows

There are several follow-on benefits from additional investment in health research, including:

- Commercialisation benefits to businesses when research is translated to marketable products and services;
- Improved diagnostics and drug development leading to improved patient health and more efficient secondary care, reducing EU hospital costs; and
- Greater labour force participation and workforce productivity as a result of improved health.

Figure 15 Summary of calculations – benefits of additional health research

Parameter	% increase in investment in health research		Annual investment in health research by companies sharing patient data		% health research that **does not** relate to **oncology clinical trials**		Average benefit-cost ratio of medical research	=	Annual value of benefits from additional health research
Value	3.6%	⊠	EUR 16.8 bn	⊠	84%	⊠	3.9	=	EUR 2.02 bn
Source	Survey		Frontier estimate based on survey and Eurostat data (2020)		Frontier estimate using Eurostat & WHO data		KPMG (2018)		

Source: Frontier Economics

[71] Our range is based on adjusting the survey result by +/-25% to reflect uncertainty about whether our sample result is representative of the effect for the broader population of EU businesses.

Applying evidence from KPMG (2018) on the economic return from investment in health research,[72] we find that EU/non-EU patient data flows generate economic value of **€0.7 billion to €2.7 billion per year** to the EU27 through **increased EU-based investment in health research**, with a 'central' estimate of €2.0 billion per year. This estimate includes 'health gains' in the form of improved patient disability-adjusted life years (DALYs)[73] and reduced public healthcare costs, as well as wider economic benefits in the form of worker productivity impacts and health business commercialisation.

We present this figure as a range to reflect the uncertainty about whether our survey results represent the impacts from the broader population of firms across the EU27 and to reflect uncertainty in the returns estimates from the KPMG (2018) study.[74]

3.8 The impact of international patient data flows involving EU businesses on healthcare systems

Patient data sharing between EU and non-EU locations that involves private sector organisations can also have an impact on healthcare systems:

- Impacts on research (reported earlier in section 3.47) ultimately determine what treatments are available and may also affect decisions taken in the public sector (for example, where research has implications for public health).
- Patient data sharing affects the ability to deliver personalised medicine, which often takes place through public primary and secondary care settings (reported earlier in section 3.5).
- Patient data sharing affects the availability, cost, quality and price of products/services supplied by private sector organisations (as described in section 3.6 on private sector revenues).
- Organisations within the healthcare system may themselves share data across borders, for example as part of pandemic preparedness or response activities.

In this section, we build on the data shown previously to further investigate how patient data sharing affects the healthcare system and, specifically, public sector hospitals. We asked respondents to our survey to assess whether the hypothetical ban on patient data sharing would affect public sector hospitals in the EU in terms of cost per patient entering care, patient

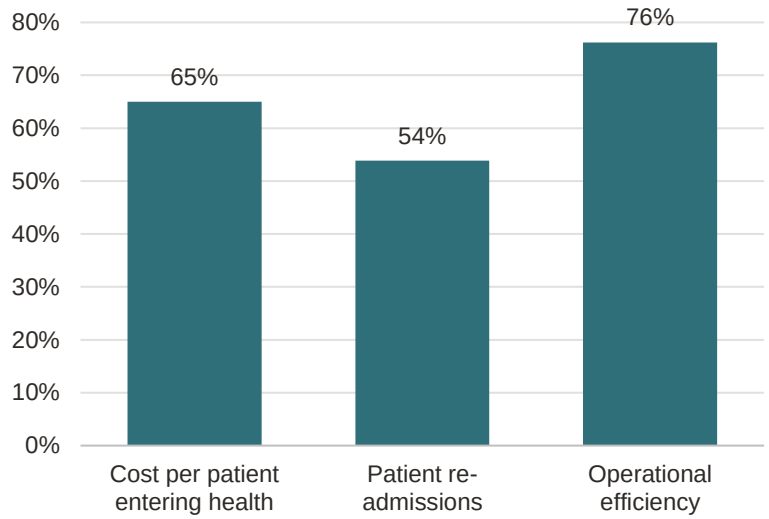
72 KPMG (2018) estimated a benefit-cost ratio of investment in medical research as 3.9 as a baseline estimate, with a lower-bound estimate of 1.8 and an upper-bound estimate of 4.2.

73 Both DALY and QALY are measures of population health used to quantify the burden of a disease or injury. A DALY is a measure of years in perfect health lost (years lost due to premature mortality and years lived in disability/disease) while QALY is a measure of the number of years lived in perfect health gained. Normally, QALYs are based on the effect of specific interventions while DALYs are based on the burden of a disease in the population.

74 Our range is based on adjusting the survey result by +/-25% to reflect uncertainty about whether our sample result is representative of the effect for the broader population of EU businesses, and the range of KPMG (2018) benefit-cost ratios of 1.8 to 4.2.

re-admission and operational efficiency. As Figure 16 shows, the majority of these companies indicated that cross-border patient data flows are likely to have an impact on EU hospital care provision.

Figure 16 Percentage of companies that indicated there were likely follow-on effects on EU hospital care provision, by type of effect

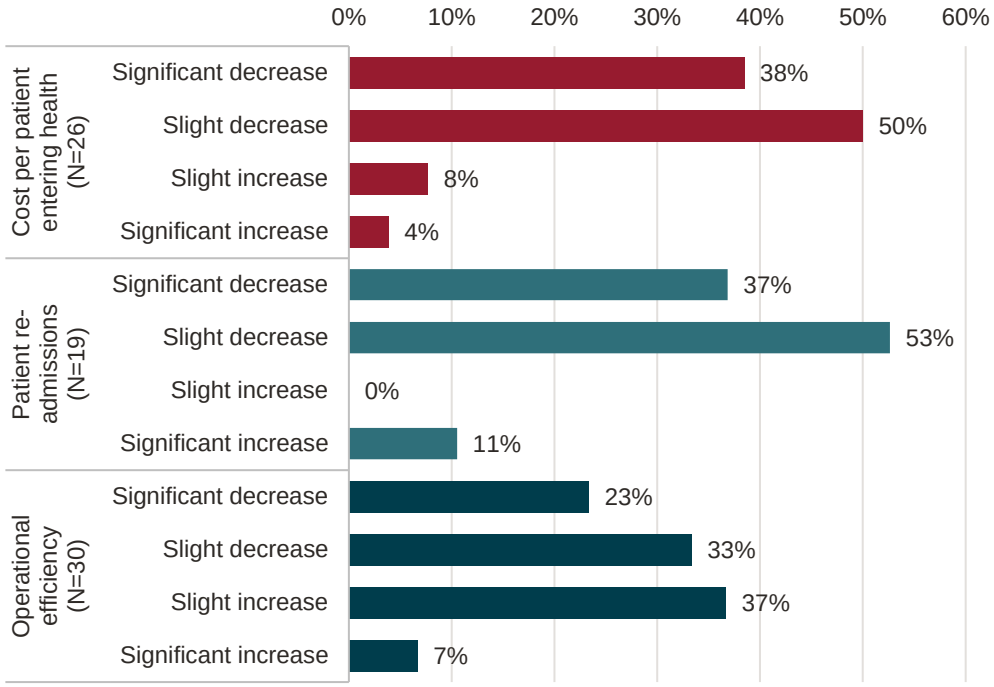


Source: *Business survey*
Note: *Questions were targeted at companies that currently share patient data between EU and non-EU locations (N=47).*

We then asked companies that thought there would be an impact to tell us their assessment of the direction of that impact. The results are shown in Figure 27. Almost 90% of companies that currently share patient data reported that international data sharing is likely to have reduced the cost per patient entering health (a significant decrease according to 38% of respondents and a slight decrease according to the remaining 50%). The same applies to the impact on patient re-admission.

However, we found mixed evidence regarding the impact of data sharing on operational efficiency, with 17 respondents (56%) stating that patient data sharing leads to a decrease in operational efficiency, compared to 13 respondents (44%) mentioning an increase. This may be explained by the fact that activities involving patient data sharing may be particularly complex and/or may involve a higher organisational and administrative burden. The administrative burden of patient data sharing may also be related to the existing barriers that healthcare providers need to overcome to be able to share and transfer patient data across borders.

Figure 27 Distribution of firms, by likely effect of international patient data sharing on EU hospital care provision



Source: *Business survey*
Note: *Questions were targeted at companies that currently share patient data between EU and non-EU locations (N=47).*

The overall picture on hospital costs from Figure 17 is mixed. On the one hand, respondents expected a decrease in cost per patient – which could result, for example, from patient data sharing making private sector suppliers more efficient and would also lead to lower costs for hospitals (discussed in section 3.68). Respondents also reported a decrease in patient re-admission, which would in turn also exert downward pressure on costs. Some of the other impacts on businesses described in section 3.6 could also lead to higher hospital costs.

The other implication for our modelling is that our estimated impact of patient data sharing on hospital costs should not be added to the other benefits of patient data sharing 'as is', as doing so might lead to double-counting.

Our modelling separately estimates the impact of patient data sharing on reducing the costs of EU27 hospitals. We focus our cost savings analysis on decreases in cost per patient as a result of data sharing. Our estimates should be interpreted with caution given that other effects may exist (e.g. operational efficiency), which we do not attempt to quantify. Therefore, the overall impact of patient data sharing on hospital costs could be higher or lower than our estimated impact. Figure 18 summarises our calculations.

Figure 38 Summary of calculations – impact on costs for healthcare providers

Source: Frontier Economics

Our sample of businesses that share patient data between EU/non-EU locations responded that the hypothetical ban would increase hospital costs per patient by 1.8% on average. Therefore, conversely, our central estimate is that EU hospitals experience approximately 1.8% lower costs per patient 'as is' due to EU/non-EU patient data flows.

We convert this percentage change figure to a euro value, by combining it with an estimate for the annual value of EU27 hospital spending which potentially involves patient data sharing, either directly (e.g. cross-border sharing of electronic health records) or indirectly (e.g. patient data sharing used in the development of medical goods supplied to hospitals). We estimate that €270 billion of EU27 hospital spending potentially involved patient data sharing, using data from Eurostat and various simplifying assumptions. Annex B.8 presents our full calculations.

By combining our inputs, we estimate that EU/non-EU patient data sharing reduces EU27 hospital costs by **€1.9 billion to €8.6 billion per year**, with a central estimate of €4.9 billion per year.[75]

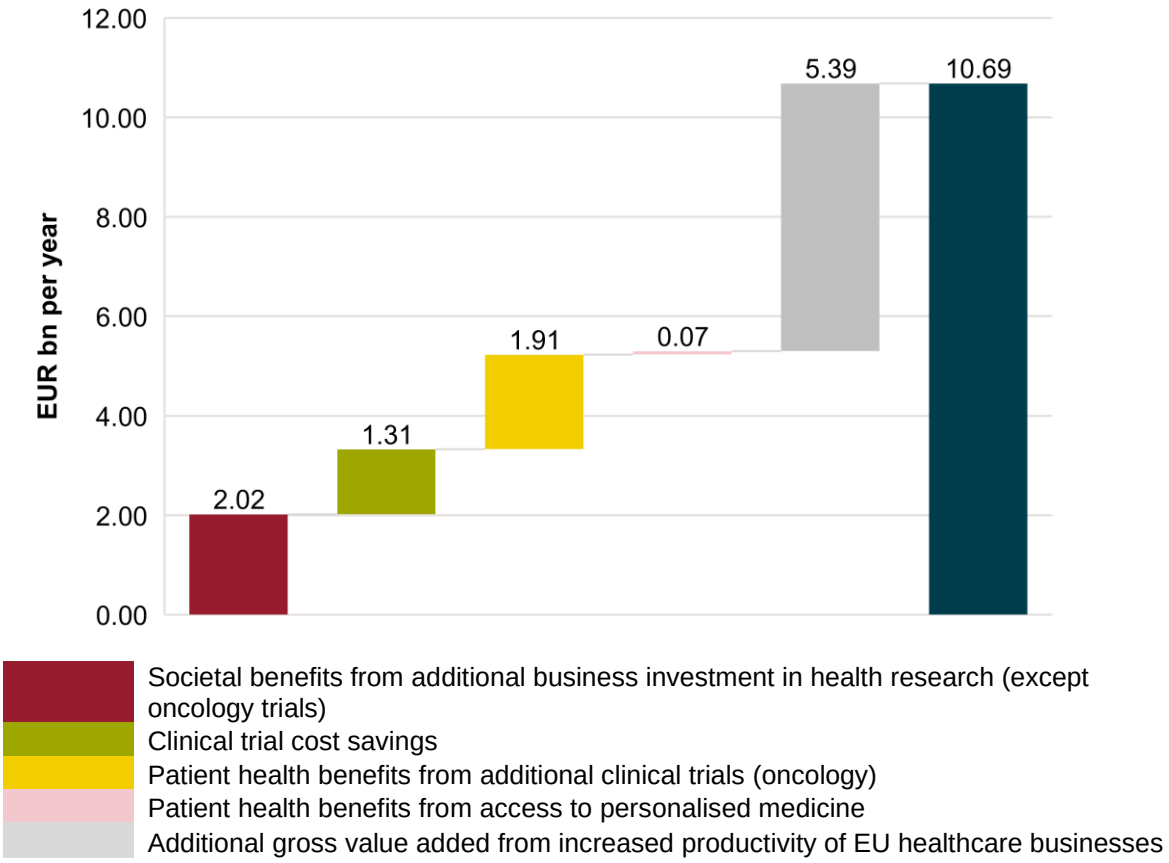
3.9 Overall impact across channels and discussion of results

Figure 49 summarises our estimates of the current value of patient data sharing between EU and non-EU locations. Adding up the central estimates across all impact channels (with the exception of hospital cost savings, to avoid double-counting), the total annual value of patient data sharing to the EU estimated in this report is €10.7 billion. For context, this is larger than

[75] Our range is based on two adjustments: (i) varying the survey result by +/-25% to reflect uncertainty about whether our sample result is representative of the true population effect, and (ii) varying the proportion of estimated hospital costs in scope of patient data use between 25% and 66%, according to whether we consider 100% and 0% of curative care use patient data, respectively.

the research funding available through the health clusters of the Horizons Europe programme over the 2021-2027 period (€8.3 billion[76]).

