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Privacy Regulation and R&D Investments

CAUSAL EVIDENCE FROM GLOBAL PHARMACEUTICAL AND BIOTECHNOLOGY FIRMS

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Abstract

This paper examines the effects of data privacy regulation on R&D investment in the pharmaceutical and biotechnology sectors. In these industries, access to personal health data is essential for innovation, particularly in clinical research. Leveraging a firm-level panel of the world's top R&D investors from 2013 to 2023, we exploit the staggered implementation of major data protection regimes to estimate their causal impact. Using a dynamic event-study design, we find that stricter privacy regulation leads to a significant decline in R&D spending. By year four after implementation, treated firms reduced R&D investment by approximately 39 percent. The effects are heterogeneous: firms without foreign affiliates and small and medium-sized enterprises experience larger declines. Our findings suggest that privacy regulation may constrain the foundations of data-driven innovation and shape the geographic distribution of R&D activity.

Tiivistelmä

Tietosuojasääntelyn vaikutukset lääketeollisuus- ja bioteknologiayritysten t&k-investointeihin

Tämä tutkimus tarkastelee henkilötietojen suojaa koskevan sääntelyn vaikutuksia tutkimus- ja kehitysinvestointeihin lääke- ja bioteknologiasektoreilla. Nämä alat ovat erityisen riippuvaisia henkilötietojen, kuten potilastietojen, saatavuudesta innovaatiotoiminnassaan. Hyödynnämme yritystason paneeliaineistoa, joka kattaa maailman suurimmat t&k-investoijat vuosina 2013–2023. Analysoimme sääntelyn kausaalivaikutuksia yritysten t&k-panostuksiin hyödyntäen eri maiden sääntelytoimien ajoituksessa ilmenevää heterogeenisuutta. Estimointitulokset osoittavat, että tiukempi tietosuojasääntely vähentää merkittävästi dataintensiivisten yritysten t&k-investointeja. Neljä vuotta sääntelyn voimaantulon jälkeen sääntelyn kohteena olevien yritysten t&k-menot olivat laskeneet keskimäärin noin 39 prosenttia. Vaikutukset eivät kuitenkaan ole yhtenäisiä: erityisesti yritykset, joiden toiminta rajoittuu tiukan tietosuojasääntelyn maihin sekä pienet ja keskisuuret yritykset vähensivät t&k-panostuksiaan muita enemmän. Tulokset viittaavat siihen, että yksityisyyden suojaa vahvistava sääntely voi rajoittaa dataan perustuvan innovaatiotoiminnan edellytyksiä ja vaikuttaa t&k-toiminnan maantieteelliseen sijoittumiseen.

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Keywords: Privacy regulation, R&D investment, Innovation, Pharmaceuticals, Biotechnology, Firm-level panel, GDPR, Compliance costs

Asiasanat: Tietosuojasääntely, T&k-investoinnit, Innovaatiot, Lääkeala, Bioteknologia, Yritystason paneeliaineisto, GDPR, Sääntelyn noudattamisen kustannukset

JEL: D22, K23, L65, O32, O38

1. Introduction

In recent years, the global policy landscape has shifted toward stricter privacy protection, reflecting both the intrinsic value of privacy and the growing economic and strategic importance of personal data. Governments across jurisdictions have implemented or expanded privacy legislation to strengthen individual protection against corporate surveillance, algorithmic profiling, and the international transfer of personal data. While such regulations aim to safeguard individual rights, they also impose constraints on how firms collect and process data, potentially affecting innovation incentives, particularly in sectors where personal data is a critical input to R&D and product development.

The pharmaceutical and biotechnology sectors are especially exposed to regulatory constraints on the use of personal data. Clinical research in these sectors depends heavily on patient-level information, making privacy regulation particularly consequential. Clinical trials also account for the largest share of R&D spending in these industries (DiMasi et al., 2016). Europe's share of global commercial clinical trials declined from 22% in 2013 to just 12% in 2023, a drop corresponding to approximately 60,000 fewer trial participants compared to 2018 (Cookson, 2024). This decline coincided with the introduction of the European Union's General Data Protection Regulation (GDPR). The regulation significantly increased compliance obligations and restricted access to sensitive health data both within the EU and EEA (which comprises the EU member states as well as Norway, Iceland, and Liechtenstein) and beyond their borders.

In addition to restricting data access, privacy regulation imposes compliance costs that require firms to invest in legal, technical, and organizational infrastructure. These burdens may, in turn, shape firms' strategic choices around resource allocation and innovation investment. Although much of the documented disruption from GDPR has concerned publicly funded health research, including thousands of international projects reportedly affected (Gourd, 2021), similar challenges have been observed in the private sector. Restrictions on cross-border transfers of health data and legal uncertainty surrounding secondary data use have affected biobanks, research consortia, and industry-led infrastructures alike (Peloquin et al., 2020). These constraints may also limit the flexibility of pharmaceutical and biotechnology firms operating in globally integrated R&D environments. This paper investigates the causal effect of

data privacy regulation on R&D investment among pharmaceutical and biotechnology companies that rank among the world's top corporate R&D investors.

Interestingly, while Europe experienced a decline in its overall share of global clinical trials, the share of new trials classified as multi-country increased within the EEA—from 29% in 2013 to 35% in 2023—contrary to trends observed in most other major regions, including Asia and the rest of Europe. One possible interpretation is that, rather than reducing clinical trial activity outright, GDPR has encouraged firms to reorganize geographically, preserving regulatory compliance within the EU while expanding recruitment and data collection in jurisdictions not covered by EU-style data protection. These patterns raise broader concerns about how privacy regulation may influence the geography of innovation and the distribution of R&D investment across borders.

Leveraging a firm-level panel derived from the *EU Industrial R&D Investment Scoreboard*, we construct a dataset of the world's top R&D-investing pharmaceutical and biotechnology firms over the period 2013–2023. We exploit the staggered adoption of major data privacy regimes, including the EU's General Data Protection Regulation (GDPR) and comparable frameworks enacted in South Korea and Japan, to estimate their causal impact on firms' R&D investment. To identify these effects, we implement a dynamic event-study specification that traces firm-level responses in the years before and after regulatory implementation.

We find that the introduction of strict data privacy regulation leads to a substantial decline in R&D investments among pharmaceutical and biotechnology firms. Four years after implementation, R&D spending fell by approximately 39% relative to pre-regulation levels. The effects are significantly larger for firms with limited geographic flexibility and for small and medium-sized enterprises (SMEs), indicating that both cross-border operational capacity and compliance resources mitigate regulatory burden. Consistent with these findings, we observe no comparable effects in non–data-intensive industries.

