The importance of cross-border data flows

An economic assessment of restrictions on extra-EU data transfers

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I. Executive summary

The exchange of data is an increasingly important driver of the global economy, with cross-border data transfers, particularly between the EU and the US, at the centre of this growth. With the Schrems II decision, the Court of Justice of the European Union (CJEU) has raised questions about the mechanisms on which companies rely to provide a legal basis for extra-EU transfers of personal data.

In its Schrems II decision, the CJEU raised concerns that US law does not adequately protect Europeans’ privacy; on that basis, it invalidated the EU-US Privacy Shield Framework, with immediate effect. At the time, over 5,300 companies relied on the Privacy Shield as a legal basis to transfer personal data from the EU to the US.

The CJEU emphasized that standard contractual clauses (SCCs) are valid but subject to specific conditions and requirements. Interpretations of the Schrems II decision have since emerged that, if applied in practice, could potentially make certain companies’ reliance on SCCs substantially more difficult.

At the time of writing, the precise policy and economic impact of the Schrems II decision is uncertain, with provisional guidance provided by the European Data Protection Board (EDPB) and the European Commission (EC) continuously evolving. Initial guidance from the EDPB suggests that the sharing of personal data may become substantially more burdensome between entities within the European Economic Area (EEA) and outside the EEA (third countries). Some commentators have stated that a strict interpretation and application of the EDPB’s initial guidance could increase transaction costs so substantially as to function, in effect, as a de facto ban on critical data transfers. The possibility of a ban, along with the uncertainty surrounding the interpretation of the Schrems II decision, has caused significant concern for businesses around the world (including many based in the EU) that depend on having reliable and lawful means to transfer Europeans’ personal data from the EU to third countries. If the outcome of the current policy debate over the scope of the Schrems II decision leads to either a de jure ban on transferring personal data outside the EEA or, by substantially increasing transaction costs, a de facto ban, then the economic impact on the European economy could be significant.

The precise implications of the Schrems II decision are yet to be determined, and in this report, we do not take a stance on the appropriate interpretation of the Schrems II decision. Instead, we illustrate the importance of extra-EU transfers of personal data by quantifying the potential economic impact that may result if companies in certain sectors could no longer conduct these transfers. We examine four case studies, each in a different industry, and use them to illustrate the substantial damage to the EU economy and consumers that may arise if extra-EU transfers of personal data are no longer possible in these industries.

For clarity, the assumptions used in the quantification are not an interpretation of the Schrems II judgment or its likely policy implications, do not represent the views of the authors or of Facebook as to the correct interpretation of the Schrems II decision, and are made solely for the purposes of the economic modelling of the quantification presented in this report.
Telecommunications

Seamless global telecommunications services are becoming increasingly important as consumers rely heavily on mobile connectivity. Currently, EU consumers can continue to use their phones in “roaming” mode while traveling abroad, which involves exchanging personal data (including metadata) between EU and third country telecommunications providers.

If telecommunications companies could not transfer personal data to third countries, it could undermine the ability of EU consumers to use roaming while traveling. With roughly 95 million trips taken by EU travellers outside the EU annually, if these travellers had to purchase pay-as-you-go (PAYG) service plans at their destination in order to stay connected, this would cost them between €1 billion and €4.5 billion annually. EU travellers may also incur additional costs, including search costs (e.g. finding networks and PAYG plans) and transaction costs (e.g. notifying contacts of their new phone numbers).

Examining the potential impact of this limitation from the network providers’ perspective, based on recent outbound roaming revenue figures, EU mobile network providers could lose €2.5 billion in revenue annually if EU consumers’ roaming functionalities were disabled. To offset this revenue loss, EU mobile network providers may increase home network service prices, reduce the quality of their service, or reduce spend on investments in an attempt to maintain profit margins, thus potentially harming even those EU customers who do not travel.
Digital payments and commerce

Digital payment transactions, which underlie the entire modern economy, involve the transaction of personal data (e.g. bank account information). A cessation of personal data transmission to third countries could substantially disrupt the payment services provided to EU consumers and stifle the economy.

If EU consumers are prohibited from providing their personal information (e.g. payment data and address) to merchants with acquiring banks based in third countries, given the difficulty of merchants switching to acquiring banks in the EEA, this would result in an effective ban on e-commerce from outside the EEA. Based on current levels of card payments sent from the EU to non-EU countries, this could result in a lost transaction value of €128 million per day immediately, and up to €4.2 billion - €9.3 billion per year in the longer term.

If, instead, EU consumers are prohibited from providing their personal data to electronic communication service providers based in third countries, they may not be able to use those mobile/digital wallets that are owned by such companies (e.g. Apple with its Apple Pay product), even within the EU. Based on current levels of mobile/digital wallet activity in Europe, this could result in a lost transaction value of €497 million - €699 million per day immediately, and €172 billion per year in the longer term. Additionally, as mobile/digital wallets reduce the risk of card fraud relative to plastic cards, decreasing usage of mobile/digital wallets could lead to increased levels of fraud if European consumers switch their current mobile/digital wallet payments to card payments.

These effects could become more pronounced in the future due to both the increasing importance of digital payment solutions (further accelerated by the COVID-19 pandemic), and the potential long-term impacts on the competitive landscape in Europe, which would impact innovation and research and development (R&D).
Global services outsourcing

Global services outsourcing, in particular offshoring, has increased business efficiency and the productivity of European companies. Offshoring business services (e.g. information technology and contact centres) often involves the transfer of personal data (such as customer names and email addresses) from the EU to third countries.

If transferring personal data were not permitted to third countries, offshoring business services from Europe to popular outsourcing destinations (such as India) would no longer be possible. As a result, firms would need to bring these offshored jobs back (“back-shore”) into the EEA. Based on EU companies’ current outsourcing demand, we estimate that back-shoring all currently outsourced jobs would increase labour costs for EU businesses by €25.5 billion - €91.7 billion per year.

While back-shoring jobs may increase employment in certain European sectors, this relationship is not clearly established. Additionally, it is unclear whether any increase in employment would outweigh the negative effects of labour cost increases, including higher consumer prices, reduced service quality (e.g. reduced customer service hours), and decreased global competitiveness of European businesses.
Pharmaceutical research and development

International data sharing is increasingly important in pharmaceutical R&D, both to reduce costs and to improve patient outcomes. As many new R&D technologies require the aggregation of large databases containing personal (e.g. genomic and medical) information, restrictions on transferring personal data to third countries could result in decreased efficiency in drug development, leading to increased costs and reduced patient outcomes.

For instance, if sharing medical data with third countries had not been possible during the global coronavirus pandemic, the development of COVID-19 vaccines likely would have been delayed, prolonging the economic damage caused by the imposition of measures to control COVID-19. We estimate that each additional month of delay in the approval of the vaccine could have caused €70 billion in damage to the EU economy.

In a clinical trial context, if medical data collected from EU patients are not allowed to be exported to third countries, pharmaceutical companies will not be able to submit clinical evidence based on these data to regulatory agencies in third countries (including the US Food and Drug Administration) for authorization. In this case, pharmaceutical companies would likely relocate their clinical trial sites from the EU to third countries, in order to be able to rely on clinical trial data for submissions to a wider range of markets (including the US, the most lucrative market in the world). We estimate that such a relocation would lead to a reduction in spending on clinical trials in Europe by pharmaceutical companies of approximately €8.9 billion per year.

Finally, emerging technologies using linked genomic and health data have great potential to reduce costs during drug development. If personal data sharing is restricted, this could lessen the chances of saving as much as €1 billion per new drug developed. Moreover, limiting data access could hamper further patient benefits, such as by limiting the development of therapies for rare diseases and restricting the provision of personalized medicine.
II. Introduction

1. The exchange of data is becoming one of the key drivers of the global economy, with digitally enabled trade worth between $800 billion and $1.5 trillion globally in 2019. The relationship between the European Union (EU) and the United States (US) is at the core of this globalization paradigm, with the transatlantic region including almost all countries with the heaviest cross-border data flows worldwide. Additionally, the US and the EU account for nearly half of each other’s “digitally deliverable service exports”, making the EU the US’s largest digital trade partner.

2. With the EU’s introduction of the General Data Protection Regulation (GDPR) in 2016, Europe enacted the “toughest privacy and security law in the world”. The GDPR provides for levying fines reaching into the tens of millions of euros on companies who breach the laws concerning personal data, defined as “any information relating to an identified or identifiable natural person” (i.e. living individual), including name, home address, email address, identification card number, location data (e.g. collected by mobile phones), and “one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person”.

3. Under the GDPR, transfers of EU personal data to a third country must occur pursuant to a valid legal basis. Furthermore, the transferred personal data must be subject to adequate privacy protections - namely, the protections provided must be equivalent to those under EU law.

4. On 16 July 2020, the Court of Justice of the European Union (CJEU) issued its judgment on Case C-311/18, Data Protection Commissioner v Facebook Ireland and Maximilian Schrems (the so-called “Schrems II” decision), with potentially significant implications for international data transfers between countries within and outside the EU, including the US.

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5 The GDPR (679/2016/EU) was adopted in 2016, and organizations have been required to be compliant since May 2018. See GDPR.EU (2021), “What is GDPR, the EU’s new data protection law?”, available at https://gdpr.eu/what-is-gdpr/.
7 The European Commission specifies that, “[d]ifferent pieces of information, which collected together can lead to the identification of a particular person, also constitute personal data. Personal data that has been de-identified, encrypted or pseudonymised but can be used to re-identify a person remains personal data and falls within the scope of the GDPR”. See European Commission, “What is personal data?”, available at https://ec.europa.eu/info/law/law-topic/data-protection/reform/what-personal-data_en#:~:text=Personal%20data%20is%20any%20information,person%2C%20also%20constitute%20personal%20data.
5. In *Schrems II*, the CJEU reached a number of conclusions in relation to international data transfers, which we summarize below.\(^{10}\)

   a. First, the GDPR is applicable to international data transfers between economic operators established in EU Member States and those in third countries\(^{11}\) (i.e. countries outside the European Economic Area (EEA)).\(^{12}\)

   b. Second, when the personal data of EU consumers (i.e. persons in the EU)\(^{13}\) are transferred to a third country, it must be ensured that GDPR-level data protection is provided for by both the contractual clauses between the economic operators and the legal system of the third country.\(^{14}\)

   c. Third, the CJEU invalidated the adequacy of the protection provided by the EU-US Privacy Shield,\(^{15}\) a framework “designed by the U.S. Department of Commerce, and the European Commission […] to provide companies on both sides of the Atlantic with a mechanism to comply with data protection requirements when transferring personal data from the European Union […] to the United States in support of transatlantic commerce.”\(^{16}\) At the time of the CJEU’s invalidation, the Privacy Shield mechanism was relied upon by over 5,300 US companies, playing a large role in the estimated $7.1 trillion transatlantic economic relationship.\(^{17}\) The CJEU specifically highlighted US public authorities’ disproportionate interference with the fundamental rights of EU consumers through surveillance programs based on Section 702 of the Foreign Intelligence Surveillance Act (FISA 702)\(^{18}\) and on Executive Order 12333\(^{19}\) (EO 12333).\(^{20}\)

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\(^{11}\) As the GDPR applies to countries in the EU and the EEA, the term “third countries” refers to those outside of the EEA. See Baker, Alice (8 January 2020), “GDPR compliance and managing personal data internationally”, available at https://www.itgovernance.eu/blog/en/gdpr-compliance-and-managing-personal-data-internationally.

\(^{12}\) Schrems II, para. 203, bullet 1.

\(^{13}\) As the GDPR applies to natural persons regardless of their citizenship as long as they are subject to the offerings of goods and services within the EU, including services provided by companies located in the EU to consumers outside the EU, in this report we refer to all consumers (regardless of citizenship) as “EU consumers” (or “EU patients”). Lexology (20 June 2018), “Whose data is protected under the GDPR?”, available at www.lexology.com/library/detail.aspx?g=0dc9663d-ac3b-438e-adcd-1415a45f99ca#:~:text=Recital%2014%20of%20the%20GDPR,to%20any%20information%20concerning%20an.

\(^{14}\) Schrems II, para. 203, bullet 2.

\(^{15}\) Schrems II, para. 203, bullet 5, and Schrems II press release.


\(^{18}\) “Section 702 of the Foreign Intelligence Surveillance Act (FISA) is a statute that authorizes the collection, use, and dissemination of electronic communications content stored by U.S. internet service providers (such as Google, Facebook, and Microsoft) or traveling across the internet’s ‘backbone’ (with the compelled assistance of U.S. telecom providers such as AT&T and Verizon).” Center for Democracy & Technology (2017), “Section 702: What It Is & How It Works”, available at https://cdt.org/wp-content/uploads/2017/02/Section-702.pdf.