Figure 49 Current value of EU/non-EU patient data sharing, by impact channel



Source: *Frontier Economics*

Note: *Includes central estimates for each impact channel.*

It is worth noting that this €10.7 billion figure does not attempt to reflect **all** ways in which patient data sharing can generate value, as described earlier in our report. This is because we selected specific key channels to keep the scope of this study manageable and because of data limitations (which means, for example, that our estimate of additional QALYs linked to clinical trials enabled by patient data sharing only includes oncology trials). Moreover, as the evidence we collected on the impact of patient data sharing on hospital costs was mixed, we do not include in the total figure our estimate of the potential size of those savings, which is around €4.9 billion. At the same time, although we took care to avoid double-counting, the channels of impact we modelled are closely related, so it is possible that there remains some overlap between the different channels we estimated.

76 https://www.hrb.ie/funding/eu-funding-support/horizon-europe-information/horizon-europe-health-guide-for-researchers/1-understanding-horizon-europe/

The largest benefit channel we estimated related to GVA (€5.4 billion). The size of this estimate is primarily driven by the fact that the increase in productivity linked to patient data sharing (3.2%) applies to a very large number of businesses: over 16,000 organisations, which generate around €160 billion in annual GVA. As discussed in section 3.66, this increase in GVA is likely to reflect a number of underlying changes, including the availability of data-driven products and services at lower cost to final customers (including healthcare systems) and the availability of higher-quality products and services.

Although we estimate that the percentage impact of data sharing is largest on the number of clinical trials that businesses are able to undertake in the EU (14% increase) and on the cost of these trials (10% cost decrease resulting from patient data sharing), the total impact of these channels is lower than the GVA channel. This is because these percentage impacts apply to fewer organisations – those that undertake clinical trials in the EU. A similar consideration applies to the personalised medicine estimate (8% increase in patients served by personalised medicine, which applies to a relatively small base of patients currently served).

It is also worth noting that some of our estimates are especially likely to be conservative:

- Our estimate of gains in QALY from additional clinical trials is likely to be especially conservative because it only reflects the potential impact of oncology clinical trials, which account for around one-fourth of all clinical trials undertaken in the EU. This is because the only evidence on the average gains in QALY from additional clinical trials that we were able to identify was specific to oncology trials.

- Similarly, again due to data limitations, we only count the impact of personalised medicine on patients who are affected by chronic diseases, excluding other conditions.

Moreover, it is worth noting that our estimate of the impact of patient data sharing on personalised medicine only reflects the current value of data sharing for the delivery of personalised medicine. It does not take account of:

- The value of data sharing for the development of new personalised medicine treatments (although this is likely to be partly reflected in our estimates of the value of patient data sharing for health research); and

- The future value of the delivery of personalised medicine. As personalised medicine includes relatively new approaches, it is likely that the number of people reached by these approaches and their effectiveness will increase over time. Therefore, our estimated impact may be an underestimate of the future value of patient data sharing for the EU as an enabler of personalised medicine.

Therefore, although the impact on sales is the largest estimate in this study, it would not be appropriate to conclude from this that the most important benefit of international patient data sharing is on business performance. This is because, while we aim to be equally conservative in our estimates across all channels of impact, it is likely that our estimates of the gains in QALY from additional clinical trials and delivery of personalised medicine are especially

conservative. Moreover, it is also worth noting that we assign a monetary value to additional QALYs for the purpose of using a comparable unit across all the estimated impact channels. However, monetary valuations of QALYs are inherently limited and cannot fully capture the importance of improvements in individuals' quality of life, nor the impact of these improvements on their families and carers.

3.9.1 Sensitivity of our results

Due to the significant uncertainty in some of the inputs used in the modelling, there is uncertainty in the values estimated above. Therefore, to reflect this uncertainty, Table 1 below presents ranges for each of the impact channels. The table shows that patient data sharing across EU and non-EU locations could generate an annual value of between **€6.8 billion and €18.5 billion** across the EU. Table 1 presents the ranges for each of the impact pathways.

Table 1 Current value of EU/non-EU patient data sharing – central, upper and lower bound, by impact channel (EUR bn)

Impact pathway	Lower bound	Central estimate	Upper bound
Economic value of additional investment in health research	€0.7	€2.0	€2.7
Cost savings for EU-based clinical trial	€1.0	€1.3	€1.6
Gains in QALY through reduced clinical trials	€1.1	€1.9	€6.3
Gains in QALY through reduced delivery of personalised medicine services	€0.04	€0.07	€1.2
Increase in GVA for businesses that share patient data	€4.0	€5.4	€6.7
Cost savings for hospitals	€1.9	€4.9	€8.6
Total value (excl. cost savings for hospitals)	**€6.8**	**€10.7**	**€18.5**

Source: *Frontier Economics*

Note: *Upper and lower bound include an adjustment of +/- 25% to the percentage change in outcomes estimated from the business survey, to reflect the uncertainty about whether our sample estimates accurately reflect true population parameters. Rows may not sum to totals due to rounding. Total row does not include the 'cost savings for hospitals' estimates.*

4 The potential impact of removing barriers to patient data flows

Headline Results

Our quantitative modelling finds that the benefits of patient data sharing between EU and non-EU locations might increase by around **€5.4 billion per year** across the EU27 if current barriers to data sharing were removed. The additional value would be realised annually, after a period of up to five years following the barriers' removal. The €5.4 billion is additional value on top of the €10.7 billion per year of value currently generated 'as is'. This additional value therefore amounts to around 50% of our estimated current value of patient data flows between EU/non-EU geographies.

We break down the EU27 aggregate additional value per year across EU-based businesses, patients and hospitals, and across different impact channels:

- **€4.9 billion** of additional value per year would be accrued as a result of businesses sharing patient data between EU/non-EU locations for the first time, which accounts for the majority of the value opportunity.
- **€0.45 billion** of additional value per year would be realised as a result of businesses that already share patient data between EU/non-EU locations but that would undertake additional data sharing if key barriers to data sharing were removed.

This value would be realised in addition to the current value of patient data flows between EU and non-EU geographies, which we estimate at €10.7 billion as described in section 3 of this report. Therefore, if barriers to these flows were removed, we estimate that the value of patient data flows would increase to around €16.1 billion per year.

4.1 Restrictions to international patient data flows

Our in-depth interviews and targeted literature review identified significant barriers to sharing patient data between EU/non-EU geographies. These included:

- Regulatory constraints, such as restrictions to transfers of personal data from the EU (particularly to countries that lack an 'adequacy decision'), or conflicting national regulations;
- Regulatory uncertainty, particularly in relation to:

- a lack of clarity around GDPR requirements and what constitutes 'sufficient anonymisation' of personal data
- uncertainty over the legal basis for data transfers between the EU and USA;

- Regulatory costs, particularly compliance and legal costs related to GDPR; and
- A lack of interoperability and/or consistent standards for health data across countries.

We assessed the prevalence and impact of various barriers to international patient data sharing in greater depth through our business survey. The responses provide a more comprehensive picture of the impact of barriers to international patient data flows relative to current evidence from a broader sample of businesses.[77]

4.1.1 The key existing barriers to international sharing of patient data

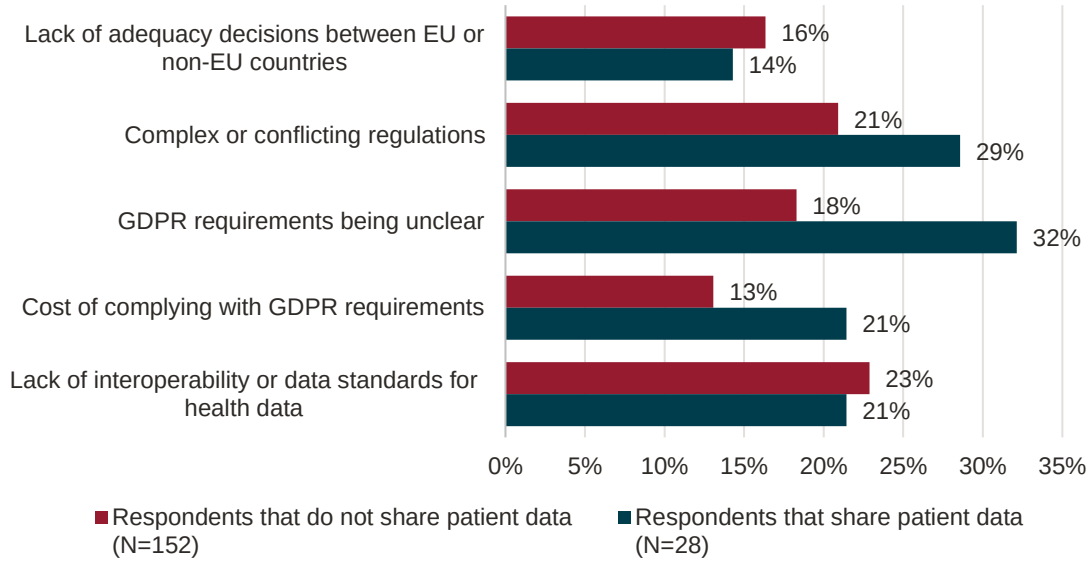
As described in section 2, our expert interviews and our desk research identified several potential barriers to international patient data sharing, with the main two repeatedly being identified as variation in the interpretation of GDPR and barriers to data sharing between the EU and the USA in particular. Recent research identified about 5,000 collaborative projects between the US National Institutes of Health and European Economic Area (EEA) countries, and at least 40 studies that have been suspended or delayed due to legal issues around data protection.[78]

As part of our survey, we asked businesses that use patient data to choose from a list of five potential barriers the main three barriers that restrict EU/non-EU patient data flows for their business. This group of businesses included only those that use patient data, but it did include businesses that currently share patient data between EU/non-EU geographies and businesses that currently do not. Figure 20 presents our results, which show the proportion of respondents who indicated each potential barrier as one of the three main barriers they face. This shows that 'GDPR requirements being unclear' was the barrier most commonly mentioned by respondents who share patient data (32% of the respondents in this group).

[77] While our survey results provide a more comprehensive picture of the impact of barriers across a broader set of businesses, they still only relate to a sample of EU health businesses and therefore may not be fully representative of the impacts faced across the broader EU business population.

[78] Eiss, R. (2020). Confusion over Europe's data-protection law is stalling scientific progress. Nature, 584(7822): 498-499.

Figure 20 Barriers to sharing patient data between EU and non-EU countries



Source: *Business survey*
Note: *Based on a sample of 181 companies. Multiple choice question, not answered by 19 of our 200 businesses.*

Our results show that a range of barriers currently restrict international patient data sharing between EU and non-EU countries. The main barriers identified are the lack of interoperability or data standards for health data, complex or conflicting regulations and the lack of clarity around GDPR requirements. These results align with the findings from our in-depth interviews. As expected, the compliance costs and clarity of GDPR requirements are more relevant for businesses that currently share patient data between EU and non-EU countries.

These barriers apply across many jurisdictions but, as reported in section 3, they are particularly likely to constrain patient data flows between the EU and USA. Notably, prior to our survey being completed an EU-US adequacy decision had not been reached, and despite the European Commission formally endorsing the 'EU-US Data Privacy Framework' (DPF) in July 2023,[79] significant uncertainty remains with multiple lawsuits filed.[80]

[79] Since we finalised our survey questionnaire, in July 2023, the European Commission formally endorsed the 'EU-US Data Privacy Framework' and stated that it considers the level of protection for personal data transferred under the DPF as 'essentially equivalent' to the protection that data would benefit from under the GDPR – akin to the standard that needs to be met for adequacy decisions.

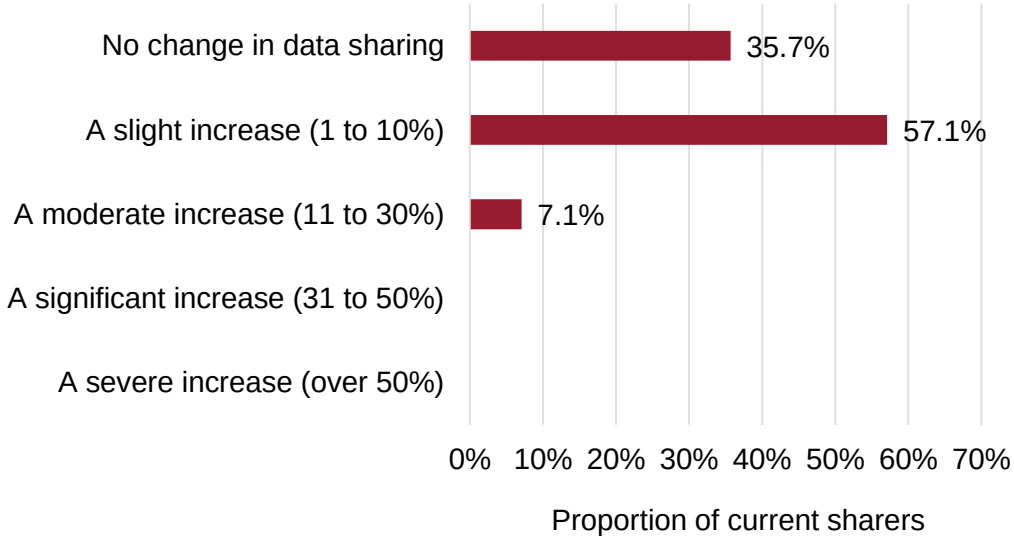
[80] Two lawsuits have been filed with the EU Court of Justice seeking to overturn the DPF, and a new lawsuit filed by Max Schrems (similar to the Schrems II case which led to the previous arrangement for transatlantic data flows being invalidated by the Court of Justice of the European Union) is also likely. (Source: https://www.euractiv.com/section/data-protection/news/new-eu-us-data-transfer-deal-also-faces-criticism-in-germany/)

4.1.2 The impact of removing barriers on international patient data sharing

Impact on businesses that currently share data

We asked businesses that currently share patient data between EU/non-EU geographies whether they would increase their data sharing if existing barriers to sharing patient data internationally were removed. We asked those businesses which responded that they would increase patient data sharing what the likely percentage increase in their EU/non-EU patient data flows would be. Figure1 presents the survey results.