Our study contributes to several strands of literature. First, it adds to a growing body of research on the *firm-level economic consequences* of data protection regulation (see Johnson, 2024, for a recent review). A number of recent studies document the negative effects of the GDPR on firm outcomes such as profits, revenue, investment, market entry and exit. For example, Demirer et al. (2024) show that GDPR significantly reduced data usage among EU firms, while Goldberg et

al. (2024) find declines in online activity and e-commerce revenue, particularly among small firms relying on personalized marketing. Jia et al. (2025) report that these frictions extended to capital markets, reducing US venture capital investments in EU-based, data-intensive startups. Blind et al. (2023) find that the GDPR shifted firm behavior from radical to incremental innovation, particularly in small and knowledge-intensive firms. These effects are reinforced by evidence on increased compliance costs and reduced economic dynamism in digital sectors (Koutroumpis et al., 2022; Janssen et al., 2022). Our study complements this literature by examining how privacy regulation affects a key innovation input, R&D investment, among firms for which personal data is central to the research process.

Second, this paper contributes to the literature on the determinants of firms' R&D investments and innovation strategy. Prior research has shown that firms' innovation decisions respond to factors such as uncertainty (e.g., Bloom, 2007), regulatory constraints (e.g., Blind, 2012; Aghion et al., 2023), competition (Aghion et al., 2005) and expected returns and market size (e.g., Acemoglu & Linn, 2004). Our analysis complements this literature by examining how data privacy regulation affects firms' R&D investments in pharmaceuticals and biotechnology sectors where compliance obligations and personal data play a central role.

Third, this paper contributes to the broader literature on regulation and innovation, which examines how institutional constraints affect not only the level but also the allocation of innovative activity across firms and geographies (Aghion et al., 2023; Blind, 2012). The broader literature, including the work by Blind (2012), highlights the ambivalent effects of regulation showing that rules can both stimulate and hinder innovation depending on compliance costs, incentive structures, and the regulatory framework. These effects extend to how innovation activities are distributed across firms and regions. While our study does not directly observe the relocation of R&D, we find that the negative effect of privacy regulation is significantly larger among firms with limited geographic flexibility. This suggests that the ability to reorganize innovation activities internationally may help mitigate regulatory burdens. Our findings thus offer indirect evidence that heterogeneous data privacy regimes can influence the geography of innovation by affecting firms differently depending on their cross-border operational capacity.

In sum, this paper provides novel firm-level evidence on how data privacy regulation affects R&D investment in data-intensive sectors. Our findings highlight data access and mobility as

critical channels through which regulation shapes innovation incentives, particularly in data-intensive sectors such as pharmaceuticals and biotechnology.

The remainder of the paper is structured as follows. Section 2 provides institutional background on the pharmaceutical and biotechnology sectors and reviews the evolution of privacy regulation in the EU, South Korea, and Japan. Section 3 introduces the conceptual framework. Section 4 describes the data and sample construction. Section 5 outlines the empirical strategy. Section 6 presents the empirical results, including heterogeneity analyses and robustness checks. Section 7 concludes with a discussion of policy implications and directions for future research.

2. Industry context and institutional background

2.1 R&D in pharmaceutical and biotechnology industries

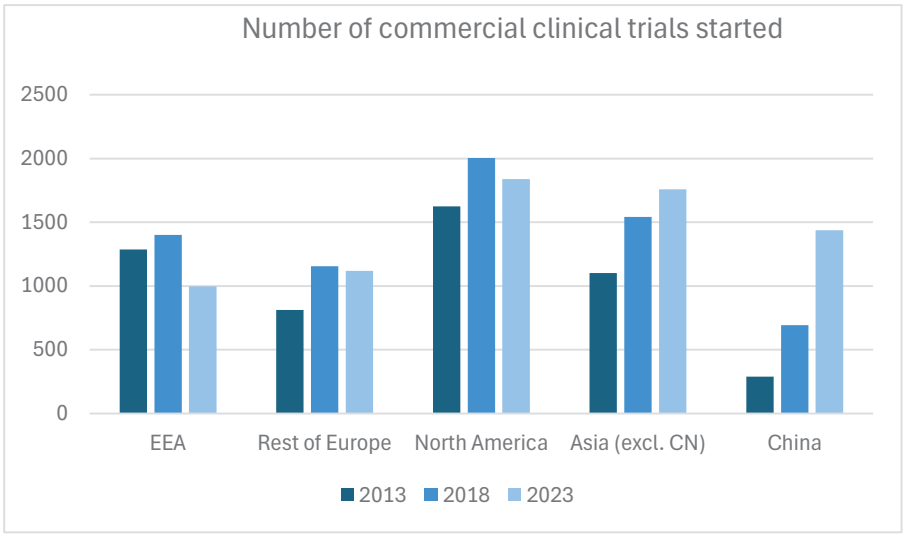
The pharmaceutical and biotechnology industries are among the most R&D-intensive sectors globally, with firms routinely investing over 15% of their annual revenues in research and development. Their innovation capacity depends heavily on firms' ability to generate, access, and share personal health data. According to the European Federation of Pharmaceutical Industries and Associations, R&D expenditures have increased substantially over the past decade, particularly in the United States and China. Between 2010 and 2022, pharmaceutical R&D spending grew by 85% in the United States (from €38.6 billion to €71.5 billion) and by 68% in Europe (from €27.9 billion to €47.0 billion).[1] China experienced the most dramatic growth over this period, with R&D expenditure rising by over 750%, albeit from a much smaller base.

According to estimates by DiMasi et al. (2016), clinical development phases account for approximately 69% of total drug development costs in pharmaceutical firms. These figures are supported by the 2023 PhRMA membership survey, which reported that 75–80% of private R&D expenditures were related to clinical development, and 48.4% specifically to clinical trials (Phases I–III). While these estimates are based primarily on pharmaceutical companies, clinical trials also represent a major investment area for biotech firms. Access to patient-level data is therefore critical across the industries. Figure 1 illustrates the global shift in clinical trial

[1] Data extracted March 29, 2025 from https://www.efpia.eu.

activity, showing how commercial trials have increasingly expanded outside the EEA and North America over the past decade.