\(^{19}\) “E.O. 12333 allows the NSA to access data ‘in transit’ to the United States, by accessing underwater cables on the floor of the Atlantic, and to collect and retain such data before arriving in the United States and being subject there to the FISA”. Schrems II, para. 63.

\(^{20}\) See, e.g., Schrems II, para. 178.
Fourth, the CJEU confirmed the validity of “standard contractual clauses” (SCCs),21 while noting that their validity depends on the existence of effective mechanisms to ensure data protection “essentially equivalent” to that guaranteed by the GDPR. The CJEU pointed out the obligations on both the data exporter (i.e. the economic operators established in EU Member States) and the data importer (i.e. the recipient of the personal data in a third country) to verify and monitor the level of data protection, and to suspend data transfers where protection essentially equivalent to the GDPR cannot be guaranteed.22 The European Data Protection Board (EDPB) has since clarified that its interpretation is that these obligations also apply to onward transfers, such as to sub-processors of the personal data.23

6. How the condition of essential equivalence is to be assessed and assured by data controllers and processors in light of Schrems II is one of the key issues of interpretation that has arisen from the judgment. A universal interpretation has yet to emerge, as data protection authorities, legal scholars, and businesses are still debating the practical implications of the decision.24

7. The uncertainty surrounding the precise legal, policy, and economic impacts of the Schrems II decision has caused significant concern for businesses around the world (including many based in the EU) that depend on having reliable and lawful means to transfer Europeans’ personal data from the EU to third countries. It has also reinforced how integral these data transfers are to the operations of nearly every industry, and to the stability and growth of the EU economy.

8. While the EDPB has released provisional guidance25 on additional safeguards companies could adopt to satisfy the condition of essential equivalence with the GDPR, commentators have noted that the guidance suggests that the sharing of personal data may become substantially more burdensome for small organisations but also large ones making hundreds, if not thousands, of transfers. See Linklaters (16 July 2020), “The Schrems judgment – Transfer Impact Assessments for international data transfers?”. Major law firms have shared similar interpretations. According to Linklaters, a global law firm, what the Schrems II judgment requires is “in effect, a Transfer Impact Assessment (which) will be burdensome for small organisations but also large ones making hundreds, if not thousands, of transfers”. See Linklaters (16 July 2020), “The Schrems judgment – Transfer Impact Assessments for international data transfers?”, available at https://www.linklaters.com/en/insights/blogs/digilinks/2020/july/the-schrems-judgment. Another global law firm, Cleary Gottlieb, highlights that one inadvertent adverse consequence would be “discouraging the transfer of data to countries simply because their data protection


22 Schrems II, paras. 122-149.


9. In the remainder of this report, we have sought to illustrate the importance of extra-EU transfers of personal data by quantifying the economic impact that may result if companies in certain sectors could no longer conduct these transfers.

10. For the purposes of this illustrative economic analysis, we have made the following assumptions about the features of a hypothetical policy that would seek to restrict the transfer of personal data from the EU to third countries. For clarity, these assumptions are not an interpretation of the Schrems II judgment or its likely policy implications, and are made solely for the purposes of the economic modelling of the quantification presented in this report.

11. Our modelling assumptions can be summarized as follows.

   a. First, we assume that a hypothetical policy would expressly ban the transfer of personal data to third countries in the case of companies subject to FISA 702, such as electronic communication service providers (ECSPs).27 We refer to this as a “de jure” ban.

   b. Second, we assume that a hypothetical policy would introduce such high transaction and monitoring costs on companies (both in the EU and in third countries) wanting to transfer personal data that it would effectively act as a “de facto” ban on many companies not subject to FISA 702.

   c. Third, we assume that a hypothetical policy would expressly state that the use of data encryption28 would not relieve companies of the de jure or de facto bans described above.

   d. Fourth, we assume that a hypothetical policy would expressly state that data localisation29 would not relieve companies of the de jure or de facto bans described above.

12. As the impacts of these assumptions may depend on the specific data flows incurred in the particular industry, in the next section we describe four example case studies and the potential impacts that restricting the flow of personal data may have in these industries.

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27 For a legal definition of ECSPs, see Legal Information Institute, “50 U.S. Code § 1881 - Definitions”, available at https://www.law.cornell.edu/uscode/text/50/1881.

28 Encryption is the process of encoding a message so that only authorized parties are able to understand the information. While the data look “scrambled” to everyone else, the intended recipient can decipher (or decrypt) the message with the use of a cryptographic key.

29 Data localization is the practice of creating local (e.g. European) data centres to avoid transferring data outside the EEA.
III. Quantifying the possible impact of suspending extra-EU data transfers in example industries

13. In this section, we discuss four case studies in the (1) telecommunications, (2) digital payments and commerce, (3) global services outsourcing, and (4) pharmaceutical R&D industries. We selected these case studies due to the relative simplicity of the data flows that would be impacted. While many other industries rely on the ability to transfer personal data to third countries and would thus also be affected if they could no longer conduct those exports, these four case studies exemplify the nature, magnitude, and variety of harm potentially suffered by EU consumers and businesses.

14. For each industry, we provide below a brief outline of the data flows that may be impacted as a result of a potential ban on personal data exports, along with high-level quantifications of potential damages and descriptions of non-quantifiable but conceivable impacts. Further details on the quantification methodologies for each case study are provided in the Methodology Annex.

30 For simplicity, in this section, the terms “third country”, “non-EU country”, and “non-EEA country” indicate a third country without a GDPR adequacy decision, i.e. an EC determination, “on the basis of article 45 of Regulation (EU) 2016/679 whether a country outside the EU offers an adequate level of data protection”. The EC has so far recognized only 12 such countries: Andorra, Argentina, Canada, Faroe Islands, Guernsey, Israel, Isle of Man, Japan, Jersey, New Zealand, Switzerland, and Uruguay. See European Commission, “Adequacy decisions: How the EU determines if a non-EU country has an adequate level of data protection”, available at https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions_en.
A. Telecommunications

Seamless global telecommunications services are becoming increasingly important as consumers rely heavily on mobile connectivity. Currently, EU consumers can continue to use their phones in “roaming” mode while traveling abroad, which involves exchanging personal data (including metadata) between EU and third country telecommunications providers.

If telecommunications companies could not transfer personal data to third countries, it could undermine the ability of EU consumers to use roaming while traveling. With roughly 95 million trips taken by EU travellers outside the EU annually, if these travellers had to purchase pay-as-you-go (PAYG) service plans at their destination in order to stay connected, this would cost them between €1 billion and €4.5 billion annually. EU travellers may also incur additional costs, including search costs (e.g. finding networks and PAYG plans) and transaction costs (e.g. notifying contacts of their new phone numbers).

Examining the potential impact of this limitation from the network providers’ perspective, based on recent outbound roaming revenue figures, EU mobile network providers could lose €2.5 billion in revenue annually if EU consumers’ roaming functionalities were disabled. To offset this revenue loss, EU mobile network providers may increase home network service prices, reduce the quality of their service, or reduce spend on investments in an attempt to maintain profit margins, thus potentially harming even those EU customers who do not travel.

15. With over 500 million active smartphone users in Europe, telecommunication through mobile devices has become part of our everyday lives. When travelling abroad, EU consumers (i.e. customers of European mobile network providers) can as of now continue to use their phones in “roaming” mode, which involves exchanging personal data between telecommunications providers in the EU and in third countries. EU consumers currently make use of such roaming functionalities, as evidenced by the approximately €2.5 billion of outbound roaming revenue that network providers were projected to make in 2019.

16. If telecommunications providers could not transfer personal data from the EU to third countries, it would have the effect of disrupting phone service for EU consumers when traveling in third countries. In this section, we describe the monetary costs (e.g. the need to obtain a separate service plan).

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35 Because the GDPR applies to natural persons regardless of their citizenship as long as they are subject to the offering of goods and services within the EU, the disruption may even result in non-EU (e.g. US) tourists and travellers not being able to use their roaming functions when travelling within the EEA (as their personal data would also be banned from leaving the EEA). Our analysis, conservatively, does not quantify the impact on these data subjects.
service plan) and non-monetary costs (e.g. the need to inform friends and relatives of how they can be reached while traveling) imposed by such a limitation.

17. International roaming for mobile devices is built upon the process of sending and receiving data across different networks. Roaming capabilities provide convenience by allowing mobile devices to make calls, send and receive text messages, and access the internet outside a user’s home network. Facilitating connectivity requires the sharing of information through ongoing data exchanges between the visited network and the home network. Though the sequence of data flow between networks varies depending on communication type (i.e. text messages, internet browsing, voice calls, etc.), metadata (including customer information) is exchanged continuously in the process of connecting mobile devices while roaming.

18. When a roaming connection is made via a mobile device, the visited network charges the home network for the services delivered to the end user. Personal data are required for this exchange in order for the home network to appropriately route and charge the end user for these roaming services. To facilitate this exchange of data, the visited network records metadata on the location, the communication sender, the communication receiver, the time and duration of the communication, and the amount of data sent. These data are transited via databases storing personal customer information and profiles to ensure that the correct person is charged for using the service. In return, the home network authenticates the customer, authorizing the visited network to provide roaming service. From the customer side, it is the constant communication between these databases that allows for seamless roaming.

19. Given the context of intra-EU and extra-EU databases exchanging customer information and service metadata, mobile device roaming may be subject to personal data transfer policies. If cross-border

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36 “Home network” refers to the network with which the subscriber is registered.
37 “Visitor network” refers to the network the subscriber roams temporarily, and which is outside the bounds of the home network.
38 “A friend sends an SMS to your mobile phone while you are roaming. His operator’s network contacts your home network to find out where you are, and then routes the SMS to the network you are roaming on in the visited country.” GSMA (2012), “Mobile SMS and Data Roaming Explained”, available at https://www.gsma.com/aboutus/wp-content/uploads/2012/03/smsdataroamingexplained.pdf.
39 Metadata is data that provide information about data, such as the title, size, and location of a file on a computer; or the origin, destination, and time of an email, phone call, or text message. Opendatasoft (25 August 2016), “What Is Metadata and Why Is It as Important as the Data Itself?”, available at https://www.opendatasoft.com/blog/2016/08/25/what-is-metadata-and-why-is-it-important-data.
41 Call detail records commonly contain phone numbers, International Mobile Equipment Identity (IMEI) numbers, and locations, among other forms of data. Digital forensic analysts can now use sophisticated software on call detail record logs to extract powerful insights such as interrelations among users and location history. See Science Direct, “Call Detail Record”, available at https://www.sciencedirect.com/topics/computer-science/call-detail-record.
42 Home Location Registers (HLRs) are “databases used to store customers’ profiles. Communication between these databases and Visitor Location Registers of the visited network allows roaming to take place.” Visitor Location Registers are “databases used to store information about customers, including those who roam. Communication between these databases and HLRs of the home network allows roaming to take place.” See GSMA (2012), “Mobile SMS and Data Roaming Explained”, available at https://www.gsma.com/aboutus/wp-content/uploads/2012/03/smsdataroamingexplained.pdf.
personal data transfer within the telecommunications industry were to be banned, roaming functionality for EU devices may be eliminated.

20. Under these conditions, an EU consumer wishing to use a mobile device for sending texts, making calls, or accessing internet-based services while traveling outside the EU may need to purchase a PAYG service plan. Purchasing a PAYG plan at the new destination would convert the user’s visiting network device into a home network device for the duration of travel, thereby avoiding the necessity of cross-border data flows. Capabilities for text, voice, and data services would be paid for and provided by the temporary home network selling the PAYG plan. Thus, EU travellers could avoid the personal data transfers associated with roaming, but at an additional cost to the traveller.

21. These policies are especially relevant for travel to the US, a popular travel destination for EU consumers, due to the fact that US telecommunications providers are subject to FISA 702. However, due to the de facto ban assumption, roaming on any non-EU network in a country without a GDPR equivalence determination could be at risk.

22. If this were to be the case, EU consumers would incur the cost of purchasing temporary PAYG plans any time they travelled outside the EU. Based on the average prices of PAYG plans in the US, we estimate that the overall impact of this cost could range from €1 billion to €4.5 billion to end users.\(^4\) Table 1 illustrates typical PAYG plan prices, ex-EU travel figures, and the overall estimated cost.