Figure 21 Current sharers' change in data sharing, if barriers were removed



Source: *Business survey*

Note: *Based on a sample of 28 companies which share patient data and mentioned that they would change data sharing activities if barriers were removed.*[81]

Sixty-four percent of businesses that currently share patient data reported that removing barriers would increase the amount of patient data they share between EU/non-EU geographies. Fifty-seven percent of all 'current sharers' reported they would slightly increase their patient data sharing, equivalent to a 1% to 10% increase. Seven percent of current sharers reported they would moderately increase their patient data sharing, equivalent to an 11% to 30% increase.

81 Of the 47 companies that currently share patient data between EU/non-EU geographies in our sample, we were only able to collect information on this question from 28 respondents.

Taking the mid-point of these ranges and including zero change responses, current sharers reported that they would increase their international patient data flows by 4.2% on average.[82]

Impact on businesses that currently do not share data

We also asked businesses that currently use patient data but that do not share it between EU/non-EU geographies whether they would start to do so if their stated key barriers to sharing patient data internationally were removed. We found that **50% of the 102 companies** in our sample that currently work with patient data but that do not share it internationally would start to share the data if key barriers were removed.

Notably, this sub-sample of 51 businesses that would start to share patient data between EU/non-EU geographies is larger than our sample of 47 businesses that currently share patient data between EU/non-EU geographies. This implies that there is significant incremental value at stake from removing restrictions to international patient data flows.

4.2 The potential impact of additional patient data sharing

Section 4.1 finds that significant additional patient data sharing between EU/non-EU geographies could take place if existing barriers to international patient data sharing were removed. Therefore, it would be useful to understand whether and to what extent this additional data sharing would generate benefits or costs for the EU. Estimating the value of this potential data sharing is challenging because this depends on how the data would be used, and we do not know this from our survey data (and indeed many respondent organisations may also not be able to fully anticipate the ways in which they would use data if barriers were removed).

However, we can estimate at a high level how much the benefits we identified in section 3 could increase if barriers to data sharing were removed. We do this by:

1. First, assessing the potential impact of additional data sharing undertaken by current sharers, i.e. organisations that already share data, if the barriers they face were removed; and
2. Second, assessing the potential impact of additional data sharing undertaken by first-time sharers, i.e. firms that currently do not share patient data.

For simplicity, we calculate the impact of removing barriers on the total value of benefits from patient data sharing identified in section 3, without separating the impact on each channel (benefits of health research excluding clinical trials, cost savings on clinical trials, health benefits for patients from additional clinical trials and from increased access to personalised medicine, additional revenues for healthcare businesses).

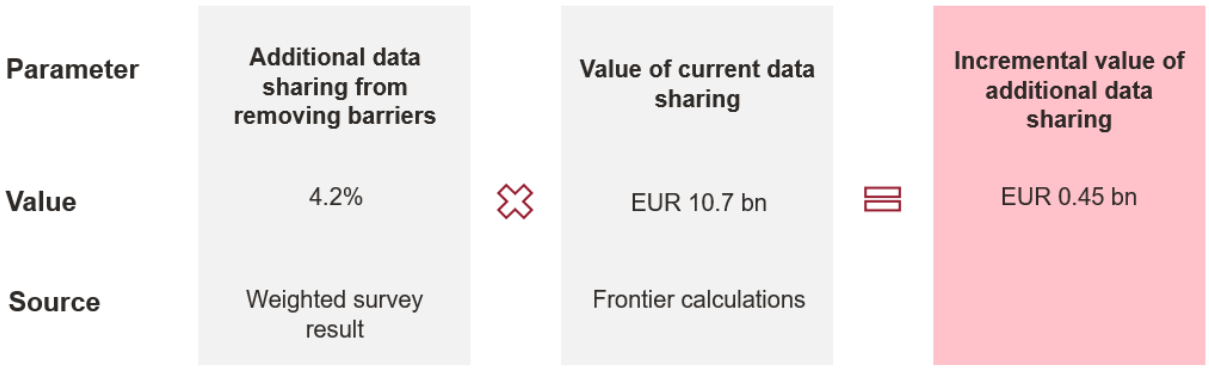
[82] This is our weighted average percentage increase, where we weighted responses by our survey sampling weights.

4.2.1 The value of removing barriers for current sharers

Our survey asked businesses that currently share patient data between EU/non-EU geographies (current sharers) to estimate the additional patient data sharing between EU/non-EU geographies that their businesses would undertake if barriers to international patient data flows were removed. Our sample of current sharers reported that they would increase patient data sharing between EU/non-EU geographies by 4.2% on average if their most important barriers to international patient data flows were removed.

We converted the additional data sharing into a value estimate by combining the percentage change figure with the current value of EU/non-EU patient data sharing. Figure 22 below summarises our calculations.

Figure 22 Summary of calculations – incremental value related to current sharers



Source: Frontier Economics

We multiplied our 4.2% parameter against our estimate for the €10.7 billion current value of international patient data sharing. This calculation implicitly assumes that a given percentage increase in data sharing leads to an equal percentage increase in the benefits of that data sharing, i.e. we assume that the 4.2% increase in data sharing translates into a 4.2% increase in the value of international patient data sharing. This is very much a simplifying assumption intended to provide a high-level assessment of the potential order of magnitude of benefits from additional sharing. In practice, the related benefits could be much lower or higher than 4.2%. Consider the example of data on patients with rare disease and imagine there are two rich datasets on this disease. One of the datasets is collected and held in an EU country (for example, Denmark) and one in a non-EU country (for example, Canada). A healthcare organisation would like to do research on this data but currently it has to analyse the two datasets separately. Being able to share this data and analyse a joint dataset that includes both patients based in Denmark and patients based in Canada could mean that:

- The organisation can do the same analysis it has done previously, but this now provides richer insights thanks to greater scale and diversity of data (proportional increase in value);
- The organisation can now undertake new and more effective types of analysis. For example, this may be the case if only by merging the two datasets the scale of the data becomes sufficient to disentangle different factors of interest (more than proportional increase in value); or
- The organisation can do the same analysis on a larger dataset, but the insights it draws do not change substantially (less than proportional increase in value).

As a result of our calculations, by extending our estimates of the current value of patient data sharing, we estimate that additional data sharing undertaken by current sharers could generate an additional **€0.45 billion per year** in value to the EU27. It is important to note that this figure is not a comprehensive estimate of the impact of removing barriers to patient data sharing as it does not include all the benefits of removing such barriers (from, for example, reduced administrative costs for organisations that share patient data) nor any of the potential costs from additional sharing.

4.2.2 The value of removing barriers for first-time sharers

Our survey asked businesses that currently use patient data but do not share it between EU/non-EU geographies whether they would begin to share patient data between EU/non-EU geographies if barriers to international patient data flows were removed. Businesses that would do so are named 'first-time sharers'.

Our survey found that 51 additional businesses using patient data would be first-time sharers. Therefore our results indicate that for every EU healthcare business (with international activities) that currently shares patient data between EU/non-EU geographies, there is another EU healthcare business that would start sharing patient data internationally if barriers were removed.[83]

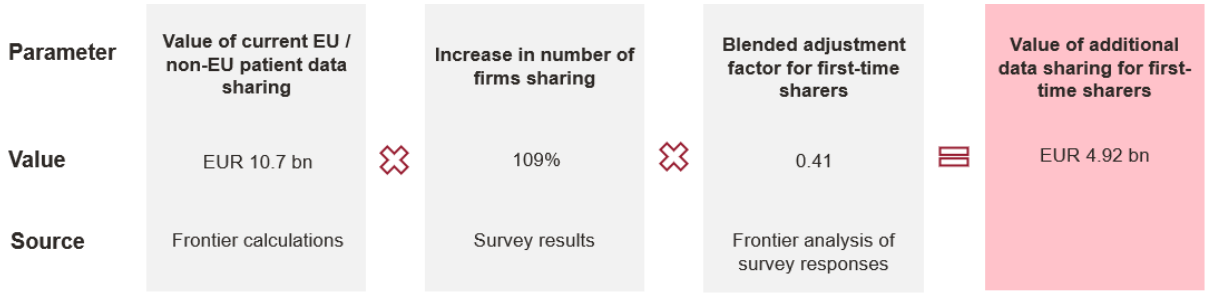
On the face of it, this could indicate that the value of data sharing could double if current barriers to sharing were removed. However, the value of additional data sharing by each first-time sharer could be different (lower or higher) than the value of data sharing generated by each current sharer.

Indeed, we observed that the first-time sharers in our sample tend to be smaller businesses and are less likely to be involved in clinical trials. As a result, we consider that it is best to assume that the benefit of international patient data sharing per first-time sharer is lower than the benefit per current sharer. We apply scaling factors that are specific to each impact

[83] The exact figure is 1.09, calculated as 51 first time sharers divided by 47 current sharers.

channel to reflect these differences between first-time sharers and current sharers. Figure 23 summarises our calculations.

Figure 23 Summary of calculations – incremental value to first-time sharers



Source: Frontier Economics

First, we took the current value of patient data flows between EU/non-EU geographies, estimated at €10.7 billion.

Then we applied evidence from the survey on the percentage increase in the number of businesses that share patient data between EU/non-EU geographies, which was 109%.[84]

We then accounted for the fact that the benefits of data sharing may not increase proportionally with the number of data sharing companies. We used an adjustment factor that reflects the differences between current data sharers and first-time data sharers.[85]

Finally, we multiplied these inputs together, as shown in Figure 23, to estimate the total first-time sharers' incremental value of data sharing as **€4.9 billion per year** to the EU27 if existing barriers to patient data sharing between EU/non-EU geographies were removed.

4.3 Overall impact and discussion

Figure 24 summarises our estimates of the incremental value related to removing existing barriers to patient data flows between EU/non-EU geographies. Our modelling finds that the annual benefits of data sharing identified in section 3 would increase by **€5.4 billion** if these barriers were removed. This is an increase of around 50% compared to our estimate of the annual current value of patient data sharing between EU/non-EU geographies. These benefits would arise as a result of companies starting to share data within a five-year period.

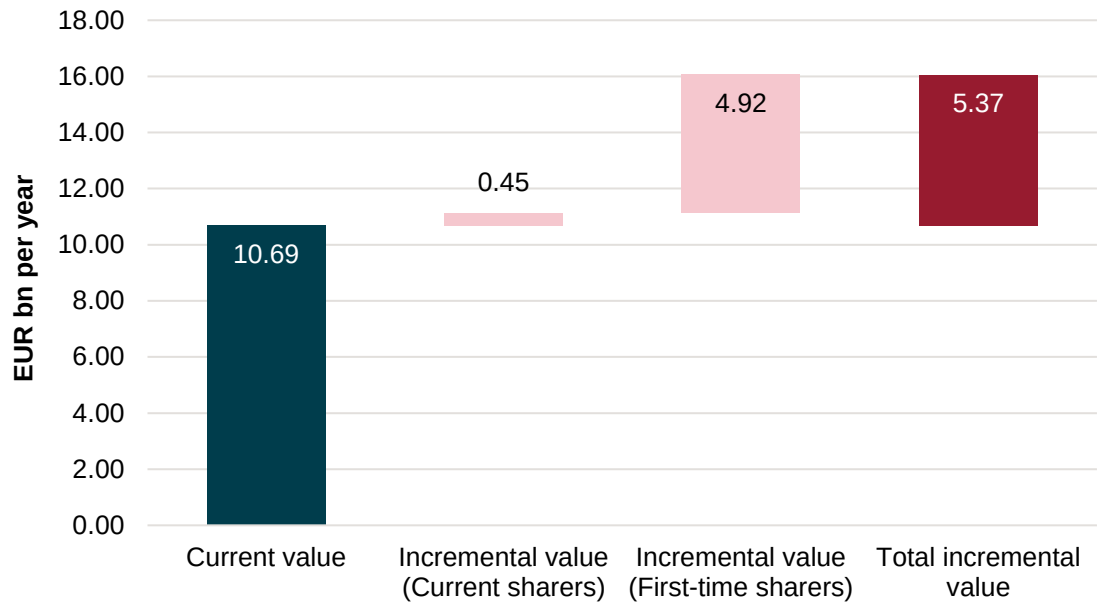
Realising this incremental value would not result in standards being lowered for the protection of patient data. Rather, it would refine aspects of existing data sharing infrastructure and

84 Calculated as 51 first-time sharers divided by 47 current sharers.

85 For example, each first-time sharer earned 48% of the turnover of the average current sharer. We applied adjustment factors in each of our impact channels, with a blended weighted average adjustment factor across all channels being 0.41.

regulations (e.g. the interpretation and implementation of GDPR, amongst others), which businesses identified as barriers to sharing patient data between EU and non-EU locations.

Figure 24 Incremental value of EU / non-EU patient data sharing



The primary reason for the large amount of incremental value is that a large number of businesses would start sharing patient data between EU/non-EU geographies (€4.9 billion) if existing barriers to sharing patient data between EU/non-EU were removed. These businesses are expected to generate significantly more incremental value than current sharers, who already generate value from international patient data flows.

However, the €0.45 billion incremental value generated through additional data sharing by current sharers also represents a significant value opportunity, representing 4% of the current value of international patient data flows.

Due to the significant uncertainty in some of the inputs used in the modelling, there is uncertainty in the values estimated above. We consider that our headline findings are conservative as we do not include the second-round indirect benefits in our value estimates. We also use conservative inputs, assuming that the turnover per firm and investment in research per firm of first-time sharers is significantly lower than current sharers.