Figure 1. Number of commercial clinical trials started, by region (2013, 2018, 2023)



Data source: FPIA & Vaccines Europe (2024)

In this context, the globalization of clinical research has gained importance. As R&D costs have increased, firms have increasingly offshored clinical trials to regions such as Eastern Europe, China, and India, where lower costs, larger patient populations, and less restrictive regulatory environments support trial activity. While offshoring is often attributed to cost savings, recent studies highlight additional drivers, including recruitment challenges in high-income countries and the scientific capacity of host regions (Kermanimojarad, 2020; Haeussler & Rake, 2017). These developments underline how cross-border data flows and global research networks have become essential to pharmaceutical R&D. At the same time, privacy regulation—such as the GDPR—may limit firms' ability to access patient data and recruit participants within the EU, potentially incentivizing the relocation of clinical research abroad.

The ability to exchange personal health data across borders is not merely a strategic concern but often a structural requirement for modern biomedical innovation. Research areas such as rare disease studies, multi-country clinical trials, and population-level comparisons rely on timely and lawful access to distributed datasets. Hallinan et al. (2021) emphasize that international data sharing is essential for producing valid, replicable, and resource-efficient research in the life sciences. Accordingly, legal constraints on the movement of personal data

may not only reduce efficiency but also affect the overall feasibility of data-intensive R&D strategies. Understanding how data-intensive firms adapt to such restrictions is key to assessing the broader impact of privacy regulation on innovation and investment.

2.2 Privacy regulation

This section reviews the key legal frameworks that define firms' ability to collect, process, and transfer personal data across borders, with a particular focus on the European Union's GDPR and subsequent similar developments in other jurisdictions. By contrast, the United States lacks a comprehensive federal law regulating the collection, use, and sale of personal information by private companies. Moreover, the United States imposes no general restrictions on cross-border personal data transfers. For multinational pharmaceutical and biotechnology firms, this regulatory environment has enabled relatively unconstrained international data flows that are often essential for multicenter clinical trials and large-scale data analysis. Consequently, the United States provides an appropriate counterfactual to jurisdictions that have implemented comprehensive privacy legislation.

EU/ETA area countries: The pharmaceutical and biotechnology industries are inherently data-intensive, relying on the collection, processing, and analysis of vast quantities of sensitive personal information including patients' medical histories, genetic data, and clinical trial outcomes. The introduction of the General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679), applicable since May 2018, marked a profound shift in the European regulatory landscape by strengthening and unifying data protection for individuals within the EU and EEA areas. Replacing the earlier Data Protection Directive 95/46/EC, the GDPR introduced a framework tying data processing to a clear legal basis and specific purpose, imposing new constraints on how research data can be collected and used.

The GDPR obligates firms to implement rigorous technical and organizational safeguards such as encryption, access controls, and breach notification systems. In pharmaceutical and biotechnology R&D, this includes obtaining patient consent for clinical trials and to use their data for research purposes. Companies must also adhere to the principles of transparency, data minimization, and individuals' rights to access, correct, or erase their data.

Because pharmaceutical and biotechnology research relies heavily on personal health data, it is especially affected by privacy regulations. The GDPR requirements increase the administrative and legal burden of conducting research in the EU. As a result, firms may find it more efficient to relocate or expand R&D activities to jurisdictions with less stringent data protection frameworks. Moreover, the risk of non-compliance and exposure to substantial fines may further incentivize re-locating data-intensive functions — such as trial data analysis, patient monitoring, or genomic research — to non-EU affiliates, particularly in countries with strong research infrastructure and more lenient regulations.

For firms engaged in clinical research, GDPR compliance constituted a structural shift that affected all stages of the R&D process from trial design and patient consent to partner coordination and data management. To ensure compliance, organizations must undertake a range of measures, such as conducting Data Protection Impact Assessments (DPIAs) and appointing Data Protection Officers (DPOs), to monitor and enforce data protection obligations. These requirements extend to non-EU firms that collect data from EU residents, thereby giving the GDPR de facto extraterritorial scope.

Although the implementation of the GDPR strengthened individual privacy and personal data protection, it also introduced significant compliance costs and legal uncertainty. Consequently, the GDPR may have created incentives for pharmaceutical and biotechnology companies active in the EU to reallocate parts of their data-intensive R&D to jurisdictions with less burdensome data protection regimes. From an institutional economics perspective, the GDPR acted as a regulatory shock that reshaped innovation costs and may also have redistributed pharmaceutical and biotechnology R&D across borders. In addition to influencing the geography of innovation, it may also have affected the expected returns to R&D by raising fixed compliance costs and extending development timelines, potentially shifting investment toward less data-intensive or lower-risk activities.

Recent evidence supports this view. Lalova-Spinks et al. (2024) document that GDPR-related restrictions, including both legal uncertainty and substantive limitations, have disrupted cross-border health research collaborations, delayed clinical trials, and increased compliance costs for data-intensive firms. The authors highlight several delayed or canceled studies, including COVID-19 trials and large-scale genomics projects.

A major regulatory shift occurred in July 2020 when the Court of Justice of the European Union (CJEU), in its *Schrems II* ruling (Case C-311/18), invalidated the EU–U.S. Privacy Shield framework. The court held that U.S. surveillance practices failed to meet the EU's standards for data protection, particularly due to insufficient legal remedies for EU citizens. Following the ruling, firms transferring personal data to the U.S. were required to conduct case-by-case assessments of the recipient country's legal landscape and implement supplementary safeguards—even when using Standard Contractual Clauses (SCCs), which remained a valid legal basis for transfer.

Prior to the ruling, over 5,300 companies had relied on the Privacy Shield to legally transfer personal data across the Atlantic, making its annulment highly disruptive for international data flows (Compagnucci et al., 2020). The enhanced obligations significantly increased compliance burdens, especially in data-intensive sectors such as pharmaceuticals and biotechnology. Cross-border clinical trials, regulatory filings, and collaborative research efforts were particularly affected, as firms navigated the complexities of aligning global operations with heightened EU privacy standards.

The Schrems II ruling triggered a chilling effect on international research collaboration. Several organizations reported delays, restructurings, or suspensions of cross-border clinical studies due to unresolved legal questions around data transfers. Hallinan et al. (2021) describe how researchers encountered growing difficulties in sharing pseudonymized datasets with partners outside the EU. Liss et al. (2021) further highlights that the ruling significantly complicated international data sharing, particularly for transatlantic collaborations, leading to the suspension of joint projects and heightened legal uncertainty for firms unable to swiftly implement adequate safeguards. The decision thus reinforced the constraints already imposed by the GDPR while introducing additional barriers to multinational R&D.