### Table 1: Total PAYG plan cost to EU travellers

<table>
<thead>
<tr>
<th></th>
<th>Lower 10%</th>
<th>Median</th>
<th>Upper 10%</th>
</tr>
</thead>
<tbody>
<tr>
<td>PAYG plan price (€)(^1)</td>
<td>[A] 10.86</td>
<td>25.39</td>
<td>48.16</td>
</tr>
<tr>
<td>Number of travellers (m)(^2)</td>
<td>[B] 94</td>
<td>94</td>
<td>94</td>
</tr>
<tr>
<td>Total cost to travellers (€ m)</td>
<td>[A] x [B] 1,024</td>
<td>2,395</td>
<td>4,543</td>
</tr>
</tbody>
</table>

Note:
- \(^1\) Costs were converted to 2020 euros by using the average USD/EUR exchange rate for the year 2020: 1.142 USD / 1 EUR\(^3\).

Sources:
- \(^2\) Data available at [https://ec.europa.eu/eurostat/statistics-explained/index.php/Tourism_statistics_-_top_destinations#United_Kingdom,2C_USA_and_Switzerland_-_top_3_destinations_outside_the_EU](https://ec.europa.eu/eurostat/statistics-explained/index.php/Tourism_statistics_-_top_destinations#United_Kingdom,2C_USA_and_Switzerland_-_top_3_destinations_outside_the_EU).

23. Additionally, EU travellers may experience other costs in the form of market effects and inconvenience factors. For example, without access to a phone or the internet upon arrival to a new

\(^4\) While travellers may benefit from some offsetting savings by not having to buy roaming packages from their EU providers when travelling, European providers increasingly include roaming to many countries (including the US) in their monthly packages. For example, Vodafone Spain’s “Tarifa Movil ilimitada” package includes roaming to the US at no extra cost. See Vodafone, “Datos ilimitados para lo que quieras”, available at [https://www.vodafone.es/c/particulares/es/productos-y-servicios/movil/contrato/tarifas-contrato/tarifa-4f](https://www.vodafone.es/c/particulares/es/productos-y-servicios/movil/contrato/tarifas-contrato/tarifa-4f).
country, a traveller may not be able to book transportation or a hotel from the airport and would therefore need to purchase a PAYG plan immediately upon landing. Phone plan vendors could capitalize on this necessity and demand higher prices for PAYG plans at the airport, targeting tourists specifically. Additionally, EU travellers may incur search costs in the form of time spent finding appropriate networks and plans in a foreign country, and further transaction costs when notifying their colleagues, friends, and family of their new phone numbers.

24. From the EU mobile service providers’ perspective, limitations on transferring personal data to a third country may impact their financial performance, which could trigger second-order economic effects. In 2019, EU mobile service providers were projected to realize €2.5 billion in outbound roaming revenue.\textsuperscript{46,47} Thus, policies prohibiting personal data transfer may cause a significant loss of revenue for EU-based firms.\textsuperscript{48} To offset this loss, EU mobile service providers may increase home network service prices, reduce the quality of their service, or reduce spend on investments in an attempt to maintain profit margins, thus potentially harming even those EU customers who do not travel. The financial and non-financial costs to consumers and mobile providers would be substantial if roaming were not available to EU consumers traveling outside the EEA.\textsuperscript{49}


\textsuperscript{48} For clarity, we assume that EU-based telecommunications providers would not be able to easily offer US PAYG packages, and therefore would not be able to offset a decrease in roaming revenue via the sales of such packages.

\textsuperscript{49} We note that the costs to the EU consumers and EU mobile service providers are not additive, as reduced roaming revenue for the EU network providers may indicate reduced spending on roaming fees by EU consumers.
B. Digital payments and commerce

Digital payment transactions, which underlie the entire modern economy, involve the transaction of personal data (e.g. bank account information). A cessation of personal data transmission to third countries could substantially disrupt the payment services provided to EU consumers and stifle the economy.

If EU consumers are prohibited from providing their personal information (e.g. payment data and address) to merchants with acquiring banks based in third countries, given the difficulty of merchants switching to acquiring banks in the EEA, this would result in an effective ban on e-commerce from outside the EEA. Based on current levels of card payments sent from the EU to non-EU countries, this could result in a lost transaction value of €128 million per day immediately, and up to €4.2 billion - €9.3 billion per year in the longer term.

If, instead, EU consumers are prohibited from providing their personal data to electronic communication service providers based in third countries, they may not be able to use those mobile/digital wallets that are owned by such companies (e.g. Apple with its Apple Pay product), even within the EU. Based on current levels of mobile/digital wallet activity in Europe, this could result in a lost transaction value of €497 million - €699 million per day immediately, and €172 billion per year in the longer term. Additionally, as mobile/digital wallets reduce the risk of card fraud relative to plastic cards, decreasing usage of mobile/digital wallets could lead to increased levels of fraud if European consumers switch their current mobile/digital wallet payments to card payments.

These effects may become more pronounced in the future due to both the increasing importance of digital payment solutions (further accelerated by the COVID-19 pandemic), and the potential long-term impacts on the competitive landscape in Europe, which would impact innovation and R&D.

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25. The payments system underlies the entire modern economy, with the total value of payment transactions in the EU reaching €300.2 trillion in 2019.\(^50\) In recent years, much of the growth in payment revenues has been fuelled partly by a continued move away from cash to digital payment solutions,\(^51\) many of which - unlike cash - inherently involve the transaction of personal data in the form of bank account information, PINs, and passwords.\(^52\) A ban or severe restriction on the transfer of personal data to third countries could result in several types of payment methods becoming inaccessible to consumers in the EU, thus harming both the European payments system and commerce more generally.

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26. While payments have been characterized by a rapid digitization even before 2020, the pandemic has accelerated this trend, as consumers have increasingly looked for payment solutions that minimize contact with frequently touched surfaces such as point-of-sale (POS) terminals. Many consumers have made their first-ever contactless transaction, while others have increased their usage of mobile payments, due to the pandemic. This increased usage of mobile/digital wallets is expected to remain even after COVID-19 ends, with industry specialists expecting that by 2030, most payments will occur via mobile payments through devices and wearables.

27. However, if it were not permitted to transfer EU consumers' personal data (including bank account information) to third countries, such consumers would be at risk of missing out on some of these developments.

28. As discussed above, we assume that a hypothetical policy would impose a de jure ban on ECSPs transferring personal data, and a de facto ban on most (if not all) other companies transferring personal data from the EEA to third countries. In the remainder of this section, therefore, we quantify the potential damage from the restriction of data flows under two interpretations. First, we estimate the potential impact if all payment-related personal data would be unable to enter third countries, meaning that EU consumers would be unable to provide their payment information to merchants and financial intermediaries based in third countries. Second, we estimate the potential effect if the ban were to impact only ECSPs based in third countries that have entered the payments space in Europe (such as Apple with Apple Pay). We note that the very existence of the uncertainty surrounding potential data restrictions in the payments industry may cause concerns for companies keen on understanding whether they are violating GDPR rules that may carry fines up to €20 million or 4 percent of annual turnover.

a. Potential impacts if EU consumers are unable to provide their payment information to merchants in third countries

29. If EU consumers were prohibited from transmitting their payment information to any payment provider outside the EEA, then, in the worst-case scenario, this could result in EU consumers being prohibited from providing their payment information to all third country-based merchants or financial intermediaries, resulting in an effective ban on e-commerce from third countries.

30. While some merchants based in third countries may be able to switch their acquiring banks to be in the EU, any such adjustment would incur substantial regulatory and transaction costs associated with setting up a legal entity in an EU country. Therefore, for the sake of simplicity, the below analysis considers that a merchant’s acquiring bank is located in the same country as the one in

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which the merchant is located, and therefore considers the impact of the ban on e-commerce from third countries on the consumer side only.

31. When quantifying the damage resulting from EU consumers not being able to order products and services from third countries, it is useful to segment the impact into an immediate-term and a long-term effect. While the precise length of these terms cannot be quantified, the immediate term is the time frame over which, when being deprived of ordering products from third countries, most consumers do not switch to an alternative product within the EU and instead abandon the purchase (i.e. because the cost of searching for an alternative is higher than the benefit from the product). This can be anywhere from a few days to a few months, depending on the specific consumer and the essentiality of the product. The long term is any time frame longer than this, i.e. when most EU consumers would spend the time and effort to switch to an alternative product within the EU (if available).

32. In the immediate term, prohibiting EU consumers from sharing their purchase information with merchants whose acquiring banks are located outside the EEA could mean that EU consumers temporarily abandon their purchases from third countries. Therefore, in the immediate term, the impact of such a limitation may be the loss of the transaction value that EU consumers have previously spent on products and services ordered online from merchants outside the EU, estimated as a total transaction volume of €46.65 billion in 2019. This translates to an impact of €128 million per day.

33. In the long term, EU consumers would likely substitute many of their previously cross-border purchases with EU-based products and services. However, the fact that they have until now been ordering such products and services from outside of the EU indicates that they placed a higher value on these cross-border transactions than on their European counterparts, e.g. due to lower prices or higher quality/variety. Therefore, it is likely that not all previously cross-border purchases would be replaced with European counterparts, and thus the long-term loss that could potentially result from such a limitation would be the value of cross-border products and services that may be abandoned by EU consumers without being replaced by those of European producers.

34. One reason why EU consumers may decide not to substitute from now-prohibited third country-based products and services to EU-based alternatives is the lack of adequate substitutes. Many innovative products and services originated in the US or in China are introduced into the EU with a few years’ delay (if ever). For example, Netflix’s movie streaming service entered the EU five years after it started in the US, and Hulu (another US-based streaming service) is still not available in

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56 This figure represents the value of cross-border card payments in 2019 with cards issued by resident PSPs, from all EU member countries (with the UK excluded) to countries outside the EU. See European Central Bank Statistical Data Warehouse, “PSS: Payments and Settlement Systems Statistics”, available at https://sdw.ecb.europa.eu/browse.do?node=9691547.

59 This figure represents €46.65 billion divided by 365 days.

the EU despite having been launched in 2008. Moreover, there is evidence that European consumers have strong brand loyalty to certain US products, and were these products, or others like them, not available in Europe, they may choose to forgo their purchases altogether.

Therefore, a potential long-term impact of such a limitation may be a loss of purchases that EU consumers cannot complete due to a lack of EU-based alternatives. To quantify this impact, it would be required to consider the proportion of current imports into the EU from third countries that EU consumers would not be able to replace with EU-based products and services. While no precise data are available on this proportion, the impact can be expected to be substantial, as shown in Table 2. If the proportion ranges between 10 percent and 25 percent, the reduction in expenditure by EU consumers would be between approximately €4.2 billion and €9.3 billion per year. Even if the proportion of currently imported products irreplaceable by EU-based alternatives is only 1 percent, the reduction in expenditure by EU consumers would be as high as €0.5 billion per year.

While no precise data are available on the proportion of imported products/services that EU-based companies do not provide, this proportion may be approximated by the difference in product innovation between the EU and third countries. Information available on the differences in product innovation and level of R&D investment between the EU and its main trading partners (i.e. the US and China) indicate that companies in third countries may have at least 25 percent more product innovation than their European counterparts (i.e. an “innovation multiplier” of 125 percent), suggesting that the reduction in expenditure may be closer to the upper end of the range shown in Table 2.

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62 In addition to online services, there are similar examples of direct-to-consumer products. For example, Glossier, the US-based innovative startup brand disrupting the beauty industry, started shipping to the UK and France more than three years after its launch in the US. Shu, Catherine (12 July 2017), “Beauty startup Glossier will start shipping to Canada, the U.K. and France, with more countries to come”, available at https://techcrunch.com/2017/07/12/beauty-startup-glossier-will-start-shipping-to-canada-the-u-k-and-france-with-more-countries-to-come/.


64 Eurostat (22 June 2020), “Impact of the COVID-19 on EU trade with China”, available at https://ec.europa.eu/eurostat/web/products-eurostat-news/-/EDN-20200622-1?inhibitRedirect=true&amp;redirect=%2Feurostat%2F. For the purpose of our analysis, we assume that as the EU’s largest overall trading partners, the US and China also are the largest e-commerce trading partners.

Note: [1] See Section B of the Methodology Annex for a full description of this analysis.

Sources:

37. In the longer term, EU companies may respond by increasing their innovative output, thereby minimizing the loss of e-commerce imports. However, since the level of R&D investments by American and Chinese companies continues to outpace that of their European counterparts, the likelihood of this occurring is not clear.  