On the other hand, our estimates for the incremental value generated are dependent on all key barriers for all firms in our sample being removed. It may not be possible to remove all barriers at the same time and, if a subset of barriers were removed instead, then it is likely that a smaller amount of incremental value would be generated.

In the round, we consider that our methodology and findings are reasonable, but further research would be useful to generate more precise estimates of the potential benefits from removing or mitigating current barriers to patient data sharing between the EU and other geographies.

5 Conclusions

This study provides new qualitative and quantitative evidence on the role and value of patient data sharing between the EU and non-EU geographies. We find that these data flows generate significant benefits through improved patient health, increased productivity in the healthcare sector and wider societal benefits from additional health research.

We also found that these benefits could increase by around 50% if current barriers to data sharing were removed, primarily as a result of new enterprises, mostly SMEs, starting to share data internationally for the first time.

The evidence we gathered suggests that the following actions could help in achieving these additional benefits:

- Providing guidance to healthcare organisations on what constitutes sufficient anonymisation of personal data under GDPR;
- Cross-border collaboration to align interpretations of GDPR requirements in a health context, to limit variation between countries and institutions; and
- Minimising uncertainty over the processes required for data sharing between the EU and certain jurisdictions, chiefly the USA.

To the best of our knowledge, there is a relatively limited evidence base on the role of international health data flows. Therefore, there are opportunities for further research, including:

- Gathering additional evidence on the extent of data sharing undertaken in EU member states that were not included in our survey, particularly those that joined the EU after 2004;
- Building on our modelling of the value of removing barriers to data sharing, which could involve gathering additional evidence on what specific activities could be undertaken in the absence of those barriers, and the value of those activities;
- Gathering additional evidence on data flows from EU public sector and academic organisations;
- Identifying and valuing international datasets that are or could be built through international data sharing; and
- Investigating the role of international data flows in enabling or hindering the development and deployment of technologies and solutions not considered explicitly in this study including, for example, the use of artificial intelligence systems.

Annex A – Further detail on survey

The business survey performs a critical role in estimating the current and incremental value of cross-border patient data flows as it provides the required inputs for the modelling (i.e. percentage change in outcomes and other qualitative information). The survey aimed at gathering evidence on health-related business activities and how European companies could be impacted by hypothetical restrictions on sharing patient data between EU and non-EU locations.

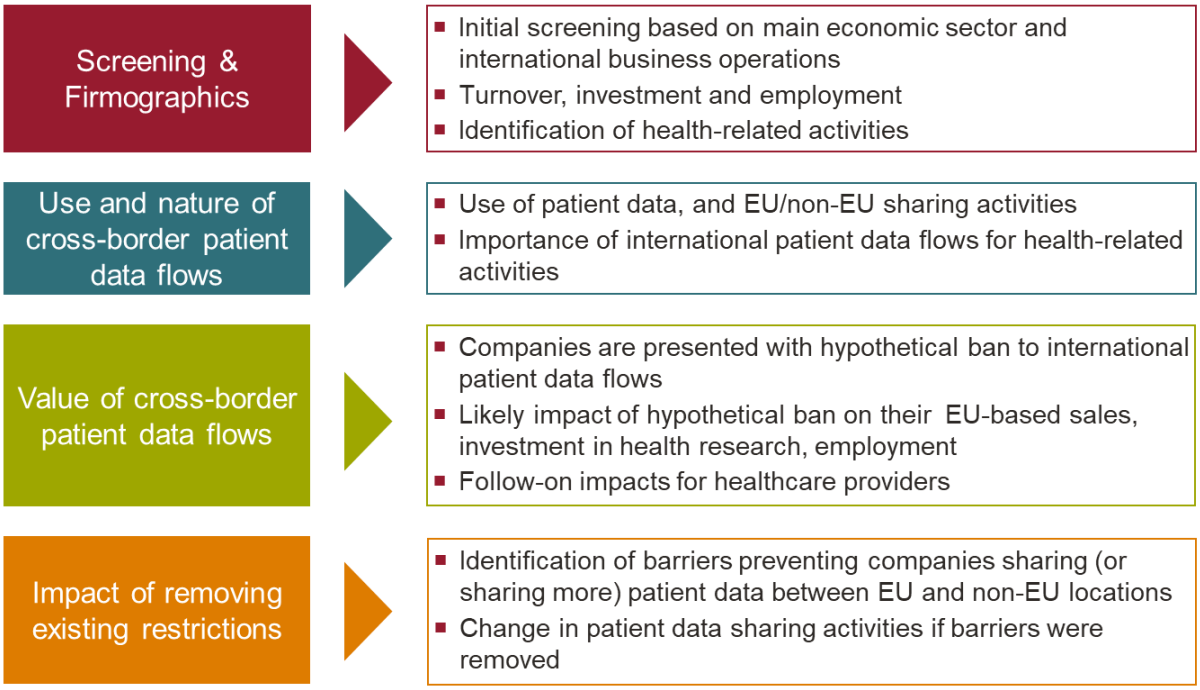
To keep the scope of our primary data collection manageable, as it is very challenging to identify and engage with organisations that share patient data across borders, we collected responses from businesses with international operations[86] located in eight EU countries: Austria, Belgium, France, Germany, Italy, Netherlands, Spain and Sweden. The companies were selected from five economic sub-sectors within the healthcare sector:

- Manufacture of basic pharmaceutical products and pharmaceutical preparations
- Manufacture of irradiation, electromedical and electrotherapeutic equipment
- Wholesale of pharmaceutical goods
- Scientific research and development
- Human health activities.

The questionnaire was developed by Frontier Economics in collaboration with Kantar Public Belgium, and it was structured around four main themes: firmographics (e.g. economic sector, employment, investment and health-related activities); use and nature of cross-border patient data flows; impact of hypothetical ban; and impact of removing existing restrictions.

86 Organisations with offices in more than one country, and/or organisations that sell their products/services abroad.

Figure 55 Summary of survey questions



Source: Frontier Economics

A survey pilot was conducted between 6th and 13th June 2023 to test a first version of the questionnaire (i.e. cognitive testing) through ten in-depth interviews prior to launching the survey fieldwork to ensure that respondents understood and felt they could answer our questions. The final version of our questionnaire was adapted based on the feedback received during this process.

The main fieldwork took place between 28th June and 24th July. Due to the difficulty of identifying target companies, the companies had to be screened at the point of recruitment to classify them based on their main economic sector and to confirm whether they performed international operations and shared patient data between EU and non-EU countries.

The survey was conducted via telephone (CATI) and was addressed at higher-level management such as C-level executives and directors as well as personnel working directly or indirectly with health data (i.e. data protection officers, data compliance officers, managers with responsibilities for data-related business functions, etc.).

Overall, the survey aimed at achieving 200 interviews among companies within the sample frame. Orbis database and Crunchbase were used to identify companies that worked in the health sector in the selected countries. Orbis is a private company database with more than 448 million private companies and Crunchbase provides information about private and public companies, particularly early-stage start-ups and tech organisations. More than 21,000 telephone numbers were dialled as part of the fieldwork.

A breakdown of the sample frame and interviews conducted by country is presented in Table 2. From the 200 companies that completed the sample, 47 were identified as currently sharing patient data between EU and non-EU countries.

Table 2 Distribution of sample frame and interviews completed by country

Country	Sample frame	Telephone numbers dialled	Interviewees completed
Austria	2,298	1,727	6
Belgium	2,928	2,224	12
France	105,213	3,949	23
Germany	26,680	3,531	22
Italy	18,599	3,366	24
Netherlands	5,142	1,487	13
Spain	18,814	1,661	37
Sweden	11,599	3,281	63
Total	**191,273**	**21,226**	**200**

Source: Business survey

The respondents were screened at the point of recruitment based on the sector in which their company operated. An additional screening question was based on whether their company shared patient data between EU and non-EU countries, as these were the main target of the survey. Companies that did not share patient data across borders were re-directed to another set of questions.

Annex B Our modelling calculations for estimating the value of EU/non-EU patient data flows 'as is'

We assessed the current value of cross-border patient data flows between EU and non-EU locations by asking survey respondents (i.e. European businesses active in the healthcare sector[87] with international activities) who share patient data to compare two states of the world:

1. The current 'factual' state where businesses use patient data and share it between EU and non-EU locations, with associated benefits to EU businesses, patients and hospitals; and
2. A hypothetical 'counterfactual' state where a hypothetical ban is imposed on cross-border patient data sharing between EU and non-EU locations, with follow-on impacts on EU business, patients and hospitals.

As it is important to properly define the relevant 'counterfactual' state, we provided additional information to survey respondents to form a consistent view of the implications of the ban on their health-related activities: the hypothetical ban is bilateral (i.e. it applies to patient data shared in both directions), it will come into effect immediately, it will last five years, and there is no way for businesses to mitigate its effects (e.g. consent mechanism, secure systems).

We chose to present survey respondents with a hypothetical scenario because we expected that they would not be able to answer more direct questions (e.g. 'how many more patients can receive personalised medicine treatments thanks to international data sharing?' or 'what is the value of international data sharing to your organisation?'). Therefore we provided them with a 'counterfactual' scenario to make the questions more concrete and easier to answer.

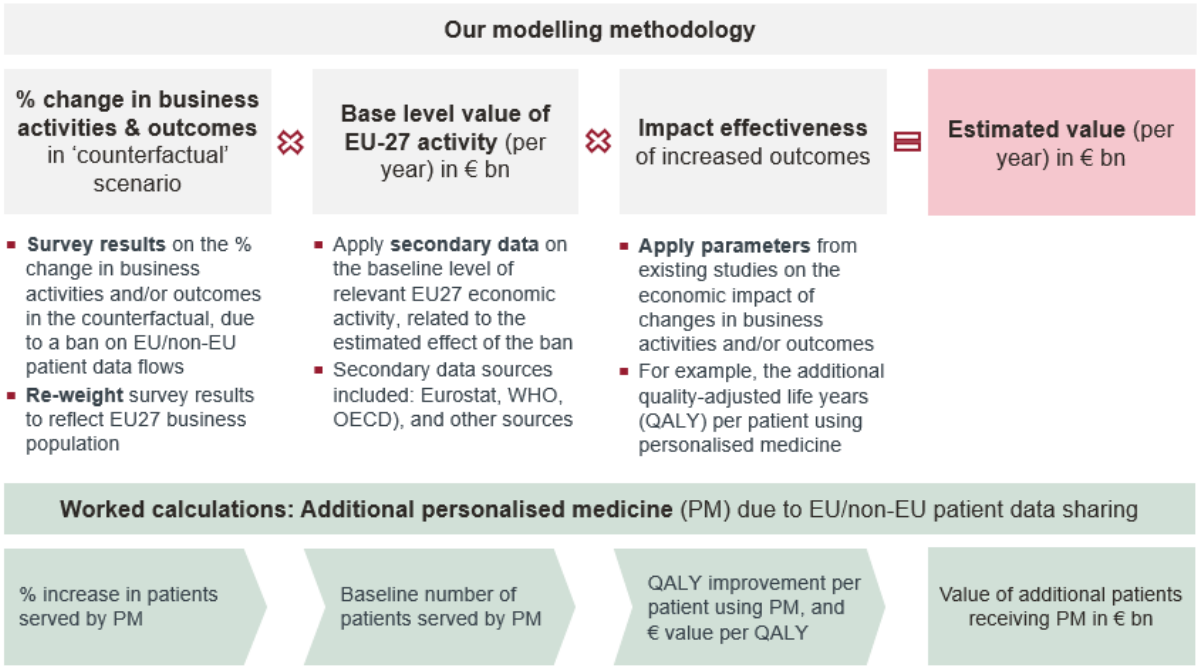
We implemented a process of 'cognitive testing' to test our survey approach through ten in-depth interviews prior to launching the survey fieldwork to ensure that respondents understood and felt they could answer our questions. The final version of our questionnaire was adapted based on the feedback received during this process.

In today's environment, this hypothetical ban is not realistic, but setting this extreme scenario was useful for survey respondents to put the role of international patient data flows into perspective. As the hypothetical ban applies to all patient data sharing, the difference in healthcare business, patient and hospital outcomes – measured in monetary value terms – between this 'factual' and 'counterfactual' of the world provides an estimation of the current value of cross-border patient data sharing for the EU.

87 We defined the healthcare sector as including the following industry codes (NACE codes): manufacture of basic pharmaceutical products and pharmaceutical preparations; manufacture of irradiation, electromedical and electrotherapeutic equipment; wholesale of pharmaceutical goods; scientific research and development (related to health); human health activities.

At a high level, our method for estimating the difference in outcomes – and therefore in monetary value terms – between these two states of the world is split into three stages.

Figure 66 Modelling methodology & worked calculations



Source: Frontier Economics

Worked example: personalised medicine

To illustrate our modelling method, Figure 26 provides a worked example which assesses the impact of increasing delivery of personalised medicine services on patient outcomes. As the figure shows, stage 1 requires estimating the contribution of patient data sharing between EU and non-EU locations to the 'outcome' of interest (e.g. increased patients served by delivery of personalised medicine).

As there is limited evidence on this effect, we relied on information provided by our business survey. In particular, we gathered information on whether our sample would experience a reduction in patients served by personalised medicine as a result of the hypothetical ban, expressed as a percentage change in the outcome of interest. We take this result as a proxy of the additional patients that are served due to cross-border patient data sharing.

In stage 2, we used secondary data on EU27-level health outcomes from different sources, including the European Commission, World Health Organization and the Institute of Cancer Research, to define the base scenario (i.e. current 'factual' state where businesses use patient data and share it between EU and non-EU locations). This allowed us to express the percentage change in outcomes from the first stage in numerical terms (e.g. number of patients served by personalised medicine).