In response to the *Schrems II* ruling, the European Commission adopted the EU–US Data Privacy Framework (DPF) in July 2023. The DPF grants the United States an adequacy decision, aiming to re-establish a legal basis for transatlantic data transfers. However, Lalova-Spinks et al. (2024) highlight that despite these efforts, clinical research data transfers remain subject to uncertainty due to persistent concerns over U.S. surveillance laws and the limited enforceability of privacy rights for EU data subjects. Legal challenges to the DPF have already been filed, casting doubt on its durability as a governance mechanism for international data

transfers. For firms in data-intensive sectors such as pharmaceuticals and biotechnology, this regulatory uncertainty raises expected compliance costs, complicates long-term planning and may weaken incentives to invest in joint transatlantic research projects.

South Korea: A similar regulatory tightening occurred in South Korea with the 2020 reform of the Personal Information Protection Act (PIPA). Originally enacted in 2011, PIPA already provided a strong foundation for personal data protection, but the amendments marked a significant step toward alignment with GDPR standards. The reform enhanced enforcement authority by establishing the independent Personal Information Protection Commission (PIPC), introduced stricter rules for cross-border data transfers, clarified lawful bases for processing, and expanded data subject rights. These changes led the European Commission to grant South Korea an adequacy decision in 2021, confirming that its data protection regime offers an essentially equivalent level of protection to the GDPR.

PIPA shares many of the GDPR's core principles: it applies extraterritorially, imposes transparency and purpose limitation requirements, and mandates breach notification and accountability obligations. While enforcement has historically been less punitive than in the EU, the regulatory framework enables the imposition of substantial administrative fines up to 3% of annual revenue derived from the related business activity. The 2020 reform positioned South Korea's privacy regime as functionally convergent with GDPR-like standards, prompting firms, particularly in data-intensive sectors such as pharmaceutical and biotechnology, to adopt more robust compliance systems and incur non-trivial costs. These heightened operational requirements may, in turn, have affected not only the overall level of R&D investment but also decisions about where such activities are conducted.

Compared to the GDPR, PIPA offers more flexibility in cross-border data transfers by permitting consent-based exceptions and recognizing international agreements, while enforcement remains less aggressive. As Lim & Oh (2025) highlight, this reflects a broader distinction in regulatory philosophy: the GDPR prioritizes strict legal equivalence and extraterritorial reach, whereas PIPA balances global alignment with domestic policy objectives and business flexibility. For firms, this results in somewhat lower compliance costs under PIPA, though operational uncertainty may persist given the evolving scope of the law.

Japan: Japan's primary data protection law, the Act on the Protection of Personal Information (APPI), was originally enacted in 2003 and has since evolved through multiple reforms. While incremental steps were taken in 2017 and 2020 toward stronger privacy safeguard, such as expanding the definition of personal data and restricting cross-border transfer, the most comprehensive GDPR-style reform came into force in April 2022. This amendment introduced key features such as a formal right to erasure, mandatory breach notification, and an expanded extraterritorial scope, positioning the APPI as substantively aligned with the GDPR and significantly raising compliance expectations particularly for firms in data-intensive sectors.

Like the GDPR, the APPI has extraterritorial reach, guarantees individual rights, and imposes obligations concerning data security and third-party transfers. However, its enforcement regime has relied more on administrative guidance than on punitive measures, and statutory penalties are generally less severe than those under the GDPR.

From the perspective of pharmaceutical and biotechnology firms, compliance with the APPI entails more moderate operational costs than the GDPR. These arise from requirements related to data governance, safeguards for cross-border transfers, and the management of individual data rights. In practice, many firms implement broad internal compliance systems that go beyond legal minimums to account for institutional convergence, reputational considerations, and global risk exposure. Such investments may affect the allocation of resources across business functions, including R&D.

Compared to the GDPR, APPI takes a more flexible approach to cross-border data transfers. While the GDPR requires adequacy decisions or binding safeguards, APPI permits transfers based on individual consent or contractual terms, with less emphasis on enforcement. As Lim & Oh (2025) note, this reflects a broader difference in regulatory philosophy: the EU prioritizes legal equivalence, while Japan emphasizes transparency and business autonomy.

These regulatory differences form the basis for our empirical classification of countries into treated and control groups. A detailed description of this classification, along with the countries included in the final matched sample, is provided in Section 4.

3. Conceptual framework

We conceptualize privacy regulation as an institutional shock that raises the cost and complexity of using personal data. Analogous to Aghion et al. (2023), who show that labor regulation in France distorts firms' innovation behavior—reducing incremental but not radical innovation—data protection laws may alter R&D incentives in ways that depend on firms' innovation models and reliance on data.

Data privacy regulation alters firms' ability to access and use personal data that is an essential input in innovation processes, particularly in pharmaceutical and biotechnology companies. Stricter personal data protection regulations impose legal and technical constraints that increase the cost, complexity, and uncertainty of data-driven research and development. These frictions may discourage investment in activities where personal data is critical, such as clinical trials, patient monitoring, and secondary data analysis.

Prior studies suggest that the GDPR substantially reduced firms' ability to process and store personal data. Demirer et al. (2024) find that GDPR led to a 26% drop in data storage and a 15% decline in computation among EU firms relative to U.S. counterparts. They also report that information production costs rose by approximately 4%, disproportionately affecting smaller firms and those in data-intensive sectors. In the pharmaceutical domain, personal data plays a critical role across multiple stages of R&D, including target identification, patient stratification, and evidence generation. Restrictions on access to health data have led to operational disruptions across biobanks, consortia, and research infrastructures (see, e.g., Peloquin et al., 2020).

During the same period, Europe's broader competitiveness in pharmaceutical R&D has come under pressure. One indicator of this trend is the EU's declining share of global clinical trials, which fell from 25% in 2013 to 19% in 2023 (EFPIA & Vaccines Europe, 2024). While trial activity reflects only part of the innovation process, the report links this decline to slower patient recruitment and increasing regulatory complexity, both of which raise frictions throughout the R&D lifecycle. At the same time, global research geography has become more fragmented, with regions such as Asia—particularly China—emerging as key locations for high-growth innovation activity.

While this section focuses on innovation-specific mechanisms, a broader body of research shows that the GDPR also negatively affected firm performance across several dimensions. Studies report declines in profitability, revenue, investment, and economic dynamism (e.g., Koski & Valmari, 2020; Jia et al., 2025). These burdens tend to fall disproportionately on smaller firms and those in data-intensive sectors, compounding innovation frictions.

In addition to raising direct compliance costs, privacy regulation introduces regulatory uncertainty that can delay or distort investment decisions. This is particularly salient in the context of cross-border data transfers, where the *Schrems II* ruling (CJEU, 2020) invalidated the EU–US Privacy Shield, and where the 2023 EU–US Data Privacy Framework has already been legally challenged (Liss et al., 2021). Such ambiguity increases the value of waiting, especially for irreversible R&D investments, thereby reinforcing real options behavior under uncertainty (Bloom et al., 2007). These broader regulatory frictions may discourage firms from initiating new innovation projects or expanding transnational research infrastructure, especially in high-friction domains like pharmaceuticals and biotechnology.