38. Moreover, following a de facto ban on imports from third countries, the loss of competition from non-EU competitors may reduce the pressure on European companies to innovate. As such, those EU consumers who do switch from non-EU to EU products following a ban, along with those EU consumers who were already purchasing EU products, may be affected by higher prices and/or lower-quality products than would be the case in the absence of a ban. Finally, a ban on e-commerce from third countries may also cause a misallocation of resources as merchants create European entities to avoid transactions to third countries, dampening valuable investment and requiring substantially enhanced EU enforcement to ensure that these entities are compliant.

b. Potential impacts if EU consumers are unable to provide their payment information to third country-based ECSPs in the EU

39. Several large US-based ECSPs (e.g. Apple with Apple Pay, Google with Google Pay, and PayPal) have been entering the European mobile/digital wallet market in recent years, with rapidly growing

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market share.\textsuperscript{67} If limitations on transfers of personal data to third countries were to prevent EU consumers from providing their payment information to third country-based ECSPs, it would substantially disrupt payment services provided to EU consumers, causing damage to the European economy. We note that PayPal’s status as an ECSP is uncertain,\textsuperscript{68} so in order to capture this uncertainty, we quantify the impact both including and excluding PayPal from the analysis.

40. As above, when quantifying the impact of EU consumers potentially not being able to use mobile/digital wallets provided by US companies, it is useful to segment the impact into an immediate-term and long-term effect. While the precise length of these terms cannot be quantified, the immediate term is the time frame over which, when being deprived of the opportunity of relying on one payment method, most consumers do not switch to an alternative payment method and instead abandon the purchase (i.e. the cost of searching for an alternative payment method is higher than the benefit of completing the purchase). This can be anywhere from a couple of days to a few months, depending on the specific consumer and the essentiality of the product. The long term is any time frame longer than this, (i.e. when being deprived of the opportunity of relying on one payment method, most consumers would spend the time and effort to substitute an alternative payment method and complete the purchase).

41. In the \textbf{immediate term}, one impact of such a limitation may be that EU consumers are cut off from accessing US-based mobile payment providers such as PayPal, Apple Pay, and Google Pay. Therefore, if this were to happen, all transactions normally performed via these platforms would be lost overnight, at least for a couple of days. As set out in Table 3 below, the value of these transactions is estimated to be \textbf{€497 million per day} when considering Apple Pay and Google Pay only, and \textbf{€699 million per day} when considering PayPal as well.\textsuperscript{69}


Table 3: Potential immediate-term impacts on digital payments and commerce

<table>
<thead>
<tr>
<th></th>
<th>All amounts in € bn</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>In-store</td>
</tr>
<tr>
<td>Volume of transactions in Europe, 2019 [1], [2]</td>
<td>[A] 5,780</td>
</tr>
<tr>
<td>Percentage of transactions conducted via Apple Pay/Google Pay [3]</td>
<td>[B] 3.0%</td>
</tr>
<tr>
<td>Including PayPal [2]</td>
<td>3.0%</td>
</tr>
<tr>
<td>Including PayPal</td>
<td>173</td>
</tr>
<tr>
<td>Volume of Apple Pay/Google Pay transactions, per day including PayPal</td>
<td>[A] * [B] / 365</td>
</tr>
<tr>
<td>Including PayPal</td>
<td>0.497</td>
</tr>
</tbody>
</table>

Note:
[1] See Section B of the Methodology Annex for a full explanation of this analysis.

Sources:

42. In the long term, EU consumers may switch from these mobile/digital wallets to alternative payment methods, such as debit/credit cards and cash. However, to the extent mobile/digital wallets facilitated any transactions that would not have taken place using other payment methods, there may be a long-term loss in total transaction volume due to imperfect substitution between mobile/digital wallets and other solutions.

43. There are many reasons why mobile/digital wallets may facilitate increased consumer spending relative to alternative payment methods (e.g. debit/credit cards). In the brick-and-mortar context, paying with a mobile phone makes shopping more convenient, as consumers can shop without their wallets. Additionally, as described above, industry experts expect that one potential longer-term impact of the COVID-19 pandemic is that consumers are increasingly turning to mobile payment solutions to minimize contact with frequently touched surfaces. For online purchases, mobile/digital

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wallets can eliminate checkout friction by introducing one-click payment options (as opposed to having to enter lengthy card numbers, CVC codes, and expiration dates), which consumers reward by tolerating higher prices and/or increased brand loyalty. Relative to cards, this technology increases both impulse purchases and the shopping conversion rate (i.e. the rate of online shopping that gets converted into a purchase as opposed to being abandoned before checkout).

Finally, the additional spending spurred by mobile/digital wallets may be on the rise, as e-wallets are being integrated with coupons, loyalty cards, and additional benefits designed to increase spending. Economists attribute some of this additional spending to the reduced “pain” consumers experience when spending using phones as opposed to cash or cards.

44. On top of the higher revenue from increased consumer spending, mobile/digital wallets also reduce transaction costs incurred by businesses, further boosting the economy relative to alternative forms of payment. By introducing biometrics and payment tokenization, mobile/digital wallets considerably increase security and reduce fraud compared to plastic cards, saving merchants the cost of having to investigate and repay fraudulent payments. Faster checkout options also mean being able to serve more customers and losing fewer customers to queues, while increased brand loyalty translates into a need for less spending in customer retention, thus freeing funds for more innovative investments. Additionally, due to the increased speed and security, many mobile/digital wallets can offer lower transaction costs, reduce the “tax gap” by converting unobservable cash payments to observable mobile payments, and reduce businesses’ cashflow issues by offering instant settlement.

45. Despite the large number of qualitative reports on the subject, there is to date limited empirical analysis on the precise extent to which mobile payments increase total consumer spending. Xu, Ghose, and Xiao (2018) found, by examining payments from over 1.5 million consumers in China

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between 2010 and 2013 (during the adoption of Alipay, the largest mobile payment platform in the world) that “mobile payment adoption leads to a 2.93% increase in total transaction amount”. They also found that while mobile payments cannibalized card payments in the offline setting (resulting in reduced card spending while increasing total offline transaction amounts), they acted as a booster for card payments in the online setting (i.e. increasing both mobile-based and PC-based online spending).80

46. In the long run, if restrictions on personal data transfers to third countries were to prevent EU consumers from providing their payment information to third country-based ECSPs, the result would be that the most popular US-based mobile payment options would be unavailable, and since many consumers are constrained to using alternative payment methods, 2.93 percent of the total consumer spend (across both offline and online channels) may not be realized. Table 4 below shows that without the 2.93 percent “boost” from mobile payments, total European transaction volume would have been lower by approximately €172 billion in 2019.

<table>
<thead>
<tr>
<th>Impact</th>
<th>Value (€ bn)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume of transactions in Europe, 2019 [1], [2]</td>
<td>[A] 6,049</td>
</tr>
<tr>
<td>Percentage increase in total spending by consumers due to mobile</td>
<td>[B] 2.93%</td>
</tr>
<tr>
<td>payments (across all payment channels) [3]</td>
<td></td>
</tr>
<tr>
<td>Volume of transactions that would have taken place without the</td>
<td>[C] = [A] / (1 + [B]) 5,877</td>
</tr>
<tr>
<td>presence of mobile payment option</td>
<td></td>
</tr>
<tr>
<td>Volume of transactions that would have been lost</td>
<td>[D] = [A] - [C] 172</td>
</tr>
</tbody>
</table>

Note:
[1] See Section B of the Methodology Annex for a full explanation of this analysis.

Sources:

47. Additionally, as described above, with the use of biometrics and payment tokenization, mobile/digital wallets offer increased security against card fraud relative to payments using plastic cards.81 If European consumers could not use mobile/digital wallets and had to instead rely on card payments,

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the level of fraud may increase, raising European merchants’ (including small businesses’) costs related to fraud investigations and repayments.\textsuperscript{82}

48. We note that the potential impacts described above assume that if US-owned mobile/digital wallet providers were not available, European consumers would switch to card-based alternatives instead of an EU-based mobile/digital wallet. While there are a number of alternative EU-based mobile/digital wallet providers, many consumers currently use US-based mobile/digital wallets, and the use of these services is growing.\textsuperscript{83} While some users of these services may switch to other EU-based mobile/digital wallets in the event of a ban, this substitution may be imperfect. A number of the available EU-based mobile/digital wallet providers are currently concentrated in specific countries and may face difficulty expanding, while others focus more on peer-to-peer transactions instead of point-of-sale transactions.\textsuperscript{84} Ultimately, one or more EU-based credible alternatives to US-based mobile/digital wallets may arise; however, the time frame is uncertain, and there may be substantial costs to the European economy during this transition.

49. Finally, for a holistic analysis, one also needs to add dynamic considerations, such as competition and innovation. For decades, banks and card schemes were the sole providers of payment services, and large incumbents had little to worry about when it came to competition, resulting in low levels of innovation. In the past decade, this trend has changed dramatically, with technology and fintech companies challenging incumbent providers along the value chain.\textsuperscript{85} Such challengers have forced the payments (and more broadly, the finance) sector to innovate and pay more attention to consumers’ and merchants’ needs.\textsuperscript{86} If third country-based technology companies are banned from providing payment solutions to EU consumers, this would result in decreased competition faced by European incumbents, and slow down or reverse the increased choice, quality, and innovation in payments that have been developing in recent years.\textsuperscript{87} Finally, the decrease in transaction volume described above may lead to strain on the margins achieved by European card issuers, potentially leading to further reductions in the quality of service or R&D investments.


\textsuperscript{86} According to a March 2020 report by Oxera Consulting, “newer, innovative payment methods are becoming popular in a number of countries. This is leading traditional players, such as banks and card schemes, to react by creating new services and entering new partnerships”. Oxera (March 2020), “The competitive landscape for payments: a European perspective”, p. 64, available at https://www.oxera.com/wp-content/uploads/2020/03/Competitive-landscape-report.pdf.

C. Global services outsourcing

Global services outsourcing, in particular offshoring, has increased business efficiency and the productivity of European companies. Offshoring business services (e.g. information technology (IT) and contact centres) often involves the transfer of personal data (such as customer names and email addresses) from the EU to third countries.

If transferring personal data were not permitted to third countries, offshoring business services from Europe to popular outsourcing destinations (such as India) would no longer be possible. As a result, firms would need to bring these offshored jobs back ("back-shore") into the EU. Based on EU companies’ current outsourcing demand, we estimate that back-shoring all currently outsourced jobs would increase labour costs for EU businesses by €25.5 billion - €91.7 billion per year.

While back-shoring jobs may increase employment in certain European sectors, this relationship is not clearly established. Additionally, it is unclear whether any increase in employment would outweigh the negative effects of labour cost increases, including higher consumer prices, reduced service quality (e.g. reduced customer service hours), and decreased global competitiveness of European businesses.

50. Global services outsourcing, in particular offshore outsourcing, has tremendously increased the business efficiency and productivity of European corporations by allowing them access to a global talent pool at a fraction of the EU labour cost. Offshore outsourcing from EU companies involves the transfer of data from the EU to third countries, often including the transfer of personal data (e.g. customer names and email addresses). If cross-border personal data flows were not permitted outside the EEA, it would result in substantially raised costs for EU companies, which would no longer have access to low-cost labour and specialized knowledge from outside the EEA. EU companies may therefore need to increase prices, reduce work hours, and cut back on R&D spending, ultimately harming EU consumers and making EU businesses less competitive on a global scale.

51. By relying on offshoring, companies in developed regions (such as the EU) can achieve cost savings in the range of 10-20 percent, along with added benefits such as streamlined operations, increased flexibility, access to the latest technologies, and improved speed to market. The EU represents an important portion of the global services outsourcing market, with EU companies being buyers in approximately 28 percent of total outsourcing deals. Moreover, outsourcing is only increasing; expectations are for the total market for business process outsourcing to grow by almost 10 percent

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88 Global services outsourcing refers to an agreement in which a company hires another company to provide services such as IT, human resources, accounting and payroll, etc.

89 Depending on the geography of the outsourced entity, outsourcing can either be local, nearshore, or offshore. In this case study, we are concerned with offshore outsourcing from companies in the EU to geographies such as the Asia-Pacific.


per year in the near future.\textsuperscript{93} With the increasing reliance on outsourcing, EU companies in advanced economies are being presented with opportunities to move additional jobs to geographies with low labour costs, such as the Asia Pacific (APAC), Latin American and Caribbean (LAC), and Central/Eastern European (CEE) regions, potentially freeing up company resources to focus on core business competencies.