As part of stage 3, we applied evidence from the literature on the relationship between health-related activities impacted by cross-border patient data sharing (e.g. personalised medicine) and impacts (e.g. QALY improvement per patient from personalised medicine). Multiplying the numeric change in EU27-level outcomes due to the hypothetical ban with statistics on the impact effectiveness of health-related activities generates estimates of the direct impact of cross-border patient data flows on health outcomes.

Finally, in stage 4, we expressed the impacts of cross-border patient data flows in monetary values using commonly used conversion figures from secondary sources like CORDIS (e.g. value per QALY). We therefore converted any improvement in health outcomes to a euro value.

We did not attempt to reflect all possible ways in which patient data sharing can generate value to EU27 businesses, patients and hospitals. We focused on modelling the impact of patient data sharing between EU27 and non-EU27 locations through six main impact channels identified from existing evidence and experts interviews and that were quantifiable with the data available. These channels were:

- Impact on patient outcomes through additional clinical trials
- Impact on clinical trial costs
- Impact of personalised medicine on patient health
- Impact on business productivity
- Impact on health research
- Impact on costs for healthcare providers (hospitals).

The next sections describe the 'counterfactual' survey questions that are most relevant for our modelling and then the specific methodology applied for estimating the value of each impact channel.

B.1 Survey questions related to the impact of the 'counterfactual'

As mentioned above, the first stage in our modelling method was to assess the impact of patient data sharing activities on our outcomes of interest. To achieve this, we asked survey respondents that currently share patient data between EU and non-EU locations to estimate the impact of the hypothetical ban on EU/non-EU patient data sharing on a set of performance indicators linked to their health-related activities (e.g. personalised medicine, clinical trials), as well as follow-on impacts for European patients and hospitals.

In particular, we asked survey respondents the following:

- What would be the effect of the ban on the organisation's core market or healthcare service over the next five years?
- For those that answered that the ban would affect their organisation, we asked whether, on average, the ban would be more likely to increase, decrease or have no impact on three annual EU-level key business indicators: employment, annual investment in health research and annual revenue from sales.
- We asked those companies that perform personalised medicine, research or clinical trials and that answered that the ban would affect their organisation whether the ban would affect the number of patients being served, number of clinical trials, cost of clinical trials and investment in health research.
- Finally, we asked survey respondents about follow-on effects of the ban on hospitals and, in particular, on the cost per patient entering care, patient re-admission and operational efficiency.

For each question, we provided respondents with a scale to assess these effects quantitatively. To estimate the percentage change in the outcomes of interest we assigned each scale a mid-point value. We then calculated the percentage average weighted by the percentage of businesses choosing each scale. As an example, we present the scales, assigned mid-point values and percentage of business in Table 3. Based on these values, the percentage change in outcome would be 2.4%.

Table 3 Assigning percentage values to survey responses

Scale	Assigned mid-point value	% business (example)
No impact/no effect of ban	0%	10%
A slight decrease (1-10%)	5%	30%
A moderate decrease (11-30%)	20%	40%
A significant decrease (31%-50%)	40%	15%
A severe decrease (more than 50%)	75%	5%

Source: Frontier Economics

Note: For those companies that answered that they would cease operations in the EU, we assumed a 100% effect.

B.2 Re-weighting survey sample results to reflect the EU27 business population

Sample weighting is an important part of the first phase of our modelling. Our business survey responses provide a percentage change figure for various business activities and outcomes

as a result of the 'counterfactual' ban, estimated as the average percentage change across all businesses that responded to the relevant survey questions. However, only 47 businesses shared patient data between EU/non-EU locations in our survey sample. It was therefore important to ensure that any of our survey estimates used in our modelling reflect the underlying population (i.e. European businesses active in the healthcare sector[88] with international activities) as closely as possible.

To do this, we used sampling weights, which are adjustment factors applied to each observation in the data to account for under-/over-representation of particular groups in the sample. It is intended to compensate for the selection of specific companies with different chances of being part of the sample or participating in a survey. This implies acknowledging that some observations may contribute more (or less) to the calculation of population estimates (e.g. percentage reduction of health research due to hypothetical ban).

An observation with a small probability of selection into the sample but with a relatively large presence in the population is considered as more important than an observation with a large probability of selection but a relatively small presence in the population. Weights (w_i) are therefore inversely proportional to the probability of being sampled (p_i) or the ratio between the proportion of companies in each sub-sector in Europe and the proportion of companies in each sub-sector in our sample:

$$w_i = \frac{1}{p_i} = \frac{\%\ population}{\%\ sample}$$

The characteristics of firms in our sample were compared with the overall population of businesses in the EU healthcare sector (using EC/Eurostat data[89]) to check the representativeness of the sample. We found that the composition of our sample reflected the broader business population in terms of firm size. However, our sample differs somewhat from the population of EU healthcare businesses in terms of sub-sector composition.

In order to account for the under-/over-representation of certain sub-sectors in our sample, we adjusted survey results (i.e. percentage change in outcomes) using sub-sector weights as presented in Table 4.

88 We defined the healthcare sector as including the following industry codes (NACE codes): manufacture of basic pharmaceutical products and pharmaceutical preparations; manufacture of irradiation, electromedical and electrotherapeutic equipment; wholesale of pharmaceutical goods; scientific research and development (related to health); human health activities.

89 EC/Eurostat - Annual enterprise statistics by size class

Table 4 Sampling weights by health sub-sector

Sub-sector	% Population EU27	% Sample	Weights
Manufacture of basic pharmaceutical products and preparations	1%	5%	0.26
Manufacture of irradiation, electromedical and electrotherapeutic equipment	1%	3%	0.21
Wholesale of pharmaceutical goods	14%	11%	1.22
Scientific research and development	5%	22%	0.21
Human health activities	80%	59%	1.36

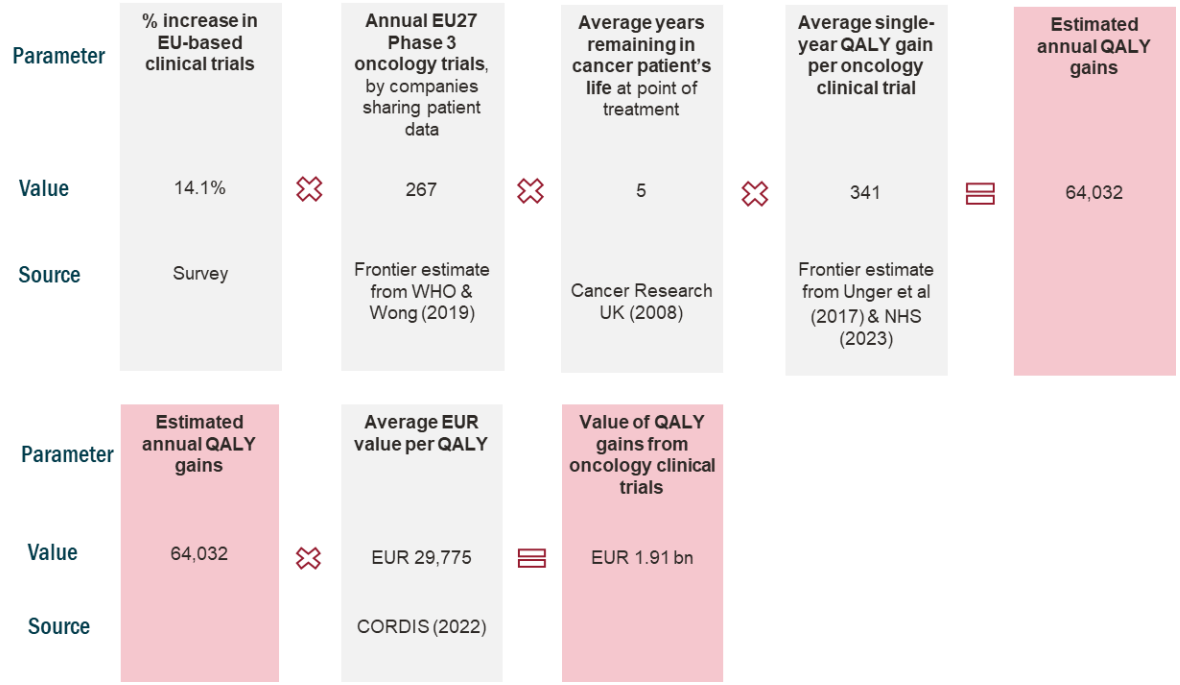
Source: Business survey and Eurostat

As an example, businesses in our sample that shared patient data between EU/non-EU locations reported a 4.9% reduction in sales as a result of the 'counterfactual' ban. However, after applying sampling weights to reflect the over-/under-representation of health sub-sectors, this impact increased to 6.1%.

B.3 Impact on patient health through additional clinical trials

We estimated the impact of EU/non-EU patient data sharing on patient health through enabling the delivery of additional clinical trials. Figure 27 summarises our modelling methodology.

Figure 27 Impact on patient outcomes through additional clinical trials – worked calculations



Source: Frontier Economics

Percentage changes in outcomes

The first step in estimating the current value of cross-border patient data sharing through additional clinical trials was to understand the impact of the hypothetical ban on the number of EU-based clinical trials for businesses that currently perform clinical trials and share patient data across borders.

Our survey identified 28 businesses that deliver clinical trials and, of these, 14 businesses also share patient data between EU/non-EU locations. These businesses were presented with the hypothetical ban, as presented in Annex B.1.

Businesses were presented with the following options and asked to select the likeliest band for the annual impact of the hypothetical ban on the number of EU-based clinical trials that they operate.

1. No increase
2. Slight increase (1-10%)
3. Moderate increase (11-30%)
4. Significant increase (31-50%)
5. Severe increase (more than 50%)

As per our approach described in Annex B.1 Table 3, we converted these responses to percentage change figures by assigning a value of 0% to option 1) ('No increase'), the mid-point percentage in the range for options 2) to 4), and then a value of 75% for option 5).

On average, these respondents indicated that the hypothetical ban would reduce the number of clinical trials they undertake by **14.1%**. Therefore, we assumed that these businesses have delivered an additional 14.1% of clinical trials due to their current patient data sharing activities.

Numerical changes in EU27-level outcomes

Second, we converted the percentage change in the number of clinical trials to an absolute increase in the number of EU27 clinical trials. We focused on Phase 3 clinical trials, as trials that are reasonably advanced. We also focused on oncology-related trials as the best available evidence on impact effectiveness from the literature related to clinical trial benefits for cancer patients.

According to WHO's Global Observatory on Health R&D, between 2019 and 2021 there was an annual average number of 1,607 Phase 3 oncology clinical trials active in EU27 countries. These related to clinical trials on any type of cancer, carcinomas, lymphoma, leukaemia, neoplasms and sarcomas, excluding benign conditions. By applying a scaling factor of 0.63, we refined the number of clinical trials to only those performed by EU clinical trial businesses with international activities that share patient data between EU/non-EU locations.

We calculated this 0.63 scaling factor as the proportion of clinical trial research value related to exporters (66%[90]), multiplied by the proportion of clinical trial research value for those firms that share patient data between EU/non-EU geographies (96%[91]). We therefore estimate that an annual average number of 1,014[92] Phase 3 oncology trials active in EU27 countries are performed on an ongoing basis by EU-based businesses with international activities that also share patient data between EU/non-EU locations.

90 We calculated the 66% figure using data from our survey responses from businesses active in clinical trials. We combined the break-down of clinical trial research value by firm size (large 87%, medium 0%, small 13%) with data from Eurostat on the proportion of exporters, by firm size (large 74%, medium 51%, small 6%). Our estimates for the proportion of exporters by firm size were taken from the EU27 aggregate level for 2018. This is because 2018 was the latest year with the full set of available data, and because the proportion of exporters for several health sector NACE codes, notably 'Human Health Activities', was not available from Eurostat.

91 We calculated the 96% figure using data from our survey responses from businesses active in clinical trials. Clinical trial businesses in our survey that also share patient data between EU/non-EU locations invested €37.4 million in health research annually, and clinical trial businesses that do not share patient data between EU/non-EU locations invested €1.5 million in health research annually.

92 Calculated as 1,607 x 0.63.

We divided the 1,014 annual trials by the median duration of a Phase 3 trial (3.8 years[93]), to estimate that **267** of these trials are due to finish in any given year.

Impact effectiveness on outcomes

Third, we applied estimates on the impact of cancer clinical trials on patient health. We started by using evidence from Unger, LeBlanc & Blanke (2017)[94], who found that the annual average life-year gain per cancer clinical trial was 5,710 life years per year of benefit among all cancer patients receiving treatment in the USA.

We calculated the life-year benefit of a given EU27 oncology trial by adjusting this estimate in three ways:

- New cancer patients as a percentage of current cancer patients (WHO's Global Cancer Observatory): 14%;
- Proportion of successful oncology clinical trials in Phase 3 (Unger, LeBlanc & Blanke, 2017): 36%; and
- EU cancer population as a percentage of US cancer population (WHO's Global Cancer Observatory): 160%.

We found that the annual average life-year gain per oncology clinical trial in Phase 3 on EU new cancer patients is 459 life years gained. We converted this value into quality-adjusted life years (QALY) by applying the NHS's conversion score of 0.74 based on the UK's Cancer Quality of Life Survey. Therefore, we estimated that the annual QALY gain per EU27 Phase 3 oncology clinical trial for new cancer patients is **341 QALY**.

This figure relates to a single year of benefit of the treatment(i.e. it assumes that EU27 annual new cancer patients benefit by 341 QALY for one year following the treatment). We applied evidence from Cancer Research UK that the average number of years remaining in a cancer patient's life at the point of treatment is **five years**. Therefore, we calculated a 1,703 QALY gain per trial over the course of a patient's expected treatment lifetime.

We multiplied this QALY gain by the expected number of additional trials due to patient data sharing between EU/non-EU locations, calculated as 37.6 additional trials completed per year on average.[95] Therefore, we estimate that additional completed EU27 Phase 3 oncology trials as a result of international patient data sharing deliver **64,032 QALY gains** expected over the course of the lifetime for annual newly diagnosed EU27 cancer patients.