Against this background, we theorize that privacy regulation affects firms' innovation incentives through three interrelated channels: their regulatory exposure, their ability to adjust R&D location, and their internal capacity to manage compliance.

First, firms headquartered and operating in jurisdictions with stringent privacy regimes, such as the EU after the GDPR, must comply fully across all operations. These firms face binding legal requirements and limited flexibility in how data can be collected, stored, or transferred. The regulation thus imposes a structural constraint on the R&D process by lowering expected returns to innovation.

Some prior studies suggest that burdensome regulation may reduce firms' R&D investment by increasing compliance costs and lowering the expected returns to innovation. Égert (2017) finds that product market regulation weakens both innovation intensity and the productivity returns to R&D, particularly in environments with high barriers to trade and investment. Similarly, Nicoletti & Scarpetta (2003) show that barriers to entry and public ownership are negatively associated with multifactor productivity, in part through their adverse effects on innovation. Although these studies do not examine data privacy regulation specifically, they highlight how regulatory frictions can distort firms' innovation incentives. In this context, data

privacy rules such as the GDPR can be understood as a domain-specific extension of these broader institutional constraints, affecting firms' ability and willingness to invest in R&D.

Building on this reasoning, we formulate the following hypothesis:

Hypothesis 1: *Firms operating within high-regulation jurisdictions reduce their R&D investment following the implementation of data privacy regulation*.

Second, firms differ in their ability to adapt geographically. Multinational companies can reallocate GDPR-sensitive operations to jurisdictions with more lenient data protection regimes or less aggressive enforcement, thus preserving the economic viability of innovation projects. As a result, even when facing stricter regulations in their home country, their overall R&D spending at the parent-company level may remain stable or even increase, due to cross-border reorganization.

This type of adaptability is supported by evidence from Ciriaci et al. (2016), who show that product market and labor regulations significantly influence the location decisions of R&D-intensive multinationals, and that companies actively shift activities to lower-friction environments. In contrast, firms that lack foreign affiliates are less able to reallocate R&D geographically. When operating solely within tightly regulated jurisdictions, these firms are more directly exposed to the reduced expected returns on innovation, leading to an actual decline in R&D investment.

Descriptive evidence from clinical trial registries reinforces this mechanism: while the EU's overall share of trials has declined, the share of multi-country trials has increased (Cookson, 2024), suggesting strategic restructuring rather than full withdrawal. This pattern implies that regulation-induced frictions may disproportionately suppress R&D investment among firms that cannot shift activity abroad. To examine how firms' geographic flexibility moderates the regulatory effect, we propose the following hypothesis:

Hypothesis 2: *The negative effect of data privacy regulation on R&D investment is more pronounced among firms that lack foreign affiliates and are geographically confined to regulated jurisdictions*.

Third, compliance costs are not uniform across firms. While large organizations typically have the legal, technical, and managerial capacity to implement GDPR-aligned systems — such as

data protection impact assessments, secure storage protocols, and dedicated compliance teams — small and medium-sized enterprises often face substantial constraints. These include limited financial and human capital, gaps in compliance expertise, and difficulties adapting internal processes to meet regulatory requirements (Smirnova & Travieso-Morales, 2024).

Evidence from Demirer et al. (2024) confirms that GDPR compliance burdens were most acute among smaller companies, both in absolute terms and relative to larger firms within the same sectors. The study finds that smaller firms experienced more severe distortionary effects, reflecting their more limited capacity to absorb regulatory costs. This is consistent with the view that larger firms are better equipped, organizationally and financially, to comply with complex regulatory requirements. These resource constraints may force SMEs to divert funds away from innovation-related activities, particularly in data-intensive industries. Additional support comes from Koski & Valmari (2020), who show that the profit margins of European data-intensive SMEs declined more sharply than those of large firms following the implementation of the GDPR.

Taken together, these findings suggest that regulatory shocks such as GDPR can disproportionately suppress R&D investment among smaller firms due to limited capacity to absorb compliance burdens. This leads to the following firm-size-based heterogeneity hypothesis:

Hypothesis 3: *The negative effect of data privacy regulation on R&D investment is stronger for smaller firms relative to larger firms*.

These hypotheses reflect the view that regulation interacts with firm-level characteristics in shaping innovation outcomes. Privacy laws are not merely legal constraints; they are institutional shocks whose effects depend on exposure, flexibility, and capacity. The empirical analysis that follows tests these hypotheses using a firm-level panel data of the world's top R&D-investing pharmaceutical and biotechnology companies, leveraging variation in regulatory adoption across countries and over time.

4. Data

Our analysis draws on firm-level data from the EU Industrial R&D Investment Scoreboard, compiled annually by the European Commission's Joint Research Centre (JRC). We use financial and R&D investment data covering the years 2013–2023 for the top 2,500 global firms and the top 1,000 EU-based firms ranked by R&D expenditure. Our analysis focuses on the pharmaceutical and biotechnology companies, based on their ICB 3-digit industry classification. After exclusions and matching, the baseline estimation sample comprises 2,523 firm-year observations from 390 firms of which 1,272 are treated and 1,251 controls. By industry, 1,149 are pharmaceuticals and 1,374 are biotechnology companies.

Our dependent variable is the natural logarithm of R&D expenditures, which captures firm-level investments in research and development. To mitigate the influence of extreme outliers, we winsorize the dependent variable at the 1st and 99th percentiles. This procedure preserves the full sample while reducing the influence of highly skewed observations in the tails of the distribution.

We define the treated group as firms headquartered in jurisdictions that adopted comprehensive, GDPR-proximate privacy regimes during our study window—namely EU and EEA member states, the United Kingdom, Japan, and South Korea.[2] We classify the UK as treated as it applied the EU's GDPR in full while it was a member state and during the transition period through 2020. Following Brexit, the UK adopted its own version of the GDPR, which remains substantively aligned with the EU regulation. Consequently, the UK's data protection regulation was functionally equivalent to the EU's GDPR throughout the period under study.