52. However, if there were a substantial reduction in the ability to transfer personal data outside the EEA, the ability of EU companies to benefit from such offshore outsourcing may become restricted, as most outsourced functions (including IT, contact centres,\textsuperscript{94} human resources (HR), legal, and real estate)\textsuperscript{95} involve personal data transfers. For example, contact centres often require access to the personal data of the outsourcer’s (e.g. the EU company’s) customers (such as their name, date of birth, and email address) for identity verification purposes. Similarly, IT operations may require remote access to employees’ computers, and all information stored on those devices, including potentially personal information.\textsuperscript{96}

53. If no personal data were permitted to leave the EEA, then data necessary for offshore outsourcing could be stopped or severely restricted. Furthermore, even if some personal data could leave the EU, but with considerable additional compliance costs for both the data exporter and data importer, there may still be an increase in the cost of outsourcing to the point that it would no longer be economical, resulting in a \textit{de facto} ban on outsourcing to countries without GDPR-equivalent data protection laws. As many data protection and privacy laws in popular outsourcing destinations, such as India, fall short of the GDPR,\textsuperscript{97} the ability of EU companies to outsource business functions may become substantially limited.

54. A lack of access to offshore outsourcing could substantially increase EU businesses’ cost base, especially due to higher labour costs in the EU compared to popular outsourcing destinations such as APAC and LAC, thus impacting these businesses’ profitability. This may also impact the price and quality of the services provided to EU consumers.

55. The impact from increased labour costs alone due to a potential restriction in offshore outsourcing would be substantial. The total (global) number of offshored jobs is estimated at 7.9 million as of


\textsuperscript{94} Contact centers include “front office services, such as customer call centers”. See UNCTAD (14 June 2004), “Service Offshoring Takes off in Europe”, available at https://unctad.org/press-material/service-offshoring-takes-europe.


2020, with EU companies being responsible for 28 percent of the global outsourcing demand.99 The most popular outsourcing destination is the APAC region (accounting for 69 percent of the offshored jobs), followed by the CEE (15 percent of jobs) and LAC (10 percent of jobs) regions.100 Using region-specific wages of contact centre workers from each of these outsourcing destinations,101 we estimate the current labour cost spend on outsourced workers as €41.5 billion.

56. If, as a result of a ban on personal data transfers outside of the EEA, EU companies would be forced to suspend outsourcing to all countries outside of the EEA (which would entail the whole of the APAC and LAC regions), then it would be reasonable to assume that they would attempt to backshore (i.e. move outsourced jobs back to Europe) these jobs into EU countries with the lowest available labour costs - in this case, the CEE region. Therefore, if all (100 percent) of the jobs offshored from the EU are moved to the CEE region (instead of the current 15 percent), the total labour cost of outsourcing from the EU is estimated to be €67.0 billion, resulting in an estimated increase in annual labour costs of €25.5 billion.

57. The CEE region is unlikely to be able to support the labour demand that would arise if jobs offshored by European companies are brought back to the EU. At least in the short and medium term, CEE countries may lack the required number of qualified workers with both specific expertise (e.g. IT and HR) and language skills.102 As a result, at least some of the offshored jobs will likely be brought back to Western Europe instead of the CEE region. In the extreme scenario where all the outsourced jobs are brought back to Western Europe, the estimated increase in total annual labour cost is €91.7 billion. Thus, assuming that some jobs would need to be relocated to CEE and some to Western Europe, we estimate that the annual increase in labour costs incurred by EU firms would be between €25.5 billion and €91.7 billion.


99 This number represents the portion of outsourcing deals in which EU companies were the buyers of outsourcing. We assume that this is also representative of the European demand for outsourced labour as a fraction of the global demand. Also, one article mentions that Europe accounts for 30 percent of the Indian outsourcing market (about 50 percent of the global outsourcing market). See Everest Group (March 2020), “Market Vista: 2019 Year in Review and Outlook for 2020”, available at https://www2.everestgrp.com/Libraries/reports/Products/EGR-2020-35-R-3638/MarketingBrochure. See also Dave, Sachin (10 August 2020), “European firms, banks take outsourced jobs back home fearing data leaks amid Covid-19”, available at https://economictimes.indiatimes.com/tech/ites/european-firms-banks-take-outsourced-jobs-back-home-fearing-data-leaks-amid-covid-19/articleshow/77465621.cms.


101 For example, companies from France have traditionally offshored their services to countries such as Morocco and Tunisia, which have a sizeable French-speaking population and in which the labour costs are lower than in Europe. See Filou, Emilie (20 January 2019), “Madagascar has become a business outsourcing hotspot thanks to its super-fast internet”, available at https://iqz.com/africa/1519409/madagascar-fast-internet-fuels-outsourcing-boom/.
Table 5: Increased labour costs of back-shoring

<table>
<thead>
<tr>
<th>Current labour costs</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Global outsourced jobs</td>
<td>7,900,000</td>
</tr>
<tr>
<td>EU share of demand for outsourcing</td>
<td>28%</td>
</tr>
<tr>
<td>EU outsourced jobs</td>
<td>2,212,000</td>
</tr>
<tr>
<td>Current EU cost of outsourced labour (€ bn)</td>
<td>41.5</td>
</tr>
</tbody>
</table>

If all outsourced jobs were transferred to CEE

<table>
<thead>
<tr>
<th>If all outsourced jobs were transferred to CEE</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>New EU cost of outsourced labour (€ bn)</td>
<td>67.0</td>
</tr>
<tr>
<td>Labour cost increase (€ bn)</td>
<td>25.5</td>
</tr>
</tbody>
</table>

If all outsourced jobs transferred to Western Europe

<table>
<thead>
<tr>
<th>If all outsourced jobs transferred to Western Europe</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>New EU cost of outsourced labour (€ bn)</td>
<td>133.2</td>
</tr>
<tr>
<td>Labour cost increase (€ bn)</td>
<td>91.7</td>
</tr>
</tbody>
</table>

Note:
[1] See Section C of the Methodology Annex for a full explanation of this analysis.

Sources:

58. These estimates are based on estimates of contact centre wages in Europe and in other countries, and therefore are likely conservative for two reasons. First, the wage gap between developed and developing countries for higher-skilled services such as software development, accounting, and HR is larger than the wage gap for contact centres.[^58] Second, blended CEE wages tend to include non-

EEA countries such as Ukraine and Belarus, where wages for outsourced labour are lower than in CEE countries within the EU.  

59. Importantly, the impact on offshore outsourcing is not limited to a few large EU companies. According to a 2004 study that surveyed a representative sample of Europe’s top 500 companies, over one-third of the companies mentioned offshoring front office functions (such as contact centres), while close to two-thirds mentioned either currently offshoring or planning to offshore back-office functions (such as finance, IT, and HR). Notably, many small businesses also engage in offshoring business services. A study published in 2018 points out that about 50 percent of the German companies which offshore are SMEs. It is thus clear that a potential de facto ban on offshore outsourcing would be systemic and widespread, affecting a large number of EU businesses.

60. We note that while back-shoring outsourced EU jobs may result in some new jobs being created in the EU, benefitting certain European workers, the magnitude of this job creation and whether it would offset the widespread and long-term harm to both EU consumers and EU businesses caused by reducing offshoring is unclear. A 2019 study examining back-shoring in Spain between 2008 and 2010 found no significant relationship between an increase in local employment and back-shoring. Moreover, the study suggested that offshore outsourcing strategies increase the competitiveness of the firms that implement them, leading to long term increases in production and employment.

104 For example, software developers earn an average of $33-$51 per hour in CEE countries that are in the EEA, while they earn an average of $27-$43 per hour in CEE countries that are not in the EEA (e.g. Ukraine and Belarus). See Daxx (18 February 2020), “The Only Offshore Developer Rates Guide You’ll Need to Choose Your Offshore Software Development Country”, available at https://www.daxx.com/blog/development-trends/average-rates-offshore-developers.


61. Finally, national governments and EU policymakers may take into account considerations other than the labour costs faced by businesses; therefore, from an industrial policy perspective they may consider that back-shoring jobs could be worthwhile even if it fails to create proportionately as many jobs in Europe as would be lost in the regions where these jobs are currently outsourced. However, there are a number of other impacts on EU consumers and business that are likely to arise from a restriction in offshoring, potentially with a wider social impact. First, European businesses may pass on some of the increases in labour costs to their consumers by raising prices.\textsuperscript{110} It is also possible that increased labour demand due to back-shoring will lead to an increase in the EU wage levels for outsourcing services, as the supply of qualified labour within the EU remains limited in the near term. This increase in wage levels may also be passed on to consumers.\textsuperscript{111} Second, high labour costs might affect businesses’ demand for labour, leading to reduced work hours and diminished customer service.\textsuperscript{112} Finally, European businesses may also cut back on their R&D spend, hampering their competitiveness in the long term.\textsuperscript{113}


\textsuperscript{111} According to the paper, for every 1 percent shock to nominal wage growth, there is a corresponding 1-1.1 percent increase in core inflation. See Boranova, Vizhdan \textit{et al.} (December 2019), “Wage Growth and Inflation in Europe: A Puzzle?”, available at https://www.imf.org/~/media/Files/Publications/WP/2019/wpiea2019280-print-pdf.ashx.


D. Pharmaceutical research and development

International data sharing is increasingly important in pharmaceutical R&D, both to reduce costs and to improve patient outcomes. As many new R&D technologies require the aggregation of large databases containing personal (e.g. genomic and medical) information, restrictions on transferring personal data to third countries could result in decreased efficiency in drug development, leading to increased costs and reduced patient outcomes.

For instance, if sharing medical data with third countries had not been possible during the global coronavirus pandemic, the development of COVID-19 vaccines likely would have been delayed, prolonging the economic damage caused by the imposition of measures to control COVID-19. We estimate that each additional month of delay in the approval of the vaccine could have caused €70 billion in damage to the EU economy.

In a clinical trial context, if medical data collected from EU patients are not allowed to be exported to third countries, pharmaceutical companies will not be able to submit clinical evidence based on these data to regulatory agencies in third countries (including the US Food and Drug Administration (FDA)) for authorization. In this case, pharmaceutical companies would likely relocate their clinical trial sites from the EU to third countries, in order to be able to rely on clinical trial data for submissions to a wider range of markets (including the US, the most lucrative market in the world). We estimate that such a relocation would lead to a reduction in spending on clinical trials in Europe by pharmaceutical companies of approximately €8.9 billion per year.

Finally, emerging technologies using linked genomic and health data have great potential to reduce costs during drug development. If personal data sharing is restricted, this could lessen the chances of saving as much as €1 billion per new drug developed. Moreover, limiting data access could hamper further patient benefits, such as by limiting the development of therapies for rare diseases and restricting the provision of personalized medicine.

62. A severe restriction of EU-US transatlantic data flows of personal healthcare or medical data, limiting the ability of pharmaceutical companies to use data to optimize R&D activities, could lead to both increased R&D costs for European pharmaceutical companies, as well as a reduction in the speed of development of new drugs brought to market in Europe.

63. The cost of bringing a new drug to market has increased over the last 10 years, resulting in pharmaceutical companies increasing their focus on "me-too" drugs. These are drugs where the mechanism of action is known and there is an established commercial market for other similar drugs. These features combine to reduce the risk for pharmaceutical companies in developing these drugs, as 1) they are more likely to be successfully developed, and 2) there is a predictable market for their


115 Me-too drugs are structurally analogous to, of the same drug class as, and used for the same indication as an original drug. They may be different in their mechanism of action, adverse event profile, or reactions with other drugs. See Aronson, Jeffery et al. (1 May 2020), "Me-too pharmaceutical products: History, definitions, examples, and relevance to drug shortages and essential medicines lists", pp. 2114-2122, available at https://bpspubs.onlinelibrary.wiley.com/doi/10.1111/bcp.14327.
sales. Novel therapeutics, in contrast, carry higher risks of both failed development and failed commercialization.

64. Against this backdrop, the EU, along with many other governments around the world, has a stated goal of encouraging pharmaceutical companies to increase their focus on novel therapies, with the hope of leading to larger consumer and patient benefits in the future.\textsuperscript{116} While there are a number of policy options being pursued by regulators in order to encourage this focus on new treatments,\textsuperscript{117} the novel use of personalized medical and genomic data in the development of new medicines is particularly promising. The use of these data has been linked to reductions in R&D costs for new therapies, which, in turn, can encourage companies to accept the higher risks to invest in new therapeutic areas.\textsuperscript{118} Therefore, restricting access to these data could hinder the cost savings potential of these connected datasets, and disincentivize the study and development of novel therapeutics by pharmaceutical companies.