93 Wong C.H., Siah K.W., Lo A.W. (2019). Estimation of clinical trial success rates and related parameters. Biostatistics, April 1, 20(2): 273-286.

94 https://pubmed.ncbi.nlm.nih.gov/28586789/

95 Calculated as 267 trials x 14.1%.

Conversion to monetary value

Finally, to convert these QALY gains to monetary value, we applied estimates from CORDIS on the euro value per QALY, which is between €22,000 and €79,000 with a central estimate of €29,775. We obtained that EU/non-EU data flows increase EU patient health by **€1.1 to €6.3 billion** for newly diagnosed EU cancer patients, with our central estimate being **€1.91 billion**.

Our range is based on two adjustments to our central calculation: (1) we adjusted the survey result by +/-25% to reflect uncertainty about whether our sample result is representative of the effect for the broader population of EU businesses, and (2) we applied a range of euro values for a QALY from CORDIS, with a lower bound value of €22,683 and an upper bound value of €78,871.

Our central estimate is also conservative for a number of reasons:

- Patient data sharing could unlock additional value through clinical trials beyond oncology.
- While we focus on benefits to new cancer patients, evidence suggests that the prevalence of cancer in Europe is increasing over time.
- Due to the emergence of new technologies, the success rate of clinical trials may increase over time.
- There is significant uncertainty over the size of our figures for the patient benefits of EU/non-EU patient data sharing as our survey results for clinical trials were generated from a particularly small sample of businesses. Nonetheless, even our lower-bound estimate for EU/non-EU data flows that enable the delivery of clinical trials generates large health benefits for EU patients.

Table 5 summarises the inputs and sources we used to estimate the impact on patient outcomes through additional clinical trials.

Table 5 Impact on patient outcomes through additional clinical trials – inputs and sources

Indicator	Value	Year	Source
% change in the number of clinical trials due to the hypothetical ban	14.1%	2023	Business survey
Annual average number of active oncology clinical trials (Phase 3) in the EU27	1,607	2019-2021	WHO's Global Observatory on Health R&D

Indicator	Value	Year	Source
Median duration of clinical trials in Phase 3	3.8 years	2000-2015	Wong, Siah & Lo (2019)
% annual investment by businesses performing clinical trials with international activities abroad and sharing patient data across borders	63%	2023	Business survey
Annual average life-year gain per clinical trial	5,710	1982-2015	Unger, LeBlanc & Blanke (2017)
Number of prevalent cancer cases in the EU	13,496,763	2015-2020	WHO's Global Cancer Observatory
Number of new cancer cases in EU	4,398,443	2020	WHO's Global Cancer Observatory
% successful oncology clinical trials in Phase 3	35.5%	2000-2015	Wong, Siah & Lo (2019)
Number of new cancer cases in the USA	2,281,658	2020	WHO's Global Cancer Observatory
Life years gained to QALY conversion ratio – cancer patients	0.74	2023	NHS - UK's Cancer Quality of Life Survey
Average number of years remaining in a cancer patient's life at the point of treatment (all cancers)	5 years	2010-2011	Cancer Research UK
Average value per QALY in the EU (EUR)	€22,683 - €78,871 with €29,775 as central estimate	2020	EC/CORDIS

Source: Various

B.4 Impact on clinical trial costs

We estimated the impact of EU/non-EU patient data sharing on reducing EU27 clinical trial cost per trial. Figure 28 summarises our modelling methodology.

Figure 28 Impact on clinincal trial costs – worked calculations

Parameter	% reduction in cost per EU-based trial		Average cost per trial		Number of EU-based clinical trials by EU organisations sharing patient data		Trial cost savings per year by EU organisations sharing patient data
Value	10.8%	⊠	EUR 2.2 mn	⊠	5,497	=	EUR 1.31 bn
Source	Survey		Frontier estimate based on survey, Eurostat (2020) and Efpia (2023)		WHO – Global Observatory on Health R&D (2021)		

Source: Frontier Economics

Percentage changes in outcomes

We used the same approach outlined in Annex B.3., where we presented the hypothetical ban to the 14 businesses that actively deliver clinical trials and share patient data internationally, and then asked them about the impact of the ban. In this case, we asked these businesses about the impact of the ban on their cost per EU-based clinical trial. We presented the same percentage impact bands as described in Annex B.3.

On average, our sample of businesses that perform clinical trials and share patient data across borders indicated that the hypothetical ban would increase their cost per trial by 10.8%. Therefore, conversely, we assume that these businesses have experienced a reduced cost per trial of 10.8% due to their current use of EU/non-EU patient data flows.

Numerical changes in EU27-level outcomes

We calculated the average annual R&D expenditure per clinical trial in the EU27 as the estimated annual R&D investment in health in the EU27 allocated to clinical trials, divided by the number of EU27 clinical trials, all for businesses with international activities that share patient data between EU and non-EU locations.

We estimated that 20.0% of EU27 business R&D expenditure is related to health, based on the EU Industrial R&D Investment Scoreboard,[96] which provides data on annual health research by the top 1,000 businesses that spend on R&D in EU27 as well as the sector of focus of these businesses. Eurostat provides data that EU27 business enterprise expenditure on R&D was €218.3 million in 2021. Combining these inputs, we estimate that healthcare businesses spend €43.6 million on R&D every year, on average.

96 Calculated as €40.5 billion health-related spending (on 'pharmaceuticals & biotechnology' or 'health care equipment & services') out of €202.9 billion total R&D spending.

We applied an estimate from EFPIA (2023) that Phase 1, 2 and 3 clinical trials account for 44% of all pharmaceutical R&D spending. We also applied the scaling factor of 0.63[97] to refine our estimate to only consider R&D spending by clinical trial businesses with international activities and which share patient data internationally. Therefore, we estimate that EU27 clinical trial businesses with international activities that share patient data internationally invest €12.1 million in business R&D every year, on average.

Separately, we collected data on the average ongoing number of EU-based clinical trials from WHO's Global Observatory on Health R&D. In particular, between 2019 and 2021, there was an annual average number of 8,711 clinical trials based in EU27 countries. This number includes both interventional and observational clinical trials, regardless of development stage and type of disease. We also applied our scaling factor of 0.63 to estimate that there are 5,497 EU-based clinical trials every year performed by businesses that share patient data between EU/non-EU locations.

Therefore, we estimate that every year businesses spend an average **€2.2 million per EU27 clinical trial**. For simplicity, we used a point estimate on the average cost per clinical trial. However, clinical trial costs are likely to vary substantially depending on the trial phase, number of sites, number of patients involved, etc. It is possible that international patient data sharing is more likely to take place in larger trials and, therefore, our cost per clinical trial figure may be underestimated.

Conversion to monetary value

Combining the €2.2 million average annual R&D expenditure per EU27 clinical trial with the 10.8% cost savings experienced by businesses due to their current use of EU/non-EU patient data sharing, we calculated that EU/non-EU patient data flows generate economic value of €1.0 billion to €1.6 billion per year to the EU27 through reduced clinical trial costs, with a 'central' estimate of €1.31 billion per year.

Our range is based on adjusting the survey result by +/-25% to reflect uncertainty about whether our sample result is representative of the effect for the broader population of EU businesses.

Table 6 summarises the inputs and sources we used to estimate the impact on the cost of clinical trials.

97 Calculated per the method in Annex B.3.

Table 6 Impact on clinical trial costs – inputs and sources

Indicator	Value	Year	Source
% change in clinical trial costs	10.8%	2023	Business survey
EU27-level annual gross R&D expenditure in health	€43.6 billion	2022	Eurostat & EU Industrial R&D Investment Scoreboard
% annual investment by businesses performing clinical trials with international activities abroad and sharing patient data across borders	63%	2023	Business survey
% R&D investment in pharma allocated to clinical trials	44%	2022	EFPIA
Annual average number of clinical trials in the EU27 (all phases, all diseases)	8,711	2019-2021	WHO's Global Observatory on Health R&D

Source: Various

B.5 Impact of personalised medicine on patient health

We estimated the impact of EU/non-EU patient data sharing on increasing delivery of personalised medicine services, with follow-on benefits to patient health. Figure 29 summarises our modelling methodology.

Figure 29 Impact of personalised medicine on patient health – worked calculations

Parameter	% Increase patients served by personalised medicine		Annual new EU27 cancer patients served by personalised medicine		QALY improvement per patient from personalised medicine		Average EUR value per QALY	=	Estimated annual QALY impact through personalised medicine
Value	8.8%	⊠	850,000	⊠	0.03	⊠	EUR 29,775	=	EUR 0.11 bn
Source	Survey		Frontier estimate based on WHO (2020) & Institute for Cancer Research (2019)		Vellekoop et al (2022)		CORDIS (2022)		

Source: Frontier Economics

Percentage changes in outcomes

We used the same approach based around the impact of a hypothetical ban as for the other impact channels presented above in Annex B.

Our survey identified 16 businesses which actively deliver personalised medicine services or develop personalised medicine products, and which share patient data between EU/non-EU locations. These businesses were presented with the hypothetical ban, as outlined in Annex B.1.

In this case, we asked these businesses about the impact of the ban on their annual sales. We presented the same percentage impact bands as described in Annex B.3.

Our sample of companies that provide personalised medicine and share patient data between EU and non-EU countries indicates that, on average, the hypothetical ban would reduce sales by **8.8%**. Therefore, we assume that these businesses are expected to be able to serve 8.8% additional patients as a result of their EU and non-EU patient data flows.

Ideally, our survey would have collected evidence on the percentage reduction in personalised medicine provision by directly asking these personalised medicine businesses about the reduction in personalised medicine treatments. However, as the sample of businesses that responded to this question was particularly low, we instead used the percentage reduction in sales due to the hypothetical ban for businesses engaged in personalised medicine activities. This is a reasonable proxy as the volume of sales would be strongly associated with the number of patients served.

Numerical changes in EU27-level outcomes

We estimated the total number of EU27 patients currently served by personalised medicine based on proxies of intensity of demand and likely uptake of personalised medicine. The best source of evidence we could identify that provided evidence on the take-up of personalised medicine was a study by the UK Institute of Cancer Research which estimated that 32% of cancer patients in their sample currently receive precision treatments (i.e. targeted therapy and/or immunotherapy). As this study's results relate to cancer patients only, we focused our modelling on this sub-group of patients.

We applied the 32% take-up rate to the annual number of new cancer patients in Europe provided by WHO's Global Cancer Observatory (4.4 million), converted to an EU27 figure based on the EU27 proportion of Europe's population in 2023,[98] to obtain a total of **850,443** annual new EU27 cancer patients receiving personalised medicine treatments. Combining this value with percentage changes in sales from companies that perform personalised medicine activities (8.8%), we calculated that 74,414 additional newly diagnosed cancer patients receive personalised medicine every year due to current cross-border patient data sharing activities between EU and non-EU locations.

Impact effectiveness on outcomes

We translated this result in terms of QALY gains based on a recent study by Vellekoop et al (2022)[99] which conducted a systematic review of 128 economic evaluations of 279 personalised medicine interventions – most of which were cancer treatments. The authors indicate that these treatments result in lifetime QALY gains of between **0.03** (50th percentile) and 0.16 (75th percentile) relative to their non-personalised medicine comparators.

Combining this result with the number of additional personalised medicine patients that are served in the EU due to current cross-border patient data sharing activities between EU and non-EU locations, we calculated that the additional delivery of personalised medicine is associated with QALY gains of 2,232 for annual newly diagnosed cancer patients.

Conversion to monetary value

Finally, to convert the 3,695 QALY gains for the EU, we applied estimates from CORDIS on the euro value per QALY which is set at **€29,775**. We obtained that EU/non-EU data flows increase EU patient health by **€40 million to €1.2 billion** for newly diagnosed EU cancer patients, with our central estimate being **€70 million**.

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98 We estimated that in 2023 the EU27 population (448 billion) was approximately 60% of the Europe population (742 billion, underlying source is United Nations statistics).

99 Vellekoop H., Versteegh M., Huygens S., Corro Ramos I., Szilberhorn L., Zelei T., Nagy B., Tsiachristas A., Koleva-Kolarova R., Wordsworth S., Rutten-van Mölken M.; HEcoPerMed consortium (2022). The net benefit of personalized medicine: A systematic literature review and regression analysis. Value Health, Aug 25(8):1428-1438.

Our range is calculated based on three adjustments to our central estimate: (1) we adjust the survey result by +/-25% to reflect uncertainty about whether our sample result is representative of the effect for the broader population of EU businesses, (2) we use lower- and upper-bound values of QALY from CORDIS ranging from €22,683 to €78,871, and (3) we use central and upper estimated QALY gains from personalised medicine ranging from 0.03 to 0.16 from the analysis by Vellekoop et al (2022).

This range is not symmetric because the upper-bound estimate also includes the 75th percentile value of QALY gains (0.16) from personalised medicine treatment, compared to the 50th percentile figure used in the central estimate and lower bound. The upper-bound monetary value of QALY (€79,000) is also considerably higher than the central estimate value (€29,775).

More generally, it is not surprising that we estimate a wide range for the potential impact through personalised medicine treatments. First, there is significant heterogeneity in the QALY effect of personalised medicine depending on the type of cancer type and the stage of the illness (disease classification), purpose of intervention (e.g. disease and/or genetic marker screening, gaining information on prognosis, identifying patients with adverse drug reaction, identifying non-responders to treatment) and the type of treatment (i.e. pharmaceutical, non-pharmaceutical or a combination of both, gene therapy). Second, as personalised medicine as a field is still developing, even if some treatments are already used regularly, we would expect greater uncertainty over the size of its potential health benefits.

We also consider that our central estimate of €70 million is conservative and likely to increase in the future:

- We focus on benefits to newly diagnosed cancer patients using data relating to the figure for 2020, but the evidence suggests that the prevalence of cancer in the EU27 is increasing over time.[100]
- As with other innovative products and services, personalised medicine treatments are still in their infancy. Their full benefits may take decades to materialise as the treatment matures and becomes used more widely. Our chosen central QALY effect parameter is 0.03, which is at the lower end of the results.

Table 7 summarises the inputs and sources we used to estimate the impact of personalised medicine on patient health.

[100] According to the European Cancer Information System, the number of people being diagnosed with cancer by 2040 in EU and EFTA countries is estimated to increase by 21%.

Table 7 Impact of personalised medicine on patient health – inputs and sources

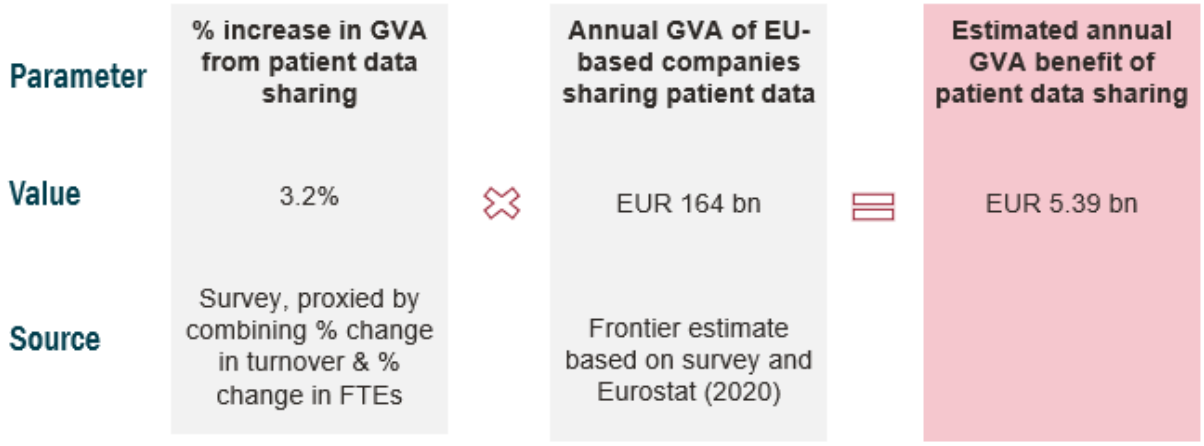
Indicator	Value	Year	Source
% change in sales by companies that perform personalised medicine activities	8.8%	2023	Business survey
% of cancer patients currently receiving precision treatments	32%	2019	UK Institute of Cancer Research
Number of new cancer cases in EU	4,398,443	2020	WHO's Global Cancer Observatory
Annual QALY gains from personalised medicine treatments	0.03-0.16	2009-2019	Vellekoop et al (2022)
Average value per QALY in the EU (EUR)	€22,683 - €78,871 with €29,775 as central estimate	2020	EC/CORDIS

Source: Various

B.6 Impact on business productivity

We estimated the impact of EU/non-EU patient data sharing on business productivity. Figure 0 summarises our modelling methodology.

Figure 30 Impact on business productivity – worked calculations



Source: Frontier Economics

Percentage changes in outcomes

We used the same approach based around the impact of a hypothetical ban as for the other impact channels presented above in Annex B.

Our survey asked businesses to estimate the impact of a hypothetical ban on EU/non-EU patient data sharing on their annual turnover from sales of health products and services and annual number of FTEs in the five-year period after the ban came into effect. On average, respondents that share patient data between EU/non-EU locations responded that the hypothetical ban would reduce their annual sales by 6.1% on average and reduce their number of FTEs by 2.8% on average.

This means that, on average, the hypothetical ban would reduce turnover per employee by **3.2%**.[101] We considered this to be a reasonable proxy for the percentage change in business productivity that would occur as a result of the ban. Therefore, conversely, EU/non-EU patient data flows support 3.2% of business productivity for those businesses that share patient data internationally.

Numerical changes in EU27-level outcomes

We estimated the total production value of the relevant business population (i.e. all healthcare businesses in the EU27 which have international activities and share patient data between EU and non-EU locations), measured as GVA.

First, we collected Eurostat data on the total EU27 GVA for our five health sub-sectors presented in Table 8.

[101] Calculated as a reduction of (((1+6.1%)/(1+2.8%)) – 1).

Table 8 EU27 GVA by health sub-sector

	GVA value (2020, €bn)
Manufacture of basic pharmaceutical products & preparations	€94.6
Manufacture of irradiation, electromedical & electrotherapeutic equipment	€24.5[102]
Wholesale of pharmaceutical goods	€76.5
Scientific research & development (health)	€22.7
Human health activities	€646.6
	€864.8

Source: *Eurostat*

Note: *Scientific research & development figure for health is estimated by multiplying the total scientific research & development value of €113.8bn by the proportion of EU27 business R&D related to Health (20.0%).*

We estimated that the five health sub-sectors generate €865 billion of GVA per year for the EU27.

We then re-scaled the GVA affected by EU/non-EU patient data sharing by combining total health sector GVA by business size with estimates for the proportion of businesses that are exporters and the proportion of businesses that share patient data between EU/non-EU geographies, for each business size group. Table 9 presents our calculations.

Table 9 Estimated number of relevant businesses by firm size

Firm size	% health sector GVA, by business size (Eurostat)[103]	% businesses with international activities (Eurostat)	% businesses that share patient data (Survey)	Estimated GVA (€bn) of affected businesses
Large	49%	74%	50%	155.7
Medium	8%	51%	23%	8.4
Small/micro	43%	6%	21%	0.4
Total				**164.5**

Source: *Eurostat and business survey*

102 This figure was not available from Eurostat. Instead, we took the annual turnover for 2021 from Eurostat and multiplied it against the GVA:turnover ratio for all other sectors (0.84).

103 We estimated this break-down across all health sub-sectors using Eurostat data on GVA for different NACE sectors, by business size.

Note: Percentage businesses with international activities proxied by percentage of exporters.

We calculated EU27 health sector GVA related to international business activities and EU/non-EU patient data sharing as **€164.5 billion per year.**

We combined this GVA figure with the 3.2% increase in business productivity to estimate that EU/non-EU patient data sharing increases EU-based business GVA by **€4.0 billion to €6.7 billion per year**, with a central estimate of **€5.39 billion per year.**

Our range is based on adjusting the survey result by +/-25% to reflect uncertainty about whether our sample result is representative of the effect for the broader population of EU businesses.

B.7 Impact on health research

Figure 31 summarises our approach to estimating the impact of cross-border patient data sharing between EU and non-EU locations on health research.

Figure 71 Impact on health research – worked calculations

Parameter	% increase in investment in health research		Annual investment in health research by companies sharing patient data		% health research that **does not** relate to **oncology clinical trials**		Average benefit-cost ratio of medical research	=	Annual value of benefits from additional health research
Value	3.6%	⊠	EUR 16.8 bn	⊠	84%	⊠	3.9	=	EUR 2.02 bn
Source	Survey		Frontier estimate based on survey and Eurostat data (2020)		Frontier estimate using Eurostat & WHO data		KPMG (2018)		

Source: Frontier Economics

Percentage changes in outcomes

We used the same approach based around the impact of a hypothetical ban as for the other impact channels presented above in Annex B.

From our survey, we identified that 45 businesses currently share patient data between EU and non-EU locations and invest in health research. On average, these respondents indicated that the hypothetical ban would reduce their annual investment in health research by **3.6%**. Therefore, we assume that these businesses have experienced an increase in health research by 3.6% due to sharing patient data between EU and non-EU locations.

It is worth mentioning that this figure represents the net impact of EU/non-EU patient data sharing on health research, as there are businesses in our sample which indicated that their EU-based investment would actually increase as a result of the hypothetical ban. This could

be the result of a greater cost of doing business in the EU rather than increased incentives to invest.

Numerical changes in EU27-level outcomes

Next, we calculated annual EU27 investment in health research. As per our approach in Annex B.4, we first calculated total annual EU27 business investment in health R&D as €43.6 million.

We applied a scaling factor of 0.39 to refine our estimate to consider only health research performed by EU27 businesses with international activities and that share patient data internationally. We calculated the 0.39 scaling factor as the proportion of business research value related to exporters (51%[104]), multiplied by the proportion of research value for those firms that share patient data between EU/non-EU geographies (75%[105]). Therefore, we estimate annual EU27 investment in health research by businesses with international activities that share patient data between EU/non-EU locations as **€16.8 billion**.

Combining this figure with the 3.6% increase in health research, we calculated that the total amount of additional investment in EU27-based health research attributable to patient data flows between EU and non-EU locations is €0.61 billion.

However, this figure includes additional investment in EU-based oncology clinical trials, which we separately included in our modelling of health benefits from additional EU-based clinical trials. We therefore removed the proportion of EU27 annual investment in oncology trials from our €0.61 billion figure to avoid double-counting their research benefits.

We estimated that EU-based oncology clinical trials account for approximately 16% of annual EU investment in health research, calculated by multiplying the proportion of EU health R&D related to biotechnology (84%[106]) by the proportion of EU-based trials that are oncology trials (18%[107]). We therefore removed 16% of the additional €0.61 billion research per year to estimate additional net investment in health research of €0.52 billion per year.

104 We calculated the 51% figure using data from our business survey responses. We combined the break-down of research value by firm size (large 67%, medium 0%, small 32%) with data from Eurostat on the proportion of exporters, by firm size (large 74%, medium 51%, small 6%). Our estimates for the proportion of exporters by firm size were taken from the EU27 aggregate level for 2018. This is because 2018 was the latest year with the full set of available data, and because the proportion of exporters for several health sector NACE codes, notably 'human health activities', was not available from Eurostat.

105 We calculated the 75% figure using data from our business survey responses. Businesses in our survey that also share patient data between EU/non-EU locations invested €38.9 million in health research annually, and businesses that do not share patient data between EU/non-EU locations invested €52.0 million in health research annually.

106 Using data from the 2022 EU Industrial R&D Scoreboard, we estimated that 84% of EU27 health research of the top 1,000 EU businesses that invest in R&D related to 'pharmaceutical & biotechnology' (€34.1 billion), compared to 'health care equipment & services' (€6.4 billion).

107 Using data from WHO, we estimated that 18% of the average number of EU27 clinical trials from 2019-2021 (8,711) related to oncology (1,607).

Impact effectiveness on outcomes and conversion to monetary value

The best recent source of evidence we could identify on the economic return from investment in health research was a report by KPMG (2018) which analysed the economic contribution of medical research to the Australian economy. It estimated a benefit-cost ratio of investment in medical research as 3.9 as a baseline estimate, with a lower-bound estimate of 1.8 and an upper-bound estimate of 4.2.

Combining this ratio with the additional investment in health unlocked by cross-border patient data sharing, we obtained that EU/non-EU patient data flows generate economic value of €0.7 billion to €2.7 billion per year to the EU27 through increased EU-based investment in health research, with a 'central' estimate of **€2.02 billion** per year. This estimate includes 'health gains' in the form of improved patient disability-adjusted life years (DALY)[108] and reduced public healthcare costs, as well as wider economic benefits in the form of worker productivity impacts and health business commercialisation.

Our range is based on adjusting the survey result by +/-25% to reflect uncertainty about whether our sample result is representative of the effect for the broader population of EU businesses and the range of KPMG (2018) benefit-cost ratios of 1.8 to 4.2.

Table 10 summarises the inputs and sources we used to estimate the impact on health research.

[108] Both DALY and QALY are measures of population health used to quantify the burden of a disease or injury. A DALY is a measure of years in perfect health lost (years lost due to premature mortality and years lived in disability/disease) while QALY is a measure of the number of years lived in perfect health gained. Normally QALYs are based on the effect of specific interventions while DALYs are based on the burden of a disease in the population.

Table 10 Impact on health research – inputs and sources

Indicator	Value	Year	Source
% change in annual investment in health research	3.6%	2023	Business survey
EU27-level annual gross R&D expenditure in health	€43.6 billion	2022	Eurostat & EU Industrial R&D Investment Scoreboard
% annual investment by businesses with international activities abroad and that share patient data across borders	38.6%	2023	Business survey
Economic return from investment in health research	1.8-3.9	1990-2004	KPMG (2018)

Source: Various

B.8 Impact on costs for healthcare providers

Figure 32 summarises our approach to estimating the impact of cross-border patient data sharing between EU and non-EU locations on EU hospital costs.

Figure 32 Impact on costs for healthcare providers – worked calculations

Source: Frontier Economics

Percentage changes in outcomes

We used the same approach based around the impact of a hypothetical ban as for the other impact channels presented above in Annex B.

More specifically, we asked those businesses that share patient data between EU and non-EU locations whether there would be a follow-on impact of the ban on the cost per patient for EU27 hospitals.

From our survey, these businesses estimated that the hypothetical ban is likely to increase the cost per patient entering healthcare by 1.8% on average. Therefore, we assume that European hospitals have experienced a reduction in costs of 1.8% due to international patient data sharing.

These estimates should be interpreted with caution because we are only looking at the 'per patient' effect and we do not attempt to quantify other effects (e.g. on operational efficiency). The overall impact of patient data sharing on hospital costs might therefore be different and could be higher or lower.

Numerical changes in EU27-level outcomes

Next, we applied the change in cost per patient to an estimate for the annual spending by EU27 hospitals that is related in some way to patient data sharing. This figure is not directly available from Eurostat, but we calculated a reasonable proxy using available data and a set of reasonable assumptions.

According to information provided by Eurostat, the annual hospital expenditure in the EU27 in 2020 was €547 billion. Eurostat did not provide a figure for 2021, but we applied the compound annual growth rate in EU27 hospital spending between 2015 and 2020 (4.2%) to estimate €570 billion of EU27 hospital spending in 2021.

We adjusted this figure by the percentage of hospital expenditure on activities that were likely to be related to patient data use, whether directly by hospitals or indirectly through development of treatment and/or diagnostic testing by suppliers. Table 11 shows which expenditure items are included in our calculation.

Unfortunately, Eurostat data on the expenditure of each of these 'patient data-intensive' items specifically by EU hospitals did not exist. Instead, we took the broader proportion of EU health spending related to these items and assumed that it was a suitable proxy for the proportion of EU hospital health spending on those items. We considered that this was a reasonable assumption in the absence of more granular data from Eurostat.

Table 11 EU27 healthcare expenditure, by item

Healthcare expenditure item	Healthcare expenditure (2020)	Reasoning for inclusion
Medical goods	€266.7 billion	Development and delivery of medical goods often uses patient data, for example in clinical trials once products are developed.
Preventive care (adjusted to exclude items)	€44.3 billion	Preventive care includes disease surveillance and detection which is likely to use patient data. We refined total preventive care (€49.8 billion) by excluding 'information & counselling programmes' and 'disaster & emergency response programmes', as these appear more closely related to the direct delivery of programmes which do not require use of patient data.
Ancillary services (adjusted to exclude patient transportation)	€50.3 billion	Ancillary services include laboratory and imaging services which both use analysis of patient data. We refined total ancillary services (€70.8 billion) by excluding patient transportation as an expenditure item, which is unlikely to use patient data.
Curative care (inpatient & day care only)	€330.0 billion	Curative care includes treatments and therapies provided with the aim of curing an illness or condition. Some of these treatments (e.g. personalised medicine) are likely to use patient data, either directly in the delivery of the treatment or through the treatment's development. We refined total curative care costs (€606.2 billion) to only those related to inpatient and day care (€330.0 billion) by excluding outpatient curative care, as we consider that the treatment for these patients is likely to be relatively more sophisticated on average, and therefore more likely to have used patient data.
Total	**€691.3 billion**	

Source: Eurostat

This estimate only relates to a subset of health expenditure items. We also excluded some expenditure items entirely: rehabilitative care (€41.4 billion), governance and health system financing and administration (€54.1 billion), and long-term care (€243.0 billion). We considered that these cost items were labour intensive, and therefore it is unlikely that a material proportion of expenditure in these items relates in some way to patient data. We also excluded other long-term care services (social care, €42.8 billion) and unknown health care services (€2.4 billion).[109]

In total, we estimate that €691.3 billion out of €1,463.2 billion EU27 healthcare expenditure in 2020[110] related to activities or treatments that would have relied upon patient data in some way, either in direct treatment delivery or through drug development. This is equivalent to 47% of total EU27 healthcare spending in 2020.

We applied the 47% estimate to our EU27 estimate of €570 billion hospital spending in 2021, to estimate that €270 billion of EU27 hospital spending related in some way to patient data use.

Next, we combined our €270 billion figure with the 1.8% reduction in costs experienced by hospitals due to their data sharing activities to estimate that EU/non-EU patient data sharing reduces EU hospital costs by €1.9 billion to €8.6 billion per year, with a central estimate of €4.9 billion per year. This range is the result of: (i) adjusting the survey result by +/-25% to reflect uncertainty about whether our sample result is representative of the true effect for the broader population, and (ii) adjusting the amount of EU health spending on curative care relating to patient data between 0% and 100% (lower and upper bounds), as we consider that there is more uncertainty over exactly what proportion of curative care uses relate to patient data use.

Table 12 summarises the inputs and sources we used to estimate the impact on costs for healthcare providers.

Table 12 Impact on hospital costs – inputs and sources

Indicator	Value	Year	Source
% change in cost per patient entering healthcare	1.8%	2023	Business survey

[109] Note that the totals across all EU27 healthcare expenditure items summed up to €1,377.2 billion, which is lower than the total EU27 healthcare expenditure figure of €1,463.2 billion in 2020. The discrepancy is due to the 'rehabilitative' and 'curative' care separate cost items summing up to a value lower than the combined 'rehabilitative and curative care' cost item, which fed into the €1463.2 billion figure. We did not use the combined figure, since our approach to assign curative care as including patient data and rehabilitative care as not including patient data required us to use separate cost items. For simplicity we assumed that the €86.0 billion difference did not relate to patient data.

[110] Statistics | Eurostat (europa.eu)

Indicator	Value	Year	Source
Annual hospital expenditure in the EU27	€547.7 billion	2020	Eurostat – Healthcare expenditure by provider
Annual hospital expenditure in the EU27	€446.5 billion	2015	Eurostat – Healthcare expenditure by provider
Compound annual growth rate in EU27 hospital expenditure	4.2%	2015-20	Frontier calculations using Eurostat data
% hospital expenditure allocated to 'patient data-intensive' uses	47%	2020	Frontier analysis of Eurostat data (central case)

Source: Various

Annex C Incremental value modelling methodology

Annex B describes our methodology for estimating the current value of patient data sharing between EU/non-EU locations. Our expert interviews[111] and business survey responses[112] also identified a range of barriers to patient data sharing between EU/non-EU locations. We also estimated the additional value that could be unlocked for the EU27 by removing these barriers to patient data sharing. Annex C describes our methodology for estimating this additional value in further detail.

First, precisely estimating the value of this potential additional data sharing is challenging because it depends on how the data would be used, and we do not know this from our survey data (and indeed many respondent organisations may not be able to fully anticipate the ways in which they would use data if barriers were removed).

However, we do estimate at a high level by how much the current benefits estimated in Annex B could increase if barriers to data sharing were removed. We do this by:

1. Assessing the potential impact of additional data sharing undertaken by 'current sharers', i.e. organisations that already share data, if barriers they face were removed; and
2. Assessing the potential impact of additional data sharing undertaken by 'first-time sharers', i.e. firms that currently do not share patient data.

For simplicity, we calculate the impact of removing barriers on the total value of benefits from patient data sharing identified in section 3 (i.e. the full €10.7 billion), without separating the impact on each channel (benefits of health research excluding clinical trials, cost savings on clinical trials, health benefits for patients from additional clinical trials and from increased access to personalised medicine, additional revenues for healthcare businesses).

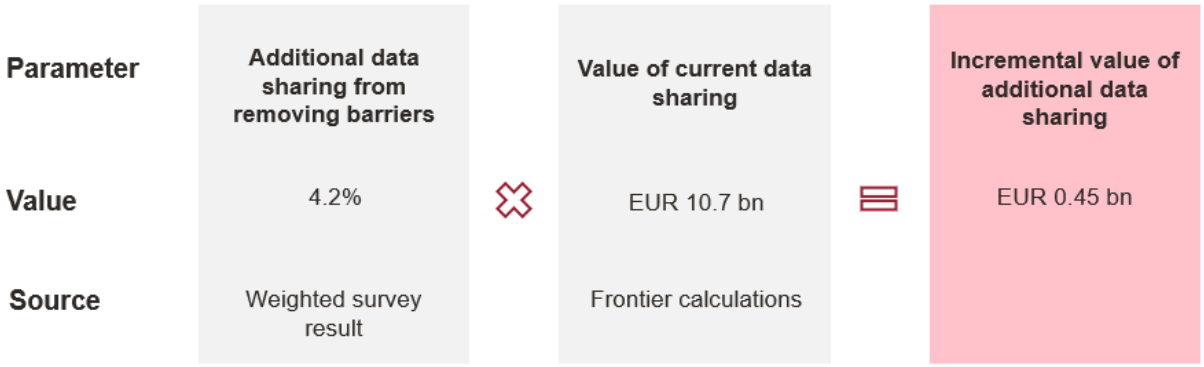
C.1 Impact of removing barriers for current sharers

Figure 33 summarises our approach to estimating the impact of removing barriers to patient data sharing between EU and non-EU locations for current sharers.

111 See section 2.6.

112 See Figure 19.

Figure 33 Impact on current sharers – worked calculations



Percentage change in data sharing

Our survey asked current sharers to identify the three most important barriers that restrict the degree to which they use EU/non-EU patient data flows from the following set of potential barriers:

1. Lack of adequacy decision between EU or non-EU countries
2. Complex or conflicting regulations (e.g. across EU GDPR, Adequacy Decisions, Data Governance Act, Data Act)
3. GDPR requirements being unclear (IF NECESSARY: e.g. threshold for ensuring non-identification of individuals, consent mechanisms)
4. Cost of complying with GDPR requirements (IF NECESSARY: e.g. requirements on localisation, data privacy, security or protection)
5. Lack of interoperability or data standards for health data
6. Patient data is not currently relevant for my business
7. Other

Our survey then told businesses to assume that these barriers were removed and asked them what the approximate percentage increase, if any, would be in their company's data-sharing activities between EU and non-EU locations in the following year. Businesses were presented with the following options and asked to select the likeliest band.

1. No increase
2. Slight increase (1-10%)
3. Moderate increase (11-30%)
4. Significant increase (31-50%)
5. Severe increase (more than 50%)
6. My business would start sharing patient data between EU and non-EU countries for the first time

As per our approach described in Annex B.1 Table 3, we converted these responses to percentage change figures by assigning a value of 0% to option 1) ('No increase'), the mid-point percentage in the range for options 2) to 4), and then a value of 75% for option 5).

Twenty-eight current sharer businesses responded to the question. We took the average percentage change values from their responses, excluding 'don't know' responses, and applied survey weights as per our current value methodology. Figure 21 in section 4.1.2. presents the full distribution of survey responses. After applying weights, we found that current sharers would increase their data sharing by 4.2% on average if the main barriers to sharing data were removed in the year following their removal.

Numerical changes in EU27-level outcomes

Next, we multiplied our 4.2% figure for additional data sharing against our estimate of the current value of EU/non-EU patient data flows (€10.7 billion). As a result, we estimated that additional data sharing undertaken by current sharers could generate an additional **€0.45 billion per year** in value to the EU27 by extending our estimates of the current value of patient data sharing.

This calculation implicitly assumes that a given percentage increase in data sharing leads to an equal percentage increase in the benefits of that data sharing, i.e. we assumed that the 4.2% increase in data sharing translated into a 4.2% increase in the value of international patient data sharing. This is very much a simplifying assumption intended to provide a high-level assessment of the potential order of magnitude of benefits from additional sharing. In practice, the related benefits could be much lower or higher than 4.2%.

C.2 Impact of removing barriers for first-time sharers

Our survey responses also found that a significant proportion of our sample use patient data but do not share it between EU/non-EU locations – 102 businesses out of our sample of 200. These businesses are also affected by barriers to international patient data sharing, but the nature of the impact is that the barriers restrict them from sharing patient data in the first place.

We also estimated the impact of removing barriers for this group of businesses. Figure 34 summarises our approach to estimating the impact of removing barriers to patient data sharing between EU and non-EU locations for first-time sharers.

Figure 34 Impact on first-time sharers – worked calculations

Parameter	Value of current EU / non-EU patient data sharing		Increase in number of firms sharing		Blended adjustment factor for 'first time sharers'		Value of additional data sharing for 'first time sharers'
Value	EUR 10.7 bn	⊠	109%	⊠	0.41	=	EUR 4.92 bn
Source	Frontier calculations		Survey results		Frontier analysis of survey responses		

Source: Frontier Economics

Percentage change in data sharing

Our methodology is based around the change in the number of businesses that share patient data between EU/non-EU locations and the additional value that is likely to be accrued per business as a result. The percentage increase in the number of firms that share patient data between EU/non-EU locations is therefore an important input to our calculations.

As explained above, 102 businesses in our sample use patient data but do not share it between EU/non-EU locations. Forty-seven businesses in our sample use patient data and do share it between EU/non-EU locations.

We asked these 102 businesses to identify the three most important barriers that restrict the degree to which they use EU/non-EU patient data flows from the same set of potential barriers presented in Annex C.1. As per our approach in Annex C.1, our survey then told businesses to assume that these barriers were removed and asked the 102 businesses whether their organisation would consider starting to access or share patient data between EU and non-EU locations for the first time in the next five years after their removal.

Fifty-one out of the 102 businesses answered 'yes' and, on that basis, we estimated that removing barriers to patient data sharing might lead to a 109% increase[113] in the number of businesses sharing patient data between EU/non-EU locations.

Numerical changes in EU27-level outcomes

We converted the percentage change in data sharing to a numerical change in EU27 value in two stages.

First, we multiplied our estimated current value of patient data flows between EU/non-EU geographies (€10.7 billion) by the 109% increase in the number of firms that share patient

[113] Calculated as the sample number of first time sharers (51) divided by the number of current sharers (47).

data internationally. This calculation implicitly assumes the same average value of data sharing per business for current sharer and first-time sharer businesses.

However, the benefits of data sharing may not increase proportionally with the number of data sharing companies. In particular, we identified that our sample of first-time sharer businesses were disproportionately more likely to be SMEs, with lower average annual turnover and investment in health research per business compared to our broader sample of current sharers. All else being the same, these differences would reduce the value of international patient data sharing per business, for first-time sharer businesses.

Second, we accounted for these differences by using a blended adjustment factor of 0.41, calculated based on the relative values of the annual turnover per FTE, annual investment in health research, the proportion of businesses active in clinical trials and the proportion of businesses that deliver personalised medicine in each group, as well as the contribution of each of these to the €10.7 billion current value estimate. The 0.41 adjustment factor means that we assumed that the annual euro value of international patient data sharing for first-time sharer businesses is 41% of the annual euro value for current sharer businesses.

We multiplied these inputs together, as shown in Figure 34, to estimate the additional value of data sharing to first-time sharers to be **€4.9 billion per year** to the EU27 following a period of up to five years after the removal of existing barriers to patient data sharing between EU/non-EU geographies.

Table 13 summarises the inputs and sources we used in our incremental value modelling.

Table 13 Incremental value – inputs and sources

Indicator	Value	Year	Source
% increase in data sharing by current sharers	4.2%	2023	Business survey
% increase in number of businesses that share patient data between EU/non-EU locations	109%	2023	Business survey
Blended adjustment factor reflecting differences between current sharer and first-time sharer businesses	0.41	2023	Frontier analysis of Business survey responses
Value of current EU/non-EU patient data sharing	€10.69 billion	2023	Frontier analysis