The control group consists of firms headquartered in the United States, Australia, Canada, Switzerland, and Taiwan, i.e., jurisdictions that did not adopt a GDPR-equivalent federal framework over our study window.[3] For pharmaceutical and biotech companies, the treated

[2] Although India, Israel, Singapore, and China have adopted stricter privacy regimes, we do not treat firms headquartered there as cleanly treated within our window and exclude them. India's comprehensive law was enacted only at the end of our period with a phased rollout, so its impact cannot be identified. Israel's regime shifted toward stronger protections during our window, with a GDPR-inspired overhaul beyond our period, leaving it neither a clean control nor a clean treated case. Singapore's PDPA predates the GDPR and major updates arrive later, yielding only partial alignment. China's PIPL is comprehensive but embedded in a security-centric governance model that differs materially from the EU regime.

[3] The United States lacks a comprehensive federal privacy statute and does not operate a GDPR-style general cross-border transfer regime. Neither Australia nor Canada adopted a GDPR-equivalent comprehensive reform

firms' regimes impose stricter constraints on processing personal (health) data and on international transfers (as discussed), making these non-EU jurisdictions a natural counterfactual.

To test the robustness of our classification, we also estimate models using a simplified institutional contrast: firms based in GDPR jurisdictions (EU and EEA countries) versus those based in the United States.

To improve covariate balance between treated and control firms, we implement one-to-one nearest-neighbor propensity score matching without replacement. Following standard guidance, we impose a caliper equal to 0.25 standard deviations of the estimated propensity score to restrict matches to reasonably similar observations (Stuart and Rubin, 2008). The propensity score is estimated using pre-treatment firm-level covariates plausibly related to R&D intensity: the number of employees, net sales (in million euros), and profits (in million euros).

Propensity score matching is performed using 2015 data, prior to the adoption or implementation of major data protection laws in any of the countries included in our sample. While the GDPR was adopted in 2016 and enforced in 2018, comparable frameworks were introduced in Japan and South Korea only several years later. As such, these countries remain untreated during the matching period. Matching is based exclusively on pre-treatment covariates, ensuring comparability between treated and control units prior to any regulatory exposure.

Following the matching procedure, we retain only firms with non-missing and strictly positive matching weights, ensuring a unique match for each treated firm. The resulting matched sample is used in the subsequent difference-in-differences analysis.

In the event study analysis, we include control variables to account for firm-level heterogeneity. Firm size is controlled by log net sales, given its strong empirical relationship with the level of R&D expenditures. We also include 4-digit industry dummies to distinguish pharmaceutical

within our study window. Switzerland's revised Federal Act on Data Protection entered into force on September 2023; it is broadly aligned but not identical to the EU regime. Taiwan is treated as a non-GDPR jurisdiction under its PDPA, which differs in scope and enforcement and has no EU adequacy decision. The sample is dominated by U.S. firms (90.4%), with smaller shares from Switzerland (4.6%), Canada (2.6%), Australia (1.4%), and Taiwan (1.1%).

companies from biotechnology firms, reflecting structural differences in business models, vertical integration, and R&D focus. Country fixed effects account for persistent national differences such as institutional structures, enforcement capacity, or how privacy regulations are implemented in practice. All models absorb firm and year fixed effects, and standard errors are clustered at the firm level.

Table 1. Descriptive statistics for treated and control firms before and after matching

Variable	Sample	Nobs: treated (control)	Treated: mean	Treated: std.dev.	Control: mean	Control: std.dev.	Std. diff.
R&D (€ million)	Pre-Matching	273 (337)	181,51	671,317	246,6977	1068,246	-0,07
R&D (€ million)	Post-Matching	127 (300)	91,98334	377,4788	175,0588	785,8511	-0,13
Profit (€ million)	Pre-Matching	274(346)	153,4852	753,6428	305,2879	1963,069	-0,10
Profit (€ million)	Post-Matching	204 (204)	118,3179	679,7284	96,9963	707,2601	0,03
Net Sales (€ million)	Pre-Matching	258 (284)	1428,374	5014,434	1574,652	7030,72	-0,02
Net Sales (€ million)	Post-Matching	204 (204)	782,458	3766,455	817,3599	4009,758	-0,01
Number of employees	Pre-Matching	247 (308)	4234,223	14553,94	2925,185	14176,84	0,09
Number of employees	Post-Matching	204 (204)	1881,755	8864,224	2132,936	10733,06	-0,03

Table 1 reports descriptive statistics for treated and control firms before and after propensity score matching, including means, standard deviations, and standardized differences. Pre-matching covariate balance was generally good, with all standardized differences within or near the conventional threshold of |0.1|. After matching, balance improved further, with all standardized differences between –0.13 and 0.03. In particular, the imbalance in profit decreased from –0.10 to 0.03. R&D is shown for descriptive purposes only.

5. Empirical Strategy

Our empirical setting involves a staggered adoption of privacy regulation across countries, where firms become exposed to treatment at different points in time depending on the timing

of national legislation. Estimating causal effects under staggered treatment adoption has recently come under increased scrutiny. A growing body of literature demonstrates that two-way fixed effects (TWFE) models may produce biased estimates when treatment timing varies across units (Baker et al., 2022; Callaway & Sant'Anna, 2021; Goodman-Bacon, 2021).

To address potential bias inherent in staggered adoption settings, we implement the three-step estimator developed by Sun & Abraham (2021), which recovers cohort-specific average treatment effects on the treated (CATTs). Specifically, we estimate the average difference in R&D expenditures for firms exposed to stricter privacy regulation—based on the year their home country adopted such regulation—relative to firms in countries that did not implement comparable data protection laws during the sample period.

In the first stage, we estimate cohort-specific event-time effects by interacting cohort indicators with dummies for relative time to treatment. This is implemented via a linear two-way fixed effects model augmented with cohort-by-event-time interactions, enabling us to trace the dynamic response of treated firms from four years before to four years after regulatory adoption. Consistent with standard practice, the year immediately preceding implementation is omitted and serves as the reference category (Baker et al., 2022).

$$Y_{ijt} = \alpha_i + \gamma_t + \sum_{l\#-1} \delta_{ql} \mathbf{1}\{Y_i = q\} D_{it}{}^{l} + \varepsilon_{it} \qquad (1)$$

where Y_{ijt} denotes a firm i's logarithmic R&D expenditures in country j at year t. Y_i is the year when the country implemented GDPR or other stricter privacy regulation, $l = t - Y_i$ (i.e., the relative years to the implementation of privacy regulation), and α_i and γ_t are the unit and time fixed effects. We categorize firms into different cohorts based on their first treatment or the year of the implementation of GDPR or similar privacy regulations. The variable $D_{it}{}^{l}$ is a dummy variable that gets a value of 1 for treated firm in the relative times, l, and 0 if a firm's headquarters was located in a country that did not adopt GDPR or similar privacy regulation over the sample time