65. In the remainder of this section, we quantify the impact of a potential restriction on cross-border personal data flows on the pharmaceutical market in three ways:

a. The possible economic impact of a delay in COVID-19 vaccine development

b. The possible economic impact on the clinical trial industry in the EU

c. The possible reduction in utility of a novel research method for drug development

\textbf{a. Potential impact of a delay in COVID-19 vaccine development}

66. The most recent examples illustrating the value of cross-border collaboration and data sharing for the purpose of novel pharmaceutical development are the SARS-CoV-19 (COVID-19) vaccines. COVID-19 vaccines were developed and released at an unprecedented pace: 12 months from pre-clinical research through global clinical testing.\textsuperscript{119} By comparison, the fastest vaccine developed prior to the COVID-19 outbreak was the mumps vaccine, which was developed over a four-year period.\textsuperscript{120} Historically, the average vaccine development timeline has been between 10 and 15 years.\textsuperscript{121} The speed at which the COVID-19 vaccines were developed required global collaboration


\textsuperscript{119} The first complete sequencing of the COVID-19 genome was conducted in January 2020. In November 2020, the FDA authorized the vaccine developed as a joint collaboration between Pfizer (USA) and BioNTech (Germany); this was the first authorization of any COVID-19 vaccine globally. The Pfizer/BioNTech vaccine was authorized for use in the EU on 21 December 2020. See GAVI (2021), “The COVID-19 vaccine race - weekly update”, available at https://www.gavi.org/vaccineswork/covid-19-vaccine-race. See also Zimmer, Carl et al. (2021), “Coronavirus Vaccine Tracker”, available at https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html.


\textsuperscript{121} HistoryofVaccines.org (2020), “Vaccine development, testing, and regulation”, available at https://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation.
and sharing of research and data (including personal data)\textsuperscript{122} throughout the entire vaccine development process. Moreover, the clinical trials of the first COVID-19 vaccine (Pfizer/BioNTech) included patients located in the EU, the US, and South America.\textsuperscript{123}

67. If regulations had been in place in 2020 preventing or severely limiting the sharing of personal data between the EU and other countries, vaccine R&D may have been delayed by at least months and perhaps longer. Even a minor delay in the widespread availability of a vaccine would likely have extended the already severe economic decline caused by COVID-19.

68. As recently as November 2019, the EU’s GDP was projected to increase by 1.4 percent in 2020.\textsuperscript{124} However, after seven consecutive years of GDP growth, the GDP began to decline in the first quarter of 2020 as the restrictions put in place to contain the spread of COVID-19 started to have an impact on the economy.\textsuperscript{125} In 2020, EU GDP decreased by 6.1 percent relative to 2019.\textsuperscript{126} Assuming, conservatively, that GDP would have remained stagnant during this period in the absence of the pandemic, the response to the pandemic cost the EU economy over €70 billion per month, and therefore each additional month of delay in the approval of the vaccine would lead to \textit{€70 billion} in damage to the economy. This damage estimate is consistent with the EC’s forecast showing that a successful vaccine rollout could lead to nearly 4 percent GDP growth in 2021 and 2022.\textsuperscript{127} Further, it is important to note that these estimates are purely economic and do not account for metrics such as number of deaths averted or quality of life gained due to widespread vaccination.\textsuperscript{128}

\textbf{b. Economic impact from reduction in Europe-based clinical trials}

69. While the COVID-19 global pandemic is a salient example of how regional data access restrictions may be costly for the economy, there are other, more common examples in pharmaceutical research that show the economic benefits of access to personal data.

70. In the context of EU-US transatlantic data flows, the clinical trial industry has the potential to be heavily impacted by policies that prevent the transfer of personal data to third countries. Pharmaceutical companies are required to submit clinical trial data to regulatory agencies (such as the European Medicines Agency (\textbf{EMA})) in order to access a specific market.\textsuperscript{129} To approve the sale of the drug in the market over which it presides, a regulatory agency, such as the EMA or the FDA,

\begin{footnotesize}


\textsuperscript{127}Fleming, Sam et al. (11 February 2021), “Brussels lifts forecasts for eurozone’s economic recovery”, available at https://www.ft.com/content/723331af-d08e-4dc3-bae4-b4f935af73fd.


\end{footnotesize}
will review the clinical trial data and may conduct its own analyses in an attempt to replicate and verify the clinical trial results. If the FDA were banned from accessing clinical trial data from EU patients, then any pharmaceutical company that has clinical trial data collected on EU patients would not be able to rely on these data in its regulatory submissions to the FDA, risking, in turn, its ability to receive drug approval in the US market. The US healthcare market is the most lucrative in the world; the US pays for approximately 70 percent of all global profits associated with patented pharmaceutical products.\textsuperscript{130} Therefore, a lack of FDA approval and subsequent lack of US market access due to inadmissible clinical trial data would be economically unsound.

71. If EU clinical trial data could not be shared with regulators outside Europe, this could lead to a substantial reduction in the number of clinical trials being performed in Europe, and the reduction in economic activity accompanying those trials. If data from EU patients could not be used in any submissions outside the EEA, research companies may decide to cease conducting clinical trials in the EU and instead relocate their research efforts to other countries where the outcome of the research can be accepted in multiple markets, in particular the US.

72. Recent data suggest that the global clinical trial market is worth €38.5 billion per year and is expected to grow at around 5.7 percent per year.\textsuperscript{131} Approximately 23 percent of all clinical trials currently take place in the EU.\textsuperscript{132} Assuming that the value of trials is equal across the world,\textsuperscript{133} then the relocation of these trials to other countries could lead to a loss of \textbf{€8.9 billion} per year in spending on clinical trials in Europe. Beyond the direct effect of a reduction in clinical trial spending, there are other, more difficult to quantify spillover effects such as the relocation of key research leaders and clinical research companies to other markets.

c. \textit{Reduced utility of novel drug development technologies}

73. Another area that could be impacted by policies limiting the transfer of personal data to third countries is the increasing use of linked genomic data (personal data) for R&D. Although this technology is still in its infancy, the potential benefits to drug development from it are very large.

74. The high costs of drug R&D are in part due to substantial failure rates during clinical development and testing; the average chance of success (defined as eventual market entry) for any new drug entering Phase I clinical testing is approximately 10 percent. (See the Methodology Annex for an outline of the different phases of pharmaceutical R&D.)\textsuperscript{134} A key driver of the failure rates in clinical

\begin{footnotesize}
\begin{enumerate}
\item[\textsuperscript{131}] Grand View Research (January 2021), "Clinical Trials Market Size, Share & Trends Analysis Report By Phase (Phase I, Phase II, Phase III, Phase IV), By Study Design (Interventional, Observational, Expanded Access), By Indication, By Region, And Segment Forecasts, 2021 - 2028", available at https://www.grandviewresearch.com/industry-analysis/global-clinical-trials-market# text=The%20global%20clinical%20trials%20market%20is%20fueling%20this%20market%20s%20growth.
\item[\textsuperscript{132}] The market share estimate of 23 percent excluded clinical trials performed in the UK. If the UK is included, then the estimate is increased to 28 percent. See Clinicaltrials.gov (2021), "Map of All Studies on ClinicalTrials.gov", available at https://clinicaltrials.gov/ct2/search/map.
\item[\textsuperscript{133}] The 23 percent EU market share is based on the total number of clinical trials rather than cost. Data suggest that it may be more expensive to conduct clinical trials in some EU countries compared with other countries, including the US; 23 percent, thus, may be an underestimate of the total market value. See FDA (2013), "FDA Perspective on International Clinical Trials", pp. 1-31, available at https://www.fda.gov/media/91849/download.
\end{enumerate}
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development is high false discovery rates\textsuperscript{135} in pre-clinical research, meaning that while a potential drug may be successful at treating the disease in the lab environment, it fails to do so within the human body and is therefore not viable. Currently, these failures are most often discovered once a drug has moved into the clinical trial phase, requiring companies to spend considerable resources on the development of drugs that ultimately will fail.

75. As discussed below, large linked genomic datasets combined with advanced analytical techniques have the potential to reduce pre-clinical false discovery rates and maximize the chances of success at the clinical research level. Such linked genomic datasets include several types of patient-level personal data, as they connect a patient’s entire genetic information (genomic data) with information on the patient’s health characteristics, e.g. diabetes status, cancer status, etc. (health data).\textsuperscript{136}

76. Linked genomic data allow researchers to understand the genetic underpinnings of specific diseases and isolate, with more accuracy and precision than current pre-clinical research methodologies, specific proteins with a causal link to a disease that can be impacted by a drug. This is of particular importance in R&D, as evidence shows that drug effectiveness is not equal across all populations, and that this is at least partly due to genetic differences across people.\textsuperscript{137} It is therefore important that researchers have access to a wealth of diverse data that can be used to understand sub-groups and genetic variation during R&D.\textsuperscript{138} Using linked genomic data can dramatically increase the chance of success for new drugs by reducing false discovery rates in pre-clinical research, allowing researchers to focus investments into therapeutics that have the best chance of success when trialled in the human body. With the use of linked genomic data, pre-clinical false discovery rates could be radically reduced,\textsuperscript{139} resulting in potential overall success rates at the clinical development stage of 80 percent,\textsuperscript{140} an eight-fold increase relative to the current value of approximately 10 percent.\textsuperscript{141}

77. Additionally, linked genomic data can also reduce the time required to proceed through each stage of development. For example, a new drug for treating obsessive compulsive disorder has recently been developed using artificial intelligence to analyse genetic signatures, and is entering Phase I

\textsuperscript{135}False discovery rate: The tested therapeutic interacts with an intended target, but within the human body, that target is not causally linked to the disease, leading to a lack of efficacy in clinical testing. See Hingorani, Aroon et al. (11 December 2019), “Improving the odds of drug development success through human genomics: modelling study”, pp.1-25, available at https://www.nature.com/articles/s41598-019-54849-w.

\textsuperscript{136}For example, data collected from genomic profiling company Foundation Medicine Inc. would contain the type of cancer, and any genomic alterations that could be used to inform treatment decisions for that cancer. See Foundation Medicine, “FoundationOne CDx sample report”, available at https://images.ctfassets.net/w98cd481gyp0/2pusoGEB1tZXWHYLY3vIDnV/8392c7cfa1ebf36f9098c936324a73e3/F1CDx_NSCLC_CDx_Elevated_TMB.pdf.


\textsuperscript{140}Hingorani, Aroon et al. (11 December 2019), “Improving the odds of drug development success through human genomics: modelling study”, available at https://www.nature.com/articles/s41598-019-54849-w.

clinical trials after only one year of pre-clinical research, compared to the industry average of five years.\textsuperscript{142}

78. The potential cost savings on drug development from leveraging genomic data are set out in Figure 1. Based on the current 10 percent chance of clinical success, the estimated total out-of-pocket (OOP) cost to successfully develop one new drug is €1.634 billion. This includes all costs for successful and failed investigational products from pre-clinical testing through clinical testing. The majority of this cost (€1.275 billion or 78 percent) is incurred during the clinical testing phase, where for each successfully commercialized drug, approximately 10.4 candidates are required to start clinical testing. To reach that threshold, approximately 29.4 pre-clinical investigational candidates are required. When the chance of clinical success is raised to 25 percent, the total OOP reduces to €854 million. To achieve one successful drug, an average of four candidates are required for clinical testing, and an average of 11.4 pre-clinical investigational candidates are required. When the chance of clinical success is 80 percent (the potential success rate afforded by the use of linked genomic data), total OOP costs are further reduced to €502 million per drug. To achieve one successful drug, an average of 3.6 pre-clinical investigational candidates are required, which leads to an average of 1.3 candidates beginning clinical testing. The difference between the current world and a world in which researchers have full access to all benefits reaped from linked genomic data may thus be as high as a savings of \textbf{€1 billion} per new drug brought to market. Such savings could either be reinvested in increased R&D or passed on to consumers and health systems in the form of lower drug prices.\textsuperscript{143}


79. Linked genomic datasets therefore have the potential to substantially reduce R&D costs. If, however, linked genomic datasets containing records of EU patients were prohibited from being shared with third countries where pharmaceutical R&D is occurring, then those R&D functions may not be fully optimized.

80. Due to the probabilistic nature and high risks of pharmaceutical development, the potential cost savings are extremely sensitive to even small changes in the chance of success at each stage of clinical research. Therefore, by restricting access to a large pool of genomic data and thus potentially reducing the chance of success at multiple stages of the development process, a potential ban on exporting EU patients’ medical information may substantially reduce the overall chance of success, thus increasing the required number of pre-clinical investigational candidates and OOP costs.

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144 The chance of clinical success is a joint probability, i.e. it depends on the chance of Phase I success times the chance of Phase II success times the chance of Phase III success times the chance of submission success. Joint probabilities decrease very rapidly - for example, while the probability of getting one head from a coin flip is 50 percent, the joint probability of getting two heads from two coin flips is only 25 percent (because \( \frac{1}{2} \times \frac{1}{2} = \frac{1}{4} \).
81. Another method for estimating the lost value caused by a potential ban on international pharmaceutical companies’ access to EU patients’ genomic data is through the market value of such datasets based on recent real-world transactions. Financial firms and pharmaceutical companies have valued genomic datasets at approximately €1,700 per DNA sample, and genomic data linked to health data has been valued as high as €5,600 per patient record. If the EU reaches its current objective of sequencing 1 million people by 2022, and assuming the current valuations hold, this dataset could be worth between approximately €1.7 billion and €5.6 billion. Importantly, however, the current valuations are based on the state of the world in which international data flows are not substantially restricted. If only a fraction of pharmaceutical companies (i.e. those within the EEA) will be able to access EU patients’ genomic and health data, this value could be reduced.

82. Finally, in addition to the monetary impacts described above, a potential exclusion of EU trial participants or EU data from international (non-EEA) R&D could even stifle the number of diseases for which a treatment is discovered and the effectiveness of treatments that are developed. A substantially reduced pool of potential trial participants (and potential impacted patients) could be bad news for many diseases, but the effect would be particularly pronounced in the case of so-called rare diseases. Such diseases affect a relatively small number of people, and it is therefore difficult to collect enough data to do the relevant research even when pooling information from all patients or clinical trial participants worldwide. If the data of EU patients is removed from such research, this could result in the R&D ceasing to have economies of scale, and such research may therefore need to be halted. With thousands of rare diseases identified to date, the World Health Organization has estimated that approximately 30 million EU patients may suffer from a rare disease, and these patients may be negatively impacted by a delay in researching therapies as a result of a ban on data sharing.

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148 With 448 million people in the EU, there may be as many as 224,000 people affected by each “rare disease” (i.e. 448 million * 5 / 10,000).

IV. Conclusion

83. In this report, we estimated the potential economic impact that restrictions on cross-border flows of personal data may have on European consumers and businesses. Our research has shown that a policy restricting personal data flows may have substantial economic consequences.

84. Across telecommunications, digital payments, global services outsourcing, and pharmaceutical R&D, the quantifiable harm that could be caused by restricting personal data flows is significant. Moreover, due to the extensive use of data and personal data in many other industries, the case studies described in this report serve only as examples of the types and magnitudes of impact of a policy that restricts the transfer of personal data to third countries. The true impact on the European economy may be substantially larger.
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V. Methodology annex

A. Telecommunications

1. PAYG plan cost analysis

   Payne price sampling was collected from a common review website of 2020 US prepaid SIM cards, and the number of European travellers was collected from the EC’s Eurostat portal. The Payne price data included 47 observations across 10 mobile providers; the full range of options was included for each provider.

   Prices were assumed to be reported in 2020 US dollars and ranged from $8.00 to $60.00.

   2020 US dollars were converted to 2020 Euros using the average USD/EUR exchange rate for the year 2020: 1.142 USD / 1 EUR.

   Summary statistics were calculated to include the following: lower 10th percentile, median, and upper 10th percentile, resulting in prices of €10.86, €25.39, and €48.16, respectively.

   The EC reported 94,322,458 trips taken by EU residents to destinations outside the EU in 2018 (the most recent data available).

   Cost to consumers (lower 10th percentile): €10.86 * 94,322,458 = €1,024,166,795 ≈ €1 billion.

   Cost to consumers (median) €25.39 * 94,322,458 = €2,395,228,795 ≈ €2.4 billion.

   Cost to consumers (upper 10th percentile) : €48.16 * 94,322,458 = €4,542,675,300 ≈ €4.5 billion.

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B. Digital payments and commerce

1. Potential impacts if EU consumers are unable to provide their payment information to merchants in third countries

i. Immediate-term analysis

2. The volume of transactions where EU consumers were ordering by card from merchants with non-EU-based banks was collected from the European Central Bank (ECB).\(^{155}\)

   a. Volume of transactions across all EU countries in 2019: €46.65 billion

   b. Per-day value: €46.7 billion / 365 = €128 million

ii. Long-term analysis

3. Three scenarios were considered to illustrate the potential long-term impact under different assumptions on the proportion of current imports from third countries that would be irreplaceable with EU-based products and services:

   a. If the proportion of current imports that are irreplaceable is \textbf{25 percent}, then the value of card payments that would have happened without product innovation from outside the EU in 2019 is €46.7 billion (Step 2) / 1.25 = €37.3 billion, and the transaction volume lost would be €46.7 billion - €37.3 billion = \textbf{€9.3 billion}.

   b. If the proportion of current imports that are irreplaceable is \textbf{10 percent}, then the value of card payments that would have happened without product innovation from outside the EU in 2019 is €46.7 billion (Step 2) / 1.10 = €42.4 billion, and the transaction volume lost would be €46.7 billion - €42.4 billion = \textbf{€4.2 billion}.

   c. If the proportion of current imports that are irreplaceable is \textbf{1 percent}, then the value of card payments that would have happened without product innovation from outside the EU in 2019 is €46.7 billion (Step 2) / 1.01 = €46.2 billion, and the transaction volume lost would be €46.7 billion - €46.2 billion = \textbf{€0.5 billion}.

4. To approximate the proportion of current imports from third countries that would be irreplaceable with EU-based products/services, the relative product innovativeness of companies in the EU and that of its main trading partners (the US and China) were used. Innovation ratios among the EU, the US, and China were collected from three sources:

   a. First, the EC’s “European Innovation Scoreboard 2020”\(^{156}\) contained several metrics about innovation, of which the four most relevant to product innovation were selected. (Figures in parentheses indicate page number.)

\(^{155}\) The data series is titled “Value of cross-border card payments - with cards issued by resident PSPs - from [each EU country] - to outside EU”, and it includes “cards issued by resident PSPs, all cards except e-money function”. See European Central Bank Statistical Data Warehouse, “Transactions per type of payment service”, available at https://sdw.ecb.europa.eu/browse.do?node=9691547.

i. For the first two metrics, “SMEs with product or process innovation”\textsuperscript{157} and “PCT patent applications”,\textsuperscript{158} the report contained the 2019 score for EU companies (p. 83). For US and Chinese companies, the report contained only their “performance in 2019 relative to EU in 2012” (p. 93). Therefore, to compare their performance in 2019, we first calculated the EU’s 2012 performance based on the available performance change (p. 84). To calculate the US:EU and China:EU ratios, we divided the respective scores.

ii. For the second two metrics, “Total early-stage entrepreneurial activity”\textsuperscript{159} and “Number of unicorns”\textsuperscript{160}, the report contained the values for the EU, the US, and China (p. 32). To calculate the US:EU and China:EU ratios, we divided the respective values.

b. Second, the European Commission’s “2020 EU Industrial R&D Investment Scoreboard”\textsuperscript{161} analysed “the 2500 companies that invested the largest sums into R&D worldwide in 2019” (p. 1).

i. The report contained the number of companies that were among the top 2500 companies worldwide with the highest R&D spending in 2019, for each country (p. 21). There were 421 companies from the EU, 536 from China, and 775 from the US. To calculate the US:EU and China:EU ratios, we divided the respective values.

ii. The report also contained the growth in corporate R&D spend in 2019 (p. 1). This was 5.6 percent in the EU, 10.8 percent in the US, and 21 percent in China. To calculate the US:EU and China:EU ratios, we divided the respective values.

c. Third, McKinsey’s “Innovation in Europe” discussion paper\textsuperscript{162} from October 2019 contained each region’s private investment in R&D as a proportion of the global total (p. 2). This was 19 percent in the EU, 24 percent in China, and 28 percent in the US. To calculate the US:EU and China:EU ratios, we divided the respective values.

\textsuperscript{157} “SMEs with product or process innovation” measures the proportion of SMEs in a country “who introduced at least one product innovation or process innovation either new to the enterprise or new to their market”. This metric can be used as a measure of product innovation, assuming a linear relationship between the number of innovative SMEs and total innovative products in a country. For China, this metric was not available. See European Commission (23 June 2020), “European Innovation Scoreboard 2020”, available at https://ec.europa.eu/docsroom/documents/42981.


\textsuperscript{159} “Total early-stage entrepreneurial activity” (TEA) measures “the share of the adult population aged 18-64 years who are in the process of starting a business (a nascent entrepreneur) or who started a business which is not older than 42 months at the time of the respective survey (owner-manager of a new business).” This metric can be used as a measure of product innovation assuming a linear relationship between the number of entrepreneurs in start-ups and total innovative products in a country. See European Commission (23 June 2020), “European Innovation Scoreboard 2020”, p. 11, available at https://ec.europa.eu/docsroom/documents/42981.

\textsuperscript{160} “Unicorns” are start-ups with a value of more than USD1 billion. This metric can be used as a measure of product innovation as widely successful start-ups typically have novel product offerings with which they entice customers. See European Commission (23 June 2020), “European Innovation Scoreboard 2020”, available at https://ec.europa.eu/docsroom/documents/42981.


5. In total, we collected seven indicators from three sources,\textsuperscript{163} resulting in a basket of 13 innovation ratios between the EU and either the US or China (shown in Table 6).\textsuperscript{164} All 13 innovation ratios were above 1.26, indicating that both the US and China were at least 26 percent more innovative than the EU across all seven metrics.

<table>
<thead>
<tr>
<th>Metric</th>
<th>US:EU ratio</th>
<th>China:EU ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>SMEs with product or process innovation</td>
<td>1.52</td>
<td>n/a</td>
</tr>
<tr>
<td>PCT patent applications</td>
<td>3.29</td>
<td>2.69</td>
</tr>
<tr>
<td>Total early-stage entrepreneurial activity</td>
<td>2.33</td>
<td>1.43</td>
</tr>
<tr>
<td>Number of unicorns</td>
<td>8.22</td>
<td>4.41</td>
</tr>
<tr>
<td>Private investment in R&amp;D as proportion of global total</td>
<td>1.47</td>
<td>1.26</td>
</tr>
<tr>
<td>Number of companies among top 2500 companies worldwide with highest R&amp;D spend</td>
<td>1.84</td>
<td>1.27</td>
</tr>
<tr>
<td>R&amp;D spend growth</td>
<td>1.93</td>
<td>3.75</td>
</tr>
</tbody>
</table>

Sources:

2. Potential impacts if EU consumers are unable to provide their payment information to third country-based ECSPs in the EU

   i. Immediate-term analysis

6. To estimate the volume of transactions conducted via digital wallets, we first collected data on the total in-store and online transaction volume in Europe.

\textsuperscript{163} Four from the ‘European Innovation Scoreboard 2020’, two from the ‘2020 EU Industrial R&D Investment Scoreboard’, and one from the ‘Innovation in Europe’ discussion paper.

\textsuperscript{164} There are 13 innovation ratios because there are two (one with the US and one with China) for each of the seven metrics, except for “SMEs with product or process innovation”, which was not available for China.
a. To estimate in-store (i.e. offline) transaction values, we collected data on the values of domestic point-of-sale (POS) transactions in Europe in 2019 from Statista\(^\text{165}\) and removed all European countries that were not part of the EU in 2019. The EU 2019 summed total value = €5,780 billion.

b. To estimate online transaction values, we collected data from PostNord’s “E-commerce in Europe 2020” report.\(^\text{166}\) Based on interviews with a total of approximately 12,800 European consumers, PostNord estimated the total value European consumers spent online in 2019 as €269 billion.\(^\text{167}\)

7. Second, we collected data on the proportion of in-store and online payments that can be attributed to US-based digital wallets (Apple Pay, Google Pay, and PayPal in particular).

a. Payments Europe published a report in December 2019 based on research conducted by FTI Consulting, titled “Cards in the Evolving European Payments Landscape”.\(^\text{168}\) The report found that consumers use Apple Pay or Google Pay for 3 percent of both their in-store spend and their online shopping. (See page 5.)\(^\text{169}\)

b. The PostNord report “E-commerce in Europe 2020” included the “most popular online payment methods” in each country. Averaging across all European countries in the study, we found that 30.4 percent of people chose “PayPal or similar”. (See page 25.)\(^\text{170}\) While the report does not detail what payment services are covered under “or similar”, we assume that it incorporates other digital wallets, i.e. Apple Pay and Google Pay.

c. Therefore, considering Apple Pay and Google Pay only, 3 percent of in-store shopping and 3 percent of online shopping is conducted via these digital wallets. Considering PayPal as well, 3 percent of in-store shopping and 30.4 percent of online shopping is conducted via these digital wallets.\(^\text{171}\)

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\(^{167}\) The interviews were conducted with consumers in Belgium, Denmark, Finland, France, Germany, Italy, the Netherlands, Norway, Poland, Spain, Sweden, and the UK (over 1000 respondents in each country). The online shopping estimate is conservative, as it includes only physical products, not services (e.g., travel, hotel, tickets) or downloads (e.g., movies, music, apps). See Postnord, “E-Commerce in Europe 2020”, p. 2 and p. 8, available at https://www.postnord.com/siteassets/documents/media/publications/e-commerce-in-europe-2020.pdf.


\(^{169}\) The research included a survey completed by 3,120 consumers in France, Germany, Italy, Poland, Sweden, and the UK (520 in each country) between September 5-20, 2019. The responses answered the questions “How would you divide the following methods you use to make payments in-store?” and “How would you divide the following methods you use to make payments online?”

\(^{170}\) The responses answered the question “Which of the following methods do you prefer to use when paying for a product you have bought online?” We note that by taking the simple average across the countries, the analysis assigns equal weight to all countries regardless of population size or online shopping penetration.

\(^{171}\) We note that this scenario assumes that PayPal’s in-store market share is close to zero. This is likely a conservative underestimate. However, it appears to be correct that PayPal’s in-store share is considerably less than its online presence. According to a McKinsey report published in January 2020, while PayPal has the highest penetration online (over 40 percent), it is not even among the top three for in-store shopping. See McKinsey & Company (January 2020), “McKinsey on Payments”, p. 26, available at https://www.mckinsey.com/~/media/Mckinsey/Industries/Financial%20Services/Our%20Insights/McKinsey%20on%20Payments%2030/McK_on_Payments_30.ashx.
d. By multiplying in-store and online transaction values in Europe in 2019 by the share of mobile/digital wallets, we found that considering Apple Pay and Google Pay only, €173 billion was spent using these wallets in-store, and €8 billion online. Considering PayPal as well, the online spend was €82 billion.
e. The daily spend using mobile/digital wallets was €497 million considering Apple Pay and Google Pay only, and €699 million considering PayPal as well.

ii. Long-term analysis

8. To estimate the additional consumer spend facilitated by the presence of mobile payments, we collected data on the percentage increase in total spending by consumers due to mobile payments.

   a. Xu, Ghose, and Xiao's 2019 study found that “mobile payment adoption leads to a 2.93 percent increase in total transaction amount” (across both online and in-store channels).172,173
   
   b. Total transaction volume that would have taken place without the “boost” from the mobile payment option: €6,049 billion174 / (1 + 2.93 percent) = €5,877 billion.
   
   c. Volume of transactions that would not have taken place without the mobile payment option: €6,049 billion – €5,877 billion = €172 billion.

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174 The total transaction volume in Europe for 2019 is the sum of €5,780 billion in-store and €269 billion online purchases.
C. Global services outsourcing

1. Labour market inputs

9. Labour market estimates for the global services outsourcing industry have been taken from industry reports by Everest Group, a consulting firm specializing in IT, business process, and engineering services. Wage information was taken from CloudTask, a B2B lead generation service.

a. To estimate the total number of offshored jobs in 2020 we applied a constant, annual growth rate of 500,000 jobs to the total 2016 offshored jobs of 5.9 million $= 5.9 \text{ million} + (500,000 \times 4) = 7.9 \text{ million}$ jobs.\(^{175}\)

b. Jobs were distributed across the following geographies: APAC (69 percent), LAC (10 percent), CEE (15 percent), Other (6 percent).\(^{177}\)

c. We assume that the geographic distribution of offshore employees is the same across all firms that decide to offshore services.

10. Next, we calculated a ‘blended hourly wage’ for contact centre jobs in different geographies.

a. CloudTask provided wage ranges split by geography. Where the wages were available at the regional level (i.e. LAC, CEE, etc.), the arithmetic mean of the wage range for each region was selected as its blended hourly wage. Where data were available at the country level, we calculated the blended hourly wage for the region as a weighted average of the country level wages.\(^{178}\)

b. Illustrative example:

i. Wage data were available for both India and The Philippines, which both fall under APAC.

ii. Within the APAC geographical region, 65 percent of outsourced jobs are located in India and 30 percent are located in The Philippines, with the remaining 5 percent distributed among other countries in the region.

iii. The hourly wage for a call centre in India is €6.6 (range: €4.9 - €8.2).

iv. The average hourly wage for a call centre in The Philippines is €9.0 (range: €6.6 - €11.5).

v. The weighted average of hourly labour costs in APAC (assumed 70:30 split between India and The Philippines for simplicity) is thus €7.3.

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\(^{176}\) This is also broadly in line with other sources which estimate around 8 million outsourcing jobs as of 2020. See AsiaNews.it (1 April 2020), “Four million jobs outsourced to India threatened by coronavirus”, available at http://www.asianews.it/news-en/Four-million-jobs-outsourced-to-India-threatened-by-coronavirus-49721.html.

\(^{177}\) Everest Group (June 2017), "Global Locations Annual Report 2017: Signs of Structure in a Disordered World", available at https://www2.everestgrp.com/Files/previews/Everest%20Group%20-%20Global%20Locations%20Annual%20Report%202017-%20Preview%20Deck.pdf. Also, according to AgileEngine, a software outsourcing company, of the total number of outsourced software developer jobs in the top 14 outsourcing countries, 70 percent of the outsourced software jobs are in APAC, 17 percent are in CEE, and 13 percent are in LAC, which is in line with the Everest Group report. See AgileEngine (12 June 2018), “Top Outsourcing Destinations To Watch in 2018”, available at https://agileengine.com/top-outsourcing-destinations.

c. Due to the ready availability of data, contact centre wages were used for all hourly wages. This likely underestimates the cost of offshored labour, since other offshored jobs, such as IT services, require advanced skills and thus will command higher wages than contact centre jobs.

d. Calculated blended hourly wage rates were: APAC (€7.3), LAC (€10.6), CEE (€15.1), Western Europe (€32.8), Other (€17.4).

11. We assumed that all employees work 40 hours per week for 50 weeks per year = 2,000 annual hours, regardless of geography. The estimated annual salary for an outsourced job, by geography: blended hourly wage * 2,000 hours.

12. The total number of offshored jobs in each geography: worldwide total (7.9 million) * share of jobs in each geography. The values were as follows: APAC (5,411,500), LAC (790,000), CEE (1,185,000), Other (474,000). The total cost of the outsourced labour force, by each geography is calculated as annual salary * number of jobs; we then sum across all geographies to obtain the total cost of outsourced labour force = approximately €148 billion.

13. The Everest Group indicates that the EU comprises 28 percent of the demand for outsourcing services.\(^\text{179}\)

14. EU offshoring labour cost: €148 billion * 28 percent = €41.5 billion.

15. If no personal data could leave the EEA, European companies would likely back-shore services to the continent. We consider two potential outcomes:

a. All offshored jobs are back-shored to Central Europe.

i. Under one extreme, all jobs currently outsourced by EU companies to third countries are back-shored to CEE countries in the EEA, where labour costs are cheaper than in Western Europe.

ii. Total labour costs under this outcome:

- 7.9 million jobs * 28 percent * 2,000 hours * €15.1 = €67.0 billion, approximately €25.5 billion more than current costs.

b. All offshored jobs are back-shored to Western Europe.

i. Under the other extreme, all jobs currently outsourced by EU companies to third countries are back-shored to Western Europe (with EU jobs currently outsourced to the CEE region remaining in the CEE region).

ii. Total labour costs under this outcome:

7.9 million jobs * 28 percent * 2,000 hours * (85 percent * €32.8 + 15 percent * €15.1) = €133.2 billion, approximately €91.7 billion more than current costs.

D. Pharmaceutical research and development

1. COVID-19 calculations

16. Unadjusted Q1 - Q4 2019 GDP data and estimated 2020 GDP losses were collected from Eurostat.\textsuperscript{180} GDP data for the 27 EU countries were used; these data exclude contributions from the UK to the EU GDP.

   b. 2020 EU GDP loss = 6.1%.
   c. 2020 EU GDP was calculated as: \( (100\% - 6.1\%) \times €13,695,411 = €13,113,549 \) million.
   d. 2020 EU GDP lost per month was calculated as: \( €13,113,549 \) million - \( €13,695,411 \) million = \( -851,892 \) million / 12 months = \( €70,991 \) million per month = approximately \( €70 \) billion per month.

2. Value of clinical trial data

17. Global clinical trial market size was collected from a recent market research report.\textsuperscript{181} The percentage of the market attributable to EU clinical studies was collected from clinical trial registries.\textsuperscript{182}

   a. The global clinical trial market value of $44 billion was assumed to be in 2020 US dollars.\textsuperscript{183}
   b. Market value was converted to 2020 Euros by using the average USD/EUR exchange rate for the year 2020: 1.142 USD / 1 EUR\textsuperscript{184} = €38.53 billion.
   c. EU clinical trial market size was calculated as the total EU clinical trials divided by global registered clinical trials.
      i. 366,534 registered clinical trials globally
      ii. 105,185 registered clinical trials in the EU (including the UK)
      iii. 19,623 registered clinical trials in the UK


d. EU clinical trial market size was calculated as: \( \frac{105,185 - 19,623}{366,534} = 23.3 \text{ percent} \).
e. EU clinical trial market value was calculated as: \( €38.53 \text{ billion} \times 23.3 \text{ percent} = €8.9 \text{ billion} \).

3. Research and development cost model

18. The cost model for pharmaceutical R&D costs was reconstructed based on a previously published R&D model from Eli Lilly and Company.\(^{185}\)

a. Costs were inflated from 2008 US dollars to 2020 US dollars using US Consumer Price Index data. Inflator value: 1.202.\(^{186}\)
b. 2020 US dollars were converted to 2020 Euros by using the average USD/EUR exchange rate for the year 2020: 1.142 USD / 1 EUR.\(^{187}\)
c. Probabilities of clinical success were updated using the updated data based on Figure 1 from a Bio.org report.\(^{188}\)
d. Model probabilities for pre-clinical success were not changed.
e. Model cycle times (the length of time to complete one phase of research) were not changed.
f. Capitalized costs were excluded from the analysis.
g. Outputs were limited to OOP costs and the number of investigational work products needed for one successful drug entry.

4. Cost model analyses

19. Three sets of inputs were used to create the cost model outputs presented in the report.

a. The first input set consisted of the base case inputs described in Section 3 above.
b. The second input set changed the probability of clinical success to the values provided in Figure 9 from a Bio.org report.\(^{189}\) These values reflected the likelihood of overall clinical success for clinical research where patient targeting based on genomics was conducted. These were the closest values found for the current value of genomic data in R&D.
c. The third input set used the upper limit of clinical success projected by a mathematical modelling paper by Hingorani 2019 (Table 4, pg. 19).\(^{190}\) To achieve an 80 percent success in clinical study, the probability of per-phase success was set to 94 percent across all four phases of clinical research (94 percent\(^4\) = 78 percent). This input set represents the

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\(^{186}\) Federal Reserve Bank of St. Louis (2021), “Consumer Price Index for All Urban Consumers: All Items in U.S. City Average”, available at https://fred.stlouisfed.org/series/CPIAUCSL#0.


maximum likelihood of overall clinical success as currently predicted by the published literature.

5. Market value of genomic data

20. The market value of genomic data was collected from a report produced by Ernst & Young (EY), and the potential market size was collected from an EC report.

a. The EY report had values of £1,500 per sample for genomic data, and up to £5,000 per record for linked genomic data (pg. 12).

b. Costs in the report were converted from British pounds to Euros using the average GBP/EUR exchange rate for the year 2020: 1 GBP / 1.128925 EUR.

c. Per sample genomic data: £1,500 * 1.128925 = €1693.38 = approximately €1,700.

d. Per record linked genomic data: £5,000 * 1.128925 = €5,644.25 = approximately €5,600.

e. The EC report projects 1,000,000 genomes sequenced by 2022.

f. Lower value of potential genomic data in EU: €1,700 * 1,000,000 = €1.7 billion.

g. Upper value of potential linked genomic data in EU: €5,600 * 1,000,000 = €5.6 billion.

6. Phases of pharmaceutical R&D

21. Figure 2 shows the two phases of R&D. The pre-clinical phases are in yellow, while the clinical phases are in blue.

![Figure 2: Phases of pharmaceutical R&D](image)

Source:

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