Data Privacy Regulation and Innovation*

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Abstract

We investigate how data privacy regulations shape research and development. While such regulations aim to increase stakeholder privacy and data security, they can also introduce costs in settings where collecting, analyzing, and sharing sensitive data is central to innovation. We examine this tension in the context of the pharmaceutical industry and the European Union's (EU) General Data Protection Regulation (GDPR), the most comprehensive data privacy regulation to date. Leveraging firm-level variation in exposure to the GDPR, we find that the regulation lowers clinical trials by 18 percent. Firms also shift the types of projects they pursue: trials are less likely to include sites in the EU, be conducted across multiple countries, and target a narrower set of diseases. Research collaborations decline overall and shift away from new partners towards established relationships. When looking at project outcomes, we observe that trials take longer to complete, are less likely to succeed, and report results with greater delay. The decline in clinical trial activity is greatest among young firms. These findings reveal how data privacy regulations shape not only the rate of innovation, but also the process by which it is pursued and its outcomes.

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1 Introduction

Firms increasingly rely on collecting, analyzing, and sharing data to develop novel products and services (Goldfarb and Que, 2023). Since data is often proprietary and sensitive, the growth of data-driven research and development (R&D) has raised public concerns regarding privacy and data security (Acquisti et al., 2016; Miller and Tucker, 2018). In response, regulatory authorities have implemented data privacy regulations designed to safeguard individual privacy rights and maintain public trust. As of 2025, data privacy laws have been implemented in 172 countries (Greenleaf, 2025).

How do data privacy regulations shape research and development (R&D)? Unlike other commonly studied forms of regulation, such as entry requirements (Stern, 2017; Grennan and Town, 2020; Gupta and Kao, 2025), product-specific policies (Yin, 2008; Chandra et al., 2024), or intellectual property protection (Williams, 2013; Sampat and Williams, 2019), data privacy regulations shape how data—a core input in the R&D process—is collected, analyzed, and shared. On the one hand, these policies may raise research costs by implementing additional regulatory requirements. On the other hand, since such regulations strengthen stakeholder privacy and improve data security, they may ultimately increase external stakeholders' willingness to participate in R&D activities that require the use of sensitive data. When data is central to innovation, this may have consequences for not only *how much* firms innovate, but also *how research* is conducted and its *outcomes* (Mahoney et al., 2009; Vakili and McGahan, 2016). Despite the key role of data in the R&D process, there is limited empirical evidence on how data privacy regulations shape these key dimensions of innovation. This paper aims to fill this gap.

In particular, we focus on the European Union (EU)'s General Data Protection Regulation (GDPR), the world's most comprehensive data privacy regulation to date (European Union, 1995). The GDPR, which was adopted in 2016 and became enforceable in 2018, expanded consent and documentation requirements; imposed limitations on data use, reuse,

and purpose; restricted data transfers between organizations and across borders; and mandated timely reporting of breaches. These requirements were backed by strong enforcement mechanisms: fines for violations could reach up to 20 million euros or 4 percent of a firm's annual global revenue.

The implications of the GDPR are particularly salient in the pharmaceutical industry, where data is not only a critical input to the drug development process but is also particularly sensitive (Vakili and McGahan, 2016; Buckman et al., 2023). Unlike in consumer data, where the GDPR could help filter out lower-value data (Aridor et al., 2023) or increase the effectiveness of user targeting (Godinho De Matos and Adjerid, 2022), pharmaceutical data is produced through costly, regulated experimentation and cannot be easily substituted when access becomes more restricted. Drug development often relies on exploratory research, secondary uses of data (e.g., to identify new indications, serve as controls for follow-on studies), and iterative research designs (e.g., adaptive trials). As a result, limitations on secondary uses of data and requirements to outline ex-ante data uses have meaningful effects. Further, the drug development process is often global and collaborative. As a result, the GDPR can affect where firms conduct trials, as well as how they coordinate with research partners. Taken together, data privacy regulations can have meaningful consequences for drug development by shaping the level and types of new drug projects that firms pursue, as well as the likelihood and speed with which those drugs ultimately come to market.

To motivate our empirical analysis, we develop a conceptual framework in which data privacy regulations affect firms' R&D decisions through two mechanisms. First, such regulations increase compliance costs by requiring investments in legal, administrative, and data infrastructure. Faced with higher costs, firms may reduce the number of projects they pursue. These costs may also raise barriers to forming new research partnerships, as organizations must establish data agreements and verify potential research partners' compliance capabilities before sharing sensitive information. Second, data privacy regulations may reduce perceived risks for external stakeholders. Trial participants may be more willing to

enroll when they have greater control over how their health data is collected, stored, and shared. Faced with uniform requirements, research partners may face lower liability exposure when collaborating with other organizations. These effects could partially offset increased compliance costs by lowering participation frictions.

The net effect of these mechanisms is ambiguous. If compliance costs dominate, we expect R&D investment to decline, particularly among new collaborations where data sharing policies must be developed from scratch. In contrast, established partnerships, which can leverage prior agreements and shared compliance practices, may be more resilient. If compliance costs also increase coordination burdens and delay data sharing, we expect longer trial durations and lower completion rates. However, if the benefits of privacy are salient, we expect higher levels of R&D investments, more new collaborations, shorter trials, and higher completion rates. Figure 1 provides preliminary evidence consistent with the first mechanism: comparing Phase II trials across EU countries before and after the GDPR, we observe a broad decline in trial activity.

-Insert Figure 1 about here-

We utilize a comprehensive dataset of clinical trials initiated between 2010 and 2023, with sites in the EU, US, and other countries. A key empirical challenge in examining the effect of the GDPR is that it is inherently a global shock, making it difficult to identify suitable treatment and control groups (Johnson, 2022). To tackle this challenge, we construct a continuous measure of exposure to the GDPR that is motivated by the idea that firms with more EU-based research activity before 2018 likely faced greater exposure to the regulation. We then use this firm-level exposure measure in a difference-in-differences design.

Our analysis yields three main findings. First, we find that firms more exposed to GDPR reduce their number of clinical trials by 18 percent relative to less exposed firms. This effect is immediate, persistent, and holds even after accounting for shifts in disease composition. Second, firms adjust the types of projects they pursue: trials are less likely to be conducted in the EU, they are less likely to operate across multiple countries, and they target a narrower

set of diseases. Overall research collaborations decline, particularly among new collaborators and among young firms. At the same time, firms modestly increase the number of collaborations with existing research partners. Finally, we show that these effects have meaningful impacts on research outcomes: trials take longer to complete, are less likely to successfully complete, and firms delay the reporting of trial results. By tracing the effects of data privacy regulation from research investments through processes and outcomes, we characterize how such regulations shape innovation in data-intensive industries, how firms shift the types of projects they pursue, and the implications this has for research outcomes.

Our findings offer several insights for managers and policymakers. For managers, our results highlight two considerations. First, investment in data protection, which is often seen as an ex-post response to regulation rather than an ex-ante capability, is an important source of competitive advantage. Firms that invest in data protection expertise and technology are better able to successfully speed new projects to market. Second, established research partnerships are important assets when faced with increased regulatory requirements. While overall collaborations decline following the GDPR, firms shift toward existing partners who offer shared compliance infrastructure and pre-existing data agreements. Younger firms, which show the largest declines in collaborative activity, may benefit from prioritizing relationship-building early or seeking partnerships with established players who can provide regulatory expertise.