In the second stage, we compute cohort-specific weights that reflect the relative frequency of each cohort across event times, following the procedure outlined by Sun & Abraham (2021). These weights capture the contribution of each cohort to the overall sample at different points in event time. In the third stage, we construct the interaction-weighted (IW) estimator by

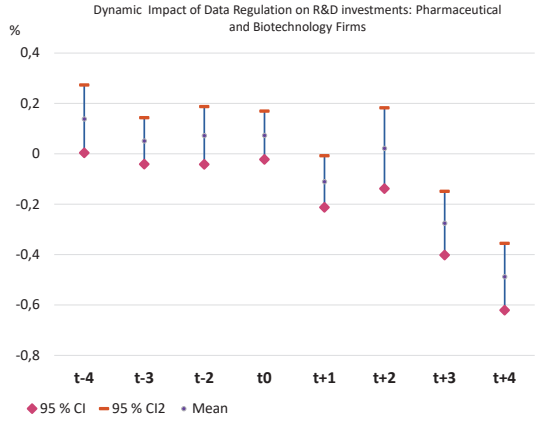
aggregating the cohort-specific average treatment effects—obtained from the first-stage regression—using the weights derived in the second stage.

6. Results

6.1 Estimation results

Figure 2 shows the dynamic effects of data privacy regulation on R&D investments among pharmaceutical and biotechnology firms. The vertical axis reports the estimated treatment effects, relative to the year prior to regulation implementation (t = -1). The pre-treatment coefficients (t–4 to t–2) are close to zero and statistically insignificant, supporting the parallel trends assumption. From the implementation year onward, R&D investment declines progressively. By year t + 4, the cumulative effect reaches -0.49 log points, corresponding to a reduction of about 39 percent relative to pre-regulation levels. These results support Hypothesis 1, suggesting that stricter personal data regulation imposes substantial constraints on innovation among companies for which personal data is a critical input. Full estimation results, including standard errors and model diagnostics, are reported in Annex 1.

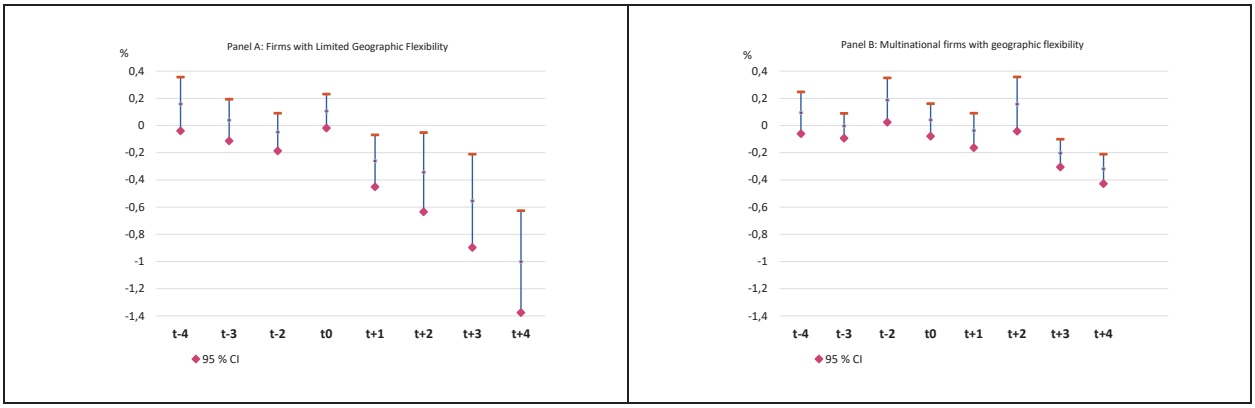
Figure 2. Dynamic Impact of Data Privacy Regulation on R&D: Pharmaceutical and Biotechnology Firms



To analyze how geographic flexibility moderate firms' exposure to data privacy regulation, we estimate treatment effects separately for domestic-only and multinational firms subject to strict personal data regulations. This approach allows us to assess whether firms with limited

ability to reallocate data-sensitive operations across borders experience stronger regulatory impacts.

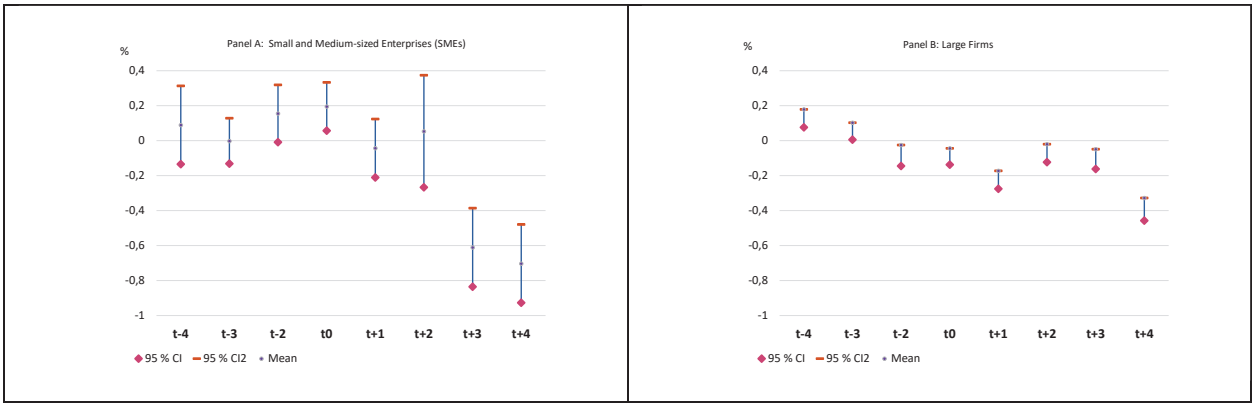
Figure 3. Dynamic Impact of Data Privacy Regulation on R&D: Geographic Flexibility and Exposure



The results reported in Figure 3 support Hypothesis 2. While both groups show a decline in R&D spending following the introduction of data privacy laws, the estimated effects for domestic firms are consistently larger, particularly in years t + 3 and t + 4. In year t + 4, the effect for domestic-only firms reaches –1 log points (i.e., a 63 percent decline), compared to –0.32 log points (i.e., a 27 percent decline) for multinationals. These findings can be contrasted with the average effect in the baseline specification, where the cumulative decline reaches –0.49 log points (i.e., a 39 percent decline) in year t + 4. The comparison suggests that full regulatory exposure, when combined with limited geographic flexibility, amplifies the costs of compliance and more severely constrains innovation investment than the average treatment effect alone would indicate.

Figure 4 reports dynamic treatment effects by firm size. Panel A shows the results for small and medium-sized enterprises, and Panel B for large firms. SMEs experience a sharper and more prolonged decline in R&D investment following the introduction of privacy regulation. By year t + 4, the estimated effect for SMEs reaches –0.7 log points, corresponding to a 50 percent reduction relative to pre-regulation levels. For large firms, the effect in year t + 4 is –0.33 log points, or about a 28 percent reduction. These results support Hypothesis 3, suggesting that firms with more limited organizational capacity and fewer compliance resources are disproportionately affected by data privacy regulation.

Figure 4. Dynamic Impact of Data Privacy Regulation on R&D by Firm Size



6.2 Robustness tests and mechanism evidence

To test the robustness of our findings, we first restrict the treated group to EU-headquartered firms and the control group to U.S.-headquartered firms. This minimizes cross-jurisdictional heterogeneity in treatment intensity and contemporaneous policy changes in the control group.

Table 2. Dynamic Effects of Data Regulation on R&D Investment: robustness tests

Year	EU-Based vs. US-Based Firms Only	Non-data-intensive Industries
t – 4	0.187 (0.182)	0.055 (0.062)
t – 3	0.065 (0.114)	0.011 (0.060)
t – 2	0.018 (0.131)	-0.023 (0.055)
t	0.051 (0.107)	0.013 (0.045)
t + 1	-0.143 (0.115)	-0.040 (0.044)
t + 2	-0.034 (0.172)	0.010 (0.048)
t + 3	-0.399 (0.135)	0.013 (0.050)
t + 4	-0.505 (0.142)	-0.052 (0.071)
Observations	1,907	1,961
Firms	300	287
R-squared	0.814	0.979

As shown in Table 2, the results remain consistent: post-treatment coefficients indicate a progressive and statistically significant decline in R&D investment, reaching –0.50 log points by year t + 4 (i.e., about 39% relative decline in R&D). Notably, the largest and most statistically significant drop in R&D investment occurs in year t + 3 (i.e., 2021), three years after the GDPR's introduction. This timing coincides with the Schrems II ruling, suggesting that the ensuing legal uncertainty may have amplified the regulation's impact.

Second, we examine a subsample of firms operating in non–data-intensive manufacturing industries, where personal data plays a limited role in the innovation process. Specifically, we include firms classified under the following ICB 3-digit industry categories: Beverages, Food Producers, Automobiles & Parts, and General Industrials. These sectors typically develop products that rely less on consumer data or personalized digital services and are therefore expected to be less affected by data privacy regulation. Consistent with this expectation, we do not find any meaningful decline in R&D investment after the introduction of regulations. Post-treatment coefficients remain small, statistically insignificant. These findings support the interpretation that the regulation primarily affects firms for which personal data is a critical input in R&D activities.

7. Discussion

Our findings suggest that stricter personal data protection regulations lead to a significant decline in R&D investments among pharmaceutical and biotechnology firms. The reduction is most pronounced among firms operating exclusively in jurisdictions that enforce comprehensive privacy rules (e.g., the EU). Firms with multinational structures, by contrast, appear to be better able to mitigate the regulatory burden, plausibly by reallocating data-intensive activities across borders. This geographic flexibility provides a strategic buffer against regulatory frictions and highlights how institutional context interacts with firm-level capabilities.

We also find that smaller firms reduce their R&D spending more sharply than larger firms, consistent with the notion that compliance costs represent a larger fixed burden relative to organizational scale. These results suggest that privacy regulation inadvertently widen

disparities, both across firms and across regions, by disproportionately constraining those with less capacity to adapt.

In the pharmaceutical and biotechnology sectors, where clinical trials account for substantial share of firms' R&D expenditures, data privacy laws can affect not only cost structures but also the feasibility of trial execution. Our findings are consistent with evidence that clinical trial activity has declined in the EU following the implementation of the GDPR, while the share of trials conducted across multiple countries has increased. This pattern suggests that regulation may be driving a strategic reorganization of R&D activities, preserving legal compliance while shifting trial activity to jurisdictions with more permissive data regimes.

Taken together, our results contribute to a growing literature on the economic effects of privacy regulation. Our empirical evidence indicates that institutional design and enforcement intensity matter not just for data governance, but also for global patterns of innovation. If regulatory fragmentation persists, it may increasingly shape the geography of R&D, the composition of participating firms, and the global accessibility of data-driven medical advances.

Beyond firm-level investment decisions, personal data regulation may also affect the broader innovation ecosystem. Recent expert surveys suggest that such restrictions delay medical discoveries, reduce the number of clinical trials, and diminish the representativeness of research data.[4] These findings suggest that GDPR-related constraints on international data use and secondary processing have materially hindered cross-border research collaboration. More broadly, stricter privacy regulation may slow biomedical progress by increasing compliance burdens, disrupting collaboration, and fragmenting research infrastructure across jurisdictions. Quantifying these systemic effects remains an important direction for future research.

[4] For example, the GDPR has been associated with a 47.5% decline in NIH-funded clinical trials in major EU countries, despite an increase in overall clinical trial activity in both the EU and the US (Brandon & Cotti, 2024).

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Annex 1. Dynamic Effects of Data Regulation on R&D Investment (log R&D)

Year	Baseline (All Firms)	Limited Geographic Flexibility	Multi-national Firms	SMEs Only	Large Firms
t–4	0.139 (0.135)	0.159 (0.198)	0.094 (0.154)	0.090 (0.223)	0.180 (0.104)
t–3	0.052 (0.092)	0.040 (0.153)	-0.002 (0.092)	-0.001 (0.130)	0.103 (0.098)
t–2	0.073 (0.115)	-0.048 (0.138)	0.188 (0.163)	0.156 (0.164)	-0.025 (0.119)
t	0.074 (0.096)	0.107 (0.125)	0.042 (0.120)	0.195 (0.138)	-0.043 (0.094)
t+1	-0.110 (0.103)	-0.260 (0.191)	-0.036 (0.127)	-0.043 (0.167)	-0.172 (0.103)
t+2	0.023 (0.161)	-0.343 (0.292)	0.158 (0.200)	0.054 (0.320)	-0.020 (0.103)
t+3	-0.275 (0.127)	-0.554 (0.343)	-0.203 (0.102)	-0.610 (0.225)	-0.048 (0.113)
t+4	-0.488 (0.133)	-1.001 (0.375)	-0.319 (0.108)	-0.702 (0.224)	-0.327 (0.130)
Observations	2,523	2,463		2,523	
Firms	390	382		390	
R-squared	0.823	0.825		0.826	

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