For policymakers, our results point to potential unintended consequences of data privacy regulation. First, the 18 percent decline in clinical trials, combined with longer durations and lower completion rates, implies delays in the development of new treatments. Second, the shift of trial activity away from the EU raises concerns about whether patient populations in clinical trials will reflect the patient populations that ultimately use approved therapies. If EU patients are underrepresented in trials, the resulting evidence base may be less informative for EU prescribers and patients. Third, the disproportionate effects on young firms and new collaborations suggest that privacy regulation may contribute to market concen-

tration, which can have implications for the types of drugs produced and patient access to those drugs. These trade-offs warrant consideration as policymakers design and refine data privacy frameworks (e.g. explicit safe harbors for pseudonymized research data, streamlined procedures for secondary analyses).

This paper contributes to several literatures. First, we contribute to the emerging literature on data privacy regulation by showing how data-related policies shape firms' R&D decisions. Prior research has primarily examined the short-run performance effects of data privacy regulations on digital services and consumer-facing firms (e.g., Goldfarb and Tucker, 2011; Miller and Tucker, 2009, 2018; Peukert et al., 2022; Johnson et al., 2023; Goldberg et al., 2024; Jia et al., 2021; Janßen et al., 2022; Jin et al., 2024). We build on this work by examining a setting where data are a core input to innovation and show that privacy regulation affects not only how much research firms undertake, but also how research is organized and its outcomes. This complements a growing view that data privacy regulation differs from other forms of regulation by directly targeting key R&D inputs (Goldfarb and Tucker, 2012; Acquisti et al., 2016; Aridor et al., 2020; Johnson, 2022; Demirer et al., 2024). By documenting substantial declines in clinical trials along with changes in research processes and outcomes, we demonstrate that data privacy regulations may meaningfully constrain a key input to innovation and shift decisions throughout the R&D process.

Second, we shed light on the drivers of R&D collaborations. Prior work has shown that collaborations are shaped by prior relationships and network position (Gulati, 1995; Gulati and Gargiulo, 1999), trust and governance mechanisms (Gulati and Nickerson, 2008; Reuer and Ariño, 2007), and opportunities for knowledge transfer (Mowery et al., 1996; Danzon et al., 2005). Our findings reveal that firms respond to regulation not by uniformly reducing collaboration, but by reallocating their collaborative efforts away from new partnerships towards established research partners. This extends existing work on alliance formation by showing how regulation leads to heterogeneous costs that may favor established relationships over new partner formation. This is consistent with the view that established partnerships

serve as valuable assets that enable firms to share regulatory compliance expertise. Combined with the decline in new collaborations, this pattern suggests that regulation may increase concentration in research networks.

Finally, we contribute to the broader literature on regulation and firm strategy by showing how data privacy regulation has heterogeneous effects across firms. Consistent with prior work that has shown that larger firms are better able to navigate regulatory requirements (Cockburn and Henderson, 2001), we find that data privacy regulations disproportionately affect younger firms. This complements prior work on regulatory capture and incumbent advantage (Mahoney et al., 2009) by highlighting a distinct mechanism by which regulations create advantages for incumbents, who can navigate costly regulatory requirements and maintain collaborative relationships essential for data-driven innovation. By showing that the GDPR disproportionately drives younger firms to reduce their research activity, we highlight a channel through which data privacy may ultimately contribute to greater market concentration (Johnson, 2022).

The paper proceeds as follows: Section 2 describes the setting and conceptual framework. Section 3 introduces the data and presents descriptive facts. Section 4 describes the empirical strategy and Section 5 presents the results. Finally, Section 6 concludes.

2 Institutional Background and Conceptual Framework

This section presents an overview of GDPR's institutional context, its implications for the research activity in the pharmaceutical industry, and a conceptual framework that connects data privacy regulation, more broadly, to R&D changes.

2.1 The European Union's General Data Protection Regulation

The EU's GDPR, which was adopted April 2016 and took effect in May 2018, represents the world's most comprehensive and stringent regulation for governing the data collection, storage, usage, and dissemination. It replaced the 1995 Data Protection Directive, which

had set minimum privacy protections but varied in its implementation across member states (European Union, 1995). In contrast, the GDPR established a unified, enforceable legal framework that was applied consistently across all EU member states. The GDPR governs personal data, which ranges from an individual's name and location to health and genetic data. It applies to any firm using the data of EU residents or offering them goods or services.

The GDPR introduced several important changes that strengthened the rights of individuals providing personal data while increasing regulatory requirements for firms. First, it expanded consent and documentation requirements. Under the GDPR, valid consent must be affirmative (pre-checked boxes are prohibited), freely given, granular to each purpose of processing, and must list all third parties who will process the data (Goldberg et al., 2024). For example, websites must now display explicit opt-in dialogs listing each type of cookie and its purpose, allowing users to consent individually; under the prior regime, websites could use pre-checked boxes or treat continued browsing as implied consent (Aridor et al., 2020).

Second, the GDPR imposed restrictions on data use, reuse, and purpose. Relatedly, individuals gained the right to access, correct, and delete their personal data. Although the 1995 Data Protection Directive included rights to access and correct data, these were implemented inconsistently across member states and lacked uniform enforcement (Peukert et al., 2022). The GDPR harmonized and strengthened these protections across all member states, and added new rights, including the right to data portability.

Third, the GDPR imposed restrictions on data transfers between organizations and across borders as data could only be transferred to entities that met GDPR standards (European Commission, 2025). Finally, the GDPR increased breach reporting and regulatory oversight. For example, following a data breach, firms would need to notify the appropriate regulatory authority within 72 hours, and in some cases, inform affected participants. The GDPR also introduced substantial fines for non-compliance: firms can be fined up to 20 million euros or 4 percent of a firm's global annual revenue for the previous year, whichever is greater. These penalties were significantly higher than most previous data privacy regulations (Intersoft

Consulting, 2025). Taken together, these features increased the cost of R&D. Indeed, Demirer et al. (2024) find that the GDPR is responsible for the 20 percent increase in the variable cost of data inputs for affected firms.

The GDPR is part of a broader global trend toward strengthening data protections, reflecting rising concerns about privacy in a digital economy. Similar regulations include the United States' Health Insurance Portability and Accountability Act (HIPAA) and California's Consumer Privacy Act (CCPA). Although these regulations share some principles such as informed consent, data minimization, and breach notification requirements, GDPR is notably more stringent (see Appendix A for a detailed comparison).

2.2 Pharmaceutical R&D and GDPR

2.2.1 Pharmaceutical R&D

Drug development relies heavily on data to evaluate the safety and efficacy of experimental therapies (DiMasi et al., 2016; Lakdawalla, 2018). These data include patient demographics, medical histories, clinical outcomes, adverse events, laboratory results, and biomarker measurements.

The drug development process typically begins with preclinical research, where compounds are tested on cells and animals to assess their potential. Promising candidates then move into human clinical trials, which are divided into three main phases: Phase I focuses on assessing safety and dosage in a small group of patients. Phase II evaluates the drug's efficacy and further assesses safety in a slightly larger group. Phase III, often the costliest and most extensive phase, involves examining efficacy and safety in a larger patient population.

Several features of clinical trial design have implications for our empirical analysis. First, trials vary in geographic scale: some operate at a single site, while others span multiple sites across several countries. Multinational trials can accelerate patient recruitment and generate evidence across diverse populations, but they also require coordination across regulatory

jurisdictions and data transfers between organizations. Second, trials vary in therapeutic scope: some target a single disease, while others study a compound's efficacy across multiple indications. Third, trials vary in their outcomes: some reach successful completion, while others are terminated early due to safety concerns, lack of efficacy, or operational challenges. Trial duration and the timely reporting of results also vary, with implications for how quickly evidence reaches regulators, clinicians, and subsequent researchers.

Within the EU, the conduct of clinical trials is governed by the Clinical Trials Regulation (Regulation EU No 536/2014), which established a single application portal and standardized authorization and safety reporting requirements across member states (European Medicines Agency, 2014). Developers can also conduct trials outside the EU with the intention of applying for EU marketing authorization, provided those trials adhere to equivalent standards. The EU offers several pathways for marketing authorization, including a centralized procedure through the European Medicines Agency that grants approval across all member states.[1]

Given the operational complexity, high costs, and regulatory demands associated with drug development, pharmaceutical firms increasingly rely on collaboration to share resources and expertise. Many trials are jointly conducted by several organizations (Srivastava et al., 2016), and trials conducted with partners tend to have higher success rates (Smietana et al., 2016). Research collaborations can help firms navigate regulatory environments, pool patient recruitment networks, and share compliance costs

At the same time, collaboration introduces its own costs and risks. Partners must align on study protocols, data practices, and compliance responsibilities. Coordination across organizations can slow decision-making, and disagreements over intellectual property or data access can strain relationships. When trials involve sensitive patient data, partners share responsibility for data protection, meaning that a compliance failure by one party can expose others to liability. Because drug development depends extensively on the collection and

[1]See Appendix B for additional details on regulatory approval processes in the EU and US.

exchange of sensitive patient data, changes to data protection laws have the potential to substantially impact R&D in such settings.

2.2.2 Pharmaceutical R&D and GDPR

The GDPR provisions described in Section 2.1 have direct implications for clinical trial practices. First, the GDPR's requirement for explicit consent complicates secondary analyses and longitudinal studies, where multiple uses of data are common. For instance, a firm seeking to test an approved compound for a new therapeutic indication may need to re-consent participants from earlier trials, which raises the cost of pursuing multiple diseases associated with a single drug. Second, the data minimization principle limits exploratory research, reducing the ability of firms to pursue innovative but initially uncertain research directions. This may lead firms to narrow the scope of data collection within individual trials, potentially reducing the number of conditions studied. Third, participants' right to request deletion of personal data poses substantial operational challenges, especially if deletion occurs mid-study, which could increase trial duration or reduce completion rates. Finally, GDPR restricts data transfers between organizations and across national borders, requiring firms to demonstrate adequate data protection standards and creating significant uncertainty about compliance (Eiss, 2020). These restrictions are particularly consequential for multinational trials and research collaborations, as partners must align data practices across jurisdictions.

Qualitative reports have highlighted these challenges. The European Federation of Pharmaceutical Industries and Associations (EFPIA) emphasizes that the implementation of the GDPR has complicated clinical research without delivering the anticipated harmonization of regulatory requirements (European Federation of Pharmaceutical Industries and Associations, 2022). Lalova-Spinks et al. (2024) documents that over 40 EU research sites were unable to enroll in NIH-sponsored COVID-19 therapeutic trials due to GDPR data transfer restrictions. Similarly, large-scale research consortia, such as the International Genomics of

Alzheimer's Project, were unable to share data across sites in real time and instead conducted separate analyses at each location, limiting statistical power and slowing the pace of discovery. These examples illustrate how GDPR's regulatory complexity can delay clinical trial enrollment, increase research costs, and reduce the feasibility of collaborative research.

These industry-specific challenges motivate a more general framework for understanding how data privacy regulations shape R&D decisions.

2.3 Conceptual Framework

This section clarifies how data privacy regulations may shape R&D. We propose that data privacy regulations affect firms' R&D decisions through two channels: by increasing compliance costs and by shaping external stakeholders' willingness to participate in research activities. Firms respond to these forces by adjusting whether to invest in projects, how they design their projects, and with whom they collaborate. These adjustments, in turn, have implications for research outcomes.

First, GDPR increases the cost of conducting research. Firms must invest in consent management systems and data protection audits (Goldberg et al., 2024). Regulatory requirements also raise the marginal cost of data acquisition and management, particularly for projects requiring large or diverse datasets (Aridor et al., 2020). Further, ongoing costs arise from monitoring, reporting, and responding to data subject requests (Demirer et al., 2024).

Higher compliance costs systematically change which projects firms pursue. GDPR's data minimization requirements constrain how much data firms can collect, while restrictions on data reuse limit the extent to which existing datasets can be repurposed for new questions (Allen and Crawford, 2019). These constraints raise the relative cost of certain types of research. Projects requiring extensive data collection or cross-border data transfers face higher compliance costs and may not be initiated. Restrictions on data transfers across borders may lead firms to reduce the geographic scope of their projects—for example, by concentrating activity in fewer jurisdictions or shifting away from regions with stricter re-

quirements. Similarly, requirements for explicit consent may discourage secondary analyses and exploratory research directions, leading firms to narrow the set of questions they investigate within a given project. In the clinical trial context, these dynamics could manifest as fewer multinational trials, reduced trial activity in EU countries, and trials targeting fewer therapeutic indications. Over time, such selection effects influence not only the quantity but also the composition of firms' research portfolios, potentially steering R&D activities away from multinational projects or research spanning multiple therapeutic areas (Buckman et al., 2023).

Second, data privacy regulations may affect external stakeholders such as test users and research partners' willingness to participate in research. The R&D process involves substantial uncertainty and risks for external stakeholders, including trial participants and research partners (Alsan et al., 2025). By strengthening privacy protections and implementing substantial penalties for non-compliance, data privacy regulations may reduce perceived risks and lower participation costs. For trial participants, stronger protections may increase willingness to enroll in studies that require sharing sensitive health information. This effect could partially offset cost-driven declines in recruitment, particularly for trials that rely on patient trust.

The net effect of GDPR on collaboration is ambiguous. On one hand, GDPR makes all participating organizations jointly responsible for compliance, which creates new costs for partner screening, contract negotiation, and oversight (Blind, 2012; Kircher and Foerderer, 2022). This joint liability increases coordination complexity: partners must align data practices, agree on responsibility allocation, and establish mechanisms for responding to data subject requests or breaches. Such coordination costs may discourage collaboration, particularly with collaborators whose data practices are uncertain (e.g., new research partners) (Jia et al., 2021). On the other hand, firms may intensify collaboration to share compliance expertise and infrastructure. For example, established partners with proven compliance practices can share resources for data protection audits and templates for consent protocols. In

this scenario, collaboration becomes a strategic response to increased costs. The net effect depends on whether coordination costs or the benefits of resource sharing dominate.

Finally, the compliance burden introduced by GDPR may affect research outcomes. Administrative requirements for consent management, data subject requests, and breach reporting may delay trial completion. Cross-border data transfer restrictions may delay data aggregation across multinational sites, further slowing progress. These requirements could also reduce the likelihood that trials reach successful completion: firms may terminate trials that become too costly or complex to manage under increased regulatory requirements. Additionally, GDPR's restrictions on data sharing and the complexity of ensuring compliance before releasing information could delay when firms report trial results. Delays in results reporting have implications beyond individual firms, as timely dissemination of clinical evidence is essential for informing subsequent research and clinical practice (Buckman et al., 2023).

Taken together, this framework thus predicts variation not only in overall R&D levels but also in the types of projects firms pursue, research collaboration decisions, and the speed and success with which new products come to market.

3 Data and Summary Statistics

3.1 Data

To empirically investigate the impact of data privacy regulation on innovation, we utilize data on clinical trials from two trial registries. First, ClinicalTrials.gov (via the Aggregate Analysis of ClinicalTrials.gov Database) provides data on trials initiated in the US and elsewhere.[2] EU Clinical Trials Register contains data on trials initiated in the EU and European Medicines Agency (EMA). Both registries provide detailed trial information, including the sponsoring firm (e.g., AstraZeneca), trial dates (start and completion), trial phase, patient enrollment

[2]Our analyses period (2010-2023) takes place after major changes in trial registration for industry-sponsored trials, the focus of our analysis. For more details, see https://clinicaltrials.gov/about-site/about-ctg.

numbers, trial duration, and locations of trial sites (e.g., EU or non-EU).

Our main analyses focus on Phase II trials as they represent a firm's first major investment for a drug and require substantial data collection and analysis. They typically enroll several hundred patients, last more than two years, and require coordination across several organizations (e.g., hospitals, contract research organizations) (Sertkaya et al., 2024). Further, unlike earlier stages (e.g., Phase I trials), Phase II trials are required to be reported in public registries, which allows us to accurately observe and measure them.

We aggregate the clinical trials data at the firm-year level, where each observation represents a unique sponsoring firm active in a given year. We supplement this trial-level data with firm-level information, including firm headquarter location and founding year, using data from Crunchbase.

The analysis is restricted to clinical trials initiated by industry sponsors between 2010 (or the sponsor's founding year if it was later than 2010) and 2023. The final sample is an unbalanced panel of 73,591 firm-year observations representing 7,508 unique firms.

Measuring Firm-Level Exposure: Our empirical strategy is motivated by the idea that firms with extensive EU-based operations prior to the GDPR's implementation face greater exposure to the regulation compared to those with minimal EU activities before the reform. For each firm, we calculate the share of its Phase II trial sites located in the EU before 2018. Figure 2 shows these shares across firms. Firms are classified as having high exposure to the GDPR if their shares are above the median; others are classified as having low exposure to the GDPR. For simplicity, our main analyses compares firms that have high vs. low exposure. However, we also show that our results are similar when using a continuous measure of exposure.

Measuring Research Processes: To characterize how GDPR shifts they types of projects that firms pursue, we examine changes in trial design and trial collaborations. For trial design, we measure several characteristics recorded in the trial registries: (i) whether the trial has a pre-specified plan to share individual-level participant data (a binary indicator);

(ii) whether the trial has sites in multiple countries; (iii) whether the trial includes sites inside vs. outside the EU; (iv) the number of patients enrolled; and (v) the number of distinct diseases targeted, measured using unique 3-digit Medical Subject Headings (MeSH) codes (e.g., musculoskeletal diseases, respiratory tract diseases).

To measure research collaborations, we identify Phase II trials that are conducted in partnership with other organizations. Following the definition used by ClinicalTrials.gov, we define a collaborative trial as one involving additional organizations that provide substantial support to a trial, including funding, study design, implementation, data analysis, or reporting. In the US trial data, collaborators are explicitly listed separately from sponsors. We flag a trial as a collaborative trial if at least one collaborator is listed. In contrast, the EU trial data does not distinguish between sponsors and collaborators. Instead, when a trial is associated with multiple sponsors, we classify it as a collaborative trial.

We further characterize the nature of collaboration by classifying collaborating trials into two mutually exclusive categories: new and established collaborators based on their relationship with the sponsoring firm. A collaborator is classified as *new* if the sponsoring firm has either never collaborated with that partner on a Phase II trial or if all prior collaborations occurred within the 2 years immediately preceding the focal trial. Collaborators with longer histories of collaboration are classified as *established*.[3]

Measuring Research Outcomes: To characterize research outcomes, we examine trial progression and the public availability of results. We measure trial duration as the number of years between the trial start date and trial completion date. We then measure the share of trials that are completed (as opposed to being terminated or suspended). To characterize data disclosure, we examine the share of trials that publicly report results within one year of trial completion (the timeline as mandated by the Food and Drug Administration Amendments Act of 2007).

Measuring Firm Characteristics: In several analyses, we examine heterogeneity by firm

[3] Appendix E shows that our results are robust to alternative measures of collaboration.

age and size. We classify firms as "Older" if their age in 2018 exceeds the median across all sponsors and "Younger" otherwise. We measure firm size by research intensity: firms are classified as "Larger" if they conducted an above-median number of Phase II trials prior to 2018 and "Smaller" otherwise.

3.2 Summary Statistics

Table 1 shows that from 2010 to 2023, the average firm-year observation has 0.96 Phase II trials. Of these trials, 37.5 percent (0.36) are multicountry trials. Firms conduct 0.12 trials with collaborators each year and firms are more likely to have novel, rather than established, collaborators (0.09 vs. 0.04, respectively). On average, trials last 2.7 years and 56 percent successfully complete. Timely trial results reporting is rare: within our sample, about one percent of trials report their results within one year. Approximately 40 percent of firm-years are associated with old firms and 20 percent are associated with large firms.

4 Empirical Strategy

We measure the causal effect of the GDPR on innovation using a DID design. Our baseline specification compares outcomes for firms with higher vs. lower exposure to the GDPR, before and after the regulation's implementation. In particular, we classify a firm as having high exposure to the GDPR if it has an above median share of phase II trial sites in the EU before 2018 and low exposure otherwise. Our dynamic specification is:

$$y_{it} = \sum_t \beta_t \mathbf{1}\{year = t\} \times \mathbf{1}\{EUSiteShare_i\} + \mathbf{1}\{EUSiteShare_i\} + \delta_i + \delta_t + \epsilon_{it} \quad (1)$$

where y_{it} denotes the firm-level outcome (e.g., the number of clinical trials initiated) for firm i in year t. The indicator $\mathbf{1}\{EUSiteShare_i\}$ identifies whether the firm has an above-median share of pre-2018 phase II trial sites based in the EU. The coefficients β_t capture changes in the outcome for firms with high vs. low GDPR exposure over time.

Appendix Table B1 shows that firms with high exposure to the GDPR systematically differ from low exposure firms. For example, they are more research-intensive and their trials are more likely to involve sites in multiple countries and to involve more patients. To account for time-invariant firm differences, we include firm fixed effects δ_i. Further, we include year fixed effects δ_t to control for common annual shocks across firms. Standard errors are clustered at the firm level.

In regression specifications, we modify equation (1) to include an indicator for years after the GDPR's implementation ($\mathbf{1}\{GDPR_t\}$) interacted with $\mathbf{1}\{EUSiteShare_i\}$. In particular, we estimate:

$$y_{it} = \beta \mathbf{1}\{GDPR_t\} \times \mathbf{1}\{EUSiteShare_i\} + \mathbf{1}\{EUSiteShare_i\} + \delta_i + \delta_t + \epsilon_{it} \tag{2}$$

In addition to a binary measure of exposure to the GPDR, we also present our main estimates using a continuous measure of firms' pre-2018 EU trial site share. This yields similar results.

5 Results

Building on the discussion in the conceptual framework, we provide empirical evidence on how the GDPR affects firms' R&D decisions along three dimensions: research levels, research processes, and research outcomes.

5.1 Impact on Research Levels

5.1.1 Baseline Results

To understand how the GDPR shaped research levels, we begin by exploring whether the regulation changed the level of phase II trials among firms more exposed to the regulation. Figure B1 shows the raw trends in the total (Panel A) and average (Panel B) number of trials across firms with below vs. above median share of phase II trial sites in the EU before 2018.

Trial counts across both groups are relatively stable before 2018. However, after 2018, firms with an above median share of phase II trial sites (i.e., those facing relatively higher exposure to the GDPR) reduce their trials. In contrast, firms with a below median share of phase II trial sites (i.e., those facing lower exposure to the GDPR) increase. While this descriptive evidence suggests that the GDPR led to a relative decline in research levels among firms more exposed to the regulation, they could also be driven by firm-level differences (e.g., in resources, R&D ability) or by changing scientific and economic opportunities. As a result, we now turn to a formal estimation of Equation (1) to investigate the causal impact of the GDPR.

To begin, we use the number of phase II trials (with the inverse hyperbolic sine transformation) and a binary measure of $EUSiteShare$. Panel A of Figure 3 shows that the difference in the inverse hyperbolic sine-transformed number of phase II trials among firms with low and high exposure prior to the GDPR is, on average, close to zero. After the implementation of the GDPR, we observe a sharp and persistent decline in the number of trials conducted by high exposure firms. The relatively quick response is consistent with the idea that the GDPR may have prevented further investment in previously developed drugs, which is common as drugs typically have multiple therapeutic uses (Greenblatt et al., 2023). The decline in the level of phase II trials remains large and statistically significant through 2023. Panel B of Figure 3 shows similar results using the direct (non-transformed) number of phase II trials.

-Insert Figure 3 about here-

Panel A in Table 2 presents the corresponding estimates from Equation (2). Column 1 shows that the GDPR is associated with an 18 percent ($\approx e^{-0.2} - 1$) decline in the relative level of clinical trials in high exposure firms. Given the skewed distribution of trial counts and the large number of zeroes, we use the inverse hyperbolic sine transformation as our preferred measure of research levels. However, by way of comparison, when looking at the direct (non-transformed) number of trials, we continue to observe that the GDPR leads firms to reduce

their research activity. Panel B in Figure 3 and Table 2 show similar patterns when using a continuous measure of $EUSiteShare_i$. Together, these results suggest that the GDPR led to meaningful declines in overall research levels.

5.1.2 Robustness Checks and Heterogeneity Analyses

We probe the robustness of our baseline findings and examine heterogeneity in several ways.

Accounting for Changing Disease Composition. One potential concern is that the observed decline in clinical trial levels following the GDPR may instead reflect a shift in the types of diseases that firms pursue. For example, firms may prioritize diseases that are more challenging to investigate, leading to a mechanical decline in research levels. To address this, Table C1 presents results from a firm-disease-year analysis, where diseases are measured at the 3-digit MeSH level (e.g., musculoskeletal diseases, respiratory tract diseases). This approach allows us to directly control for shifts in disease composition by including disease fixed effects. Table C1 shows that the GDPR has a consistent, negative, and statistically significant effect on clinical trial levels even with the addition of disease fixed effects. These findings suggest that shifts in disease composition are unlikely to be the primary driver of the observed relative decline in clinical trial levels among firms more exposed to the GDPR.

Confounding Events. Another potential concern may be that our results are driven by concurrent events, such as the onset of Covid-19. To address this, we rerun our main analysis using only firm-year observations with years before 2020. Column 1 of Table C2 shows that the effect of GDPR remains negative and statistically significant, suggesting that our findings are not primarily driven by disruptions related to Covid-19.

Alternative Firm Samples. A related concern is that firms with high exposure to the GDPR may be systematically different from other firms as they are more likely to be multinational. To address these concerns, we restrict the sample to multinational firms, which we define as those with at least some clinical trial activity in both EU and non-EU countries

before the implementation of the GDPR. Note that this also limits the sample to firms with some pre-GDPR prior research activity. Column 2 of Table C2 shows that the effect of GDPR remains negative and statistically significant when restricting the sample to multinational firms, suggesting that our results are not driven by differences between multinational and single-country firms.

Heterogeneity Across Firms. The effects of the GDPR may vary across firm age. Older firms may have more experience with regulators and established processes for complying with regulations. In contrast, younger firms may have less expertise in dealing with regulators and changing regulatory requirements. The effects of GDPR may also vary by firm size. Firm size may reflect a firm's ability to meet regulatory requirements. Larger firms often have in-house legal teams and data protection resources. In contrast, smaller firms may not be able to afford the infrastructure needed to meet GDPR standards.

Table C3 shows that the level of trials declines among both younger and older firms, but the decline is significantly larger among younger firms. We observe that the decline is greater among smaller firms than larger firms, though the difference between the two is not statistically significantly different, likely due to small sample sizes. Taken together, these findings provide suggestive evidence that regulatory experience and resources plays an important role in shaping the types of firms most affected by the GDPR.

Differences Across Phases. Table C4 examines the effect of the GDPR across different trial phases. We find a small, but statistically significant decline in phase I trials and no significant decline in phase III trials. The larger effect in phase II trials relative to phase I may be explained by two factors: First, phase II trials are substantially more data-intensive relative to phase I trials and thus may be particularly impacted by the regulatory requirements imposed by the GDPR. Second, as discussed in Section 3.1, phase II trials are better reported in clinical trial registries compared to phase I trials. The lack of a measurable effect among phase III trials may be partially explained by the longer lag between the GDPR and the onset of phase III trials.

5.2 Impact on Research Processes

5.2.1 Trial Design

To further shed light on how the GDPR shaped the types of projects firms pursue, we examine Phase II trial design. Table 3 shows firms with high exposure to the GDPR are significantly more likely to conduct trials with pre-specified plans for sharing individual participant data. This is consistent with the view that the GDPR shapes how firms plan and manage trial data.

Columns 2 and 3 shed light on where trial activity declines. Consistent with the GDPR's geographic focus, we find that high exposure firms significantly reduce the level of trials taking place in the EU (i.e., trials with at least one EU site). In contrast, the reduction in trial activity in non-EU countries is notably lower. Among trials that are conducted, we observe little change in the average number of enrolled patients. This is consistent with the possibility that declines associated with increased costs related to regulatory compliance may be partially offset by the benefits associated with trial participants' perceptions of increased data privacy and security. In turn, this may increase their willingness to participate in the R&D process.

Finally, we observe a significant decline in the average number of diseases studied in a given trial, suggesting that in response to the GDPR, firms reduce their research scope. Taken together, these findings are consistent with the view data privacy regulations cause firms to meaningfully shift the design of research activity.

-Insert Table 3 about here-

5.2.2 Trial Collaboration

The previous results suggest that regulatory requirements associated with the GDPR increased the cost of research. Given the importance of data sharing in the research process and the GDPR's focus on data sharing, this should also affect certain forms of collaboration

between firms. Column 1 in Table 4 shows a significant decline in the level of collaboration between firms: in particular, column 1 shows a 1.8 ($\approx e^{-0.0189} - 1$) percent decline in the level of Phase II collaborative trials in a given year. This decline is modest compared to the overall 18 percent reduction in total trials, suggesting research collaborations showed some resilience to the broader effects of the GDPR.

-Insert Table 4 about here-

There are several reasons for the relatively small decline in trials conducted with collaborators relative to to overall effect on trial levels. First, collaborations offers a way to share the rising costs of compliance. Second, rather than moving away from collaboration, firms may be responding to new data privacy requirements by being more selective about who they work with. Specifically, we compare collaborations with relatively new partners (i.e., those that have no prior collaboration or the collaboration began within 2 years of the focal trial) to those with relatively established partners (i.e., those with whom the firm has had long-standing relationships).

Columns 2 and 3 in Table 4 suggests that the overall decline in collaborative trials is driven by a significant drop in collaborations with relatively new partners (column 2). At the same time, collaborations with established partners modestly increase (column 3).

5.2.3 Robustness Checks and Heterogeneity Analyses

The preceding analysis shows that firms reduce collaborative trials following the GDPR, with the decline concentrated among new rather than established partners. Several questions arise from these findings. We probe the robustness of these findings and examine heterogeneity in several ways in Appendix E.

Alternative Measures of Collaboration Novelty. The distinction between new and established collaborators depends on how we define prior collaborative experience. Table D1 shows that our results hold when we use an alternative definition of new vs. existing collaborators using a 5-year threshold instead of the baseline 2-year threshold for prior collaborative

experience with phase II trials. Table D2 shows that the results are similar when measuring new vs. existing collaborators based on prior collaborative experience with phase III trials.

Heterogeneity Across Firms. If established relationships help firms navigate regulatory requirements, we would expect the effects to vary by firm age (which proxies for the opportunity to develop partnerships) and potentially by firm size (which proxies for the ability of a firm to comply with regulatory requirements and share regulatory costs).

Table D3 shows that the decline in collaborative trials is driven by younger firms (column 1), while older firms (column 2) show no significant change. The difference in effects is statistically significant. This suggests that older firms are better able to maintain collaborations despite the added requirements introduced by GDPR. Columns 3 and 4 show results by firm size. While the estimated effect is slightly more negative for small firms, the differences between small and large firms are not statistically significant. This is consistent with the view that the ability to share compliance costs across collaborators is less important than having established relationships in shaping firms' collaboration decisions.

Deal-based Measures of Collaboration. While earlier analyses focused on one measure of collaboration (collaborative clinical trials), collaboration can also take other forms, such as R&D-related licensing deals between firms. We examine two types of deals: R&D collaboration deals, where firms jointly work on developing a drug, and asset transfer deals, where one firm acquires the rights to a compound or technology developed by another. Consistent with the findings outlined in Table 4, Table D4 shows that the GDPR led to a significant decline across both types of deal-based collaborative activity.

Geographic Distance Between Collaborators' Headquarters. If GDPR's data transfer restrictions drive the decline in collaboration, effects may vary with geographic distance between partners. To the extent that firms' research activities take place closer to their headquarters, greater geographic distance could increase the costs of compliance with the GDPR (e.g., by requiring data transfers across borders) and make it more difficult to establish trust between partners (Catalini et al., 2020). Table D5 examines whether the effects of

GDPR vary depending on the geographic distance between collaborators' headquarters. The results show that GDPR does not significantly affect collaborations with either EU-based or non-EU-based partners, regardless of whether the focal firm is located within or outside the EU.

There are several explanations for this. First, geographic-related frictions (which may increase coordination costs or increase the challenge of forming trust) may not be the primary drivers of the observed decline in collaboration. Instead, firms appear to respond more broadly to the regulatory environment, regardless of their partners' locations. Second, given the global nature of drug development, the location of a firm's headquarter may be an imperfect proxy for where research activities actually take place. Depending on where firms would like to launch the drug, they may operate through subsidiaries in different countries. As a result, where a firm is located may not fully reflect their expected exposure to the regulation.

5.3 Impact on Research Outcomes

While the prior results indicate that the GDPR led to an overall decline in research levels, the effect on trial outcomes remains unclear. On the one hand, faced with increased costs, firms may be more selective about the projects they initiate and only conduct trials with a greater likelihood of successful completion. We would expect the share of trials that complete successfully to increase following the GDPR. On the other hand, increased costs associated with collecting, analyzing, and sharing data may increase trial durations and cause firms to increase trial terminations. Table 5 provides evidence consistent with this latter channel. Column 1 shows that following the GDPR, trials take 12 percent longer to complete and the share of trials that successfully complete declines. These results, combined with the previous findings on trial levels, are consistent with the view that the GDPR shapes both the number of projects that firms initiate and the number that successfully come to market. Finally, Table 5 shows delays in the availability of information about trial outcomes: following the

GDPR, the share of trials reporting results within one year of completion declines.

-Insert Table 5 about here-

6 Conclusion

Understanding how data privacy regulation shapes innovation is of substantial interest to strategy and innovation scholars, managers, and policymakers. Yet prior empirical work has largely focused on examining how regulation shapes immediate firm performance outcomes, raising open questions about how such regulation alters firms' R&D decisions. Using variation in firms' pre-GDPR geographic distribution of clinical trials, we show that the GDPR led firms to reduce their clinical trial levels by 18 percent and led to meaningful shifts in their research processes and outcomes.

Our analysis has several limitations that suggest opportunities for future work. First, our data measures investment in clinical trials but not the downstream outcomes, such as drug quality or patient health. Future research could examine whether GDPR exposure ultimately affects the quality of therapies developed or consumer access to treatment. Second, while we study the pharmaceutical industry, future research could explore whether similar outcomes operate in other data-intensive industries. Third, our firm-level analysis restricts our analysis to examining responses among existing firms. Future work should examine how the GDPR shaped firm entry and exit, and examine how these changes may shape clinical trial activity in other jurisdictions (e.g., Asia) (Liu et al., 2025).

These findings carry broader implications. First, the GDPR was designed to protect EU citizens' privacy, but our results suggest it may inadvertently affect their long-term outcomes by slowing medical innovation. An 18 percent reduction in clinical trials, combined with longer trial durations and lower completion rates, suggests that some valuable treatments may be delayed or never reach patients. Given the growth in the number of privacy regulations modeled after the GDPR Greenleaf (2025), our findings suggest that policymakers should consider the effects of regulations in research-intensive industries. For instance,

through explicit safe harbors for pseudonymized research data or streamlined consent procedures for secondary analyses. Third, the shift from new to established collaborators suggests that data privacy regulation may lead to the concentration of research among a narrow set of researchers, potentially disadvantaging younger firms that lack established relationships. Combined with evidence that the GDPR reduced venture investment in technology firms (Jia et al., 2021), this pattern raises questions about long-run effects on competition and the distribution of innovative activity.

Taken together, our study highlights how data privacy regulation and innovation are closely linked. By documenting how GDPR reshaped firms' research levels, processes, and outcomes, we provide evidence that privacy regulation not only shapes short-term performance but also leads to meaningful shifts in firms' R&D decisions. These findings advance understanding of how regulation shapes firms' R&D decisions in data-intensive industries and its broader effects for the rate and direction of subsequent innovation.

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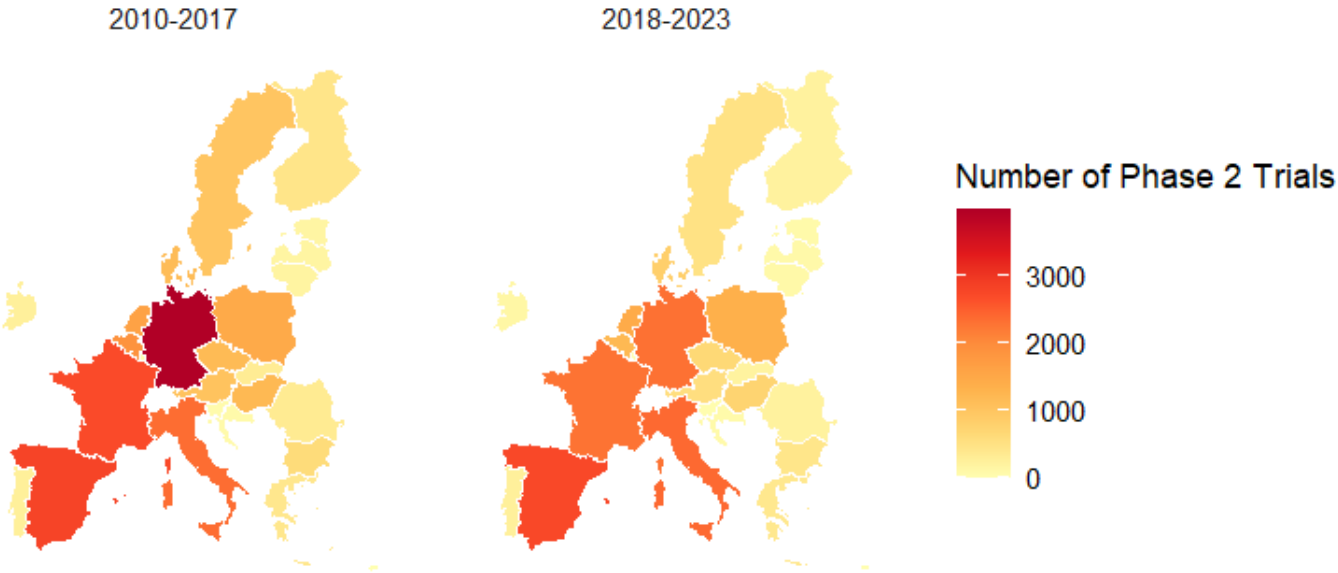
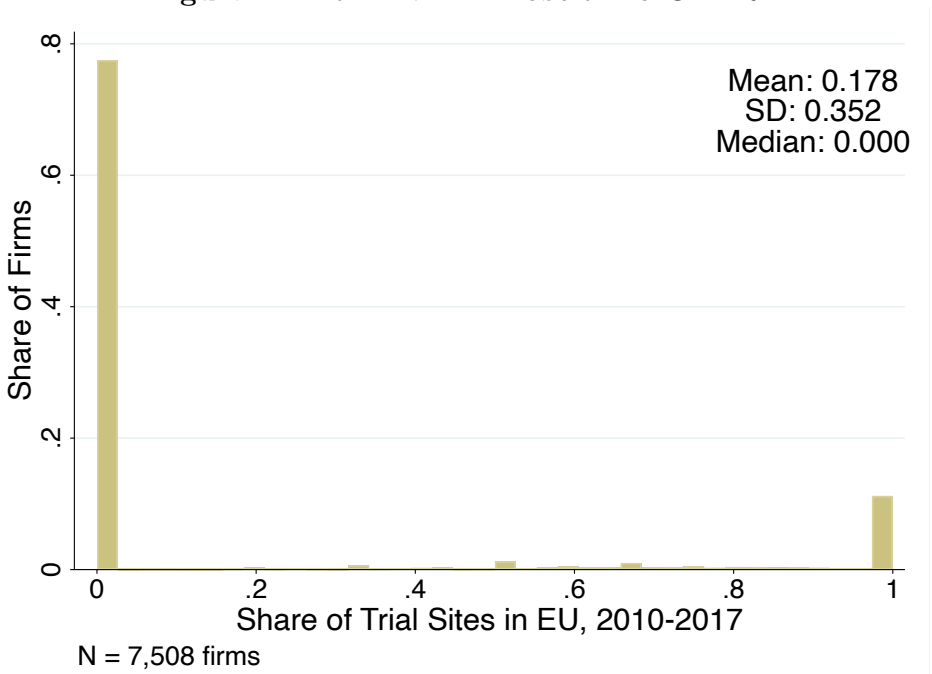
7 Main Figures and Tables

Figure 1: Phase II Clinical Trials in the EU Before and After GDPR



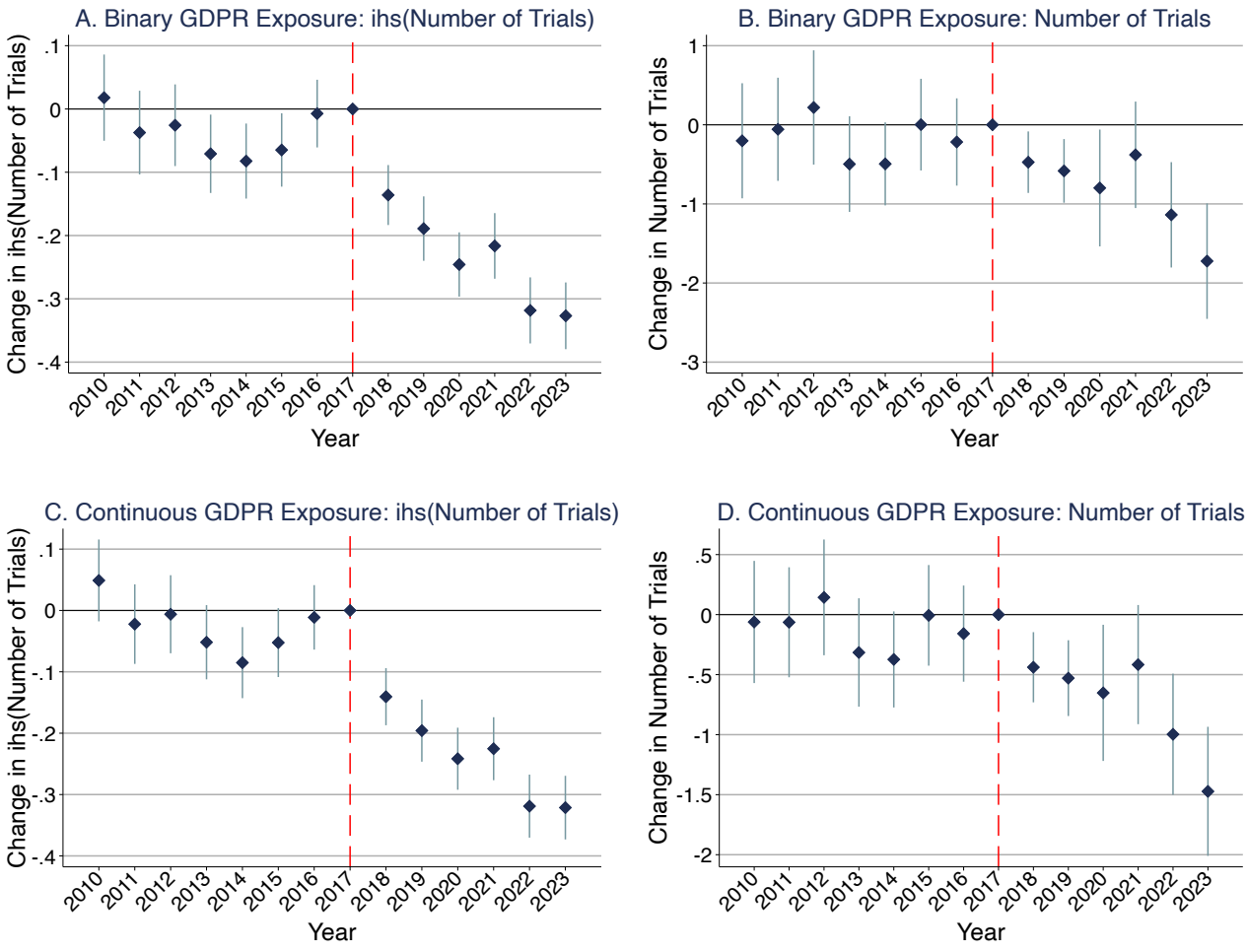
Notes. This figure shows the number of Phase II clinical trials initiated in EU countries before the GDPR (2010–2017) and after its implementation (2018–2023). Darker shading indicates more trials.

Figure 2: Firm-level Exposure to GDPR



Notes. This figure shows the distribution of firms' pre-2018 share of phase II trial sites in the EU.

Figure 3: Impact of GDPR on Trial Levels



Note: Panels A and B present coefficients from firm-year regressions that regresses the outcome on an indicator for after the GDPR interacted with an indicator for whether a firm has an above median share of phase II trial sites in the EU prior to 2018. Panels C and D present coefficients from firm-year regressions where an indicator for after the GDPR interacted with a continuous rather than binary measure of share of Phase II trial sites in the EU prior to 2018. In all regressions, we include year fixed effects and firm fixed effects and cluster standard errors at the firm level. In Panels A and C, the outcome is the inverse hyperbolic sine transformed number of phase II trials in a year. In Panels B and D, the outcome is the number of phase II trials in a year. Solid vertical lines are 95 percent confidence intervals. The dotted vertical line represents the year before the GDPR's implementation.

Table 1: Firm-Year Level Summary Statistics

	Count (1)	Mean (2)	SD (3)	Min (4)	Max (5)
Research Levels					
# Trials	73,591	0.96	10	0	559
# EU Trials	73,591	0.83	10	0	554
# Non-EU Trials	73,591	0.13	1	0	30
# Multicountry Trials	73,591	0.36	2	0	97
# Diseases	73,591	0.18	1	0	18
Research Process					
Share of Trials with Pre-specified Plans for Sharing Participant Data	9,973	0.05	0	0	1
# Patients Per Trial	9,973	117.22	166	0	5,000
# Trials with Collab.	73,591	0.12	1	0	149
# Trials with New Collab.	73,591	0.09	1	0	95
# Trials with Established Collab.	73,591	0.04	1	0	67
Research Outcomes					
Duration Per Trial (Years)	7,647	2.70	2	0	16
Share of Trials Completed	9,973	0.56	0	0	1
Share of Trials Reporting Results Within 1 Year	9,973	0.01	0	0	1
Firm Characteristics					
0/1: Old Firm	69,174	0.39	0	0	1
0/1: Large Firm	73,591	0.19	0	0	1

Notes. This table reports firm-year level summary statistics of key research characteristics. There are 73,591 firm-year observations, representing 7,508 unique firms. Certain variables (e.g., "# Patients Per Trial") may have fewer observations since they are only reported for the firm-year observations with at least one clinical trial.

Table 2: Impact of GDPR on Trial Levels

	ihs(# Trials) (1)	# Trials (2)
A. Binary GDPR Exposure		
$\mathbf{1}\{GDPR\} \times \mathbf{1}\{EUSiteShare\}$	-0.205***	-0.695***
	(0.0147)	(0.195)
Mean of Dep. Var.	0.219	0.965
Observations	73,253	73,253
Firm FEs	Yes	Yes
Year FEs	Yes	Yes
B. Continuous GDPR Exposure		
$\mathbf{1}\{GDPR\} \times EUSiteShare$	-0.216***	-0.645***
	(0.0146)	(0.143)
Mean of Dep. Var.	0.219	0.965
Observations	73,253	73,253
Firm FEs	Yes	Yes
Year FEs	Yes	Yes

Notes. Panel A presents coefficients from firm-year regressions that regresses the outcome on an indicator for after the GDPR interacted with an indicator for whether a firm has an above median share of phase II trial sites in the EU prior to 2018. Panel B presents coefficients from firm-year regressions where an indicator for after the GDPR interacted with a continuous rather than binary measure of share of Phase II trial sites in the EU prior to 2018. In both, we include year fixed effects and firm fixed effects. Estimates are based on OLS regressions. Standard errors are clustered at the firm level and reported in parentheses, with *** p<0.01, ** p<0.05, * p<0.1.

Table 3: Impact of GDPR on Trial Design

	Share with Pre-specified Plans for Sharing Individual Participant Data (1)	ihs(# EU Trials) (2)	ihs(# Non-EU Trials) (3)	ihs(# Multicountry Trials) (4)	ihs(# Patients Per Trial) (5)	ihs(# Diseases Per Trial) (6)
$\mathbf{1}\{GDPR\} \times \mathbf{1}\{EUSiteShare\}$	0.0821***	-0.212***	-0.0164***	-0.0616***	0.0282	-0.0936***
	(0.0191)	(0.0141)	(0.00605)	(0.0145)	(0.0853)	(0.0254)
Mean of Dep. Var.	0.0605	0.153	0.0891	0.196	4.749	1.024
Observations	8,106	73,253	73,253	73,253	8,106	8,106
Firm FEs	Yes	Yes	Yes	Yes	Yes	Yes
Year FEs	Yes	Yes	Yes	Yes	Yes	Yes

Notes. This table presents coefficients from firm-year regressions that regresses the outcome on an indicator for after the GDPR interacted with an indicator for whether a firm has an above median share of phase II trial sites in the EU prior to 2018. Columns 5 and 6 contain fewer than 73,591 observations because their outcomes are only defined when there is a non-zero number of trials. Estimates are based on OLS regressions with year fixed effects and firm fixed effects. Standard errors are clustered at the firm level and reported in parentheses, with *** p<0.01, ** p<0.05, * p<0.1.

Table 4: Impact of GDPR on Trial Collaboration

	Dependent variable: ihs(# Trials)		
	With Any Collaborator	With New Collaborators	With Established Collaborators
	(1)	(2)	(3)
$\mathbf{1}\{GDPR\} \times \mathbf{1}\{EUSiteShare\}$	-0.0189**	-0.0249***	0.00922*
	(0.00722)	(0.00686)	(0.00428)
Mean of Dep. Var.	0.047	0.040	0.011
Diff. Wald Test p-value		0.00	
Observations	73,253	73,591	73,591
Firm FEs	Yes	Yes	Yes
Year FEs	Yes	Yes	Yes

Notes. This table presents coefficients from firm-year regressions that regresses the outcome on an indicator for after the GDPR interacted with an indicator for whether a firm has an above median share of phase II trial sites in the EU prior to 2018. The outcome in column 1 is the number of trials conducted by research partners with no prior phase II collaboration or phase II collaborations that began within three years of the focal trial. The outcome in column 2 is the number of other trials conducted by research partners. Outcomes are transformed with the inverse hyperbolic sine transformation. Column 1 reports OLS estimates. Columns 2 and 3 report estimates from seemingly unrelated regressions. The "Wald Test p-value" is the p-value comparing the $GDPR \times HighExposure$ coefficient in columns 2 vs. 3. Standard errors are clustered at the firm level and reported in parentheses, with *** p<0.01, ** p<0.05, * p<0.1.

Table 5: Impact of GDPR on Trial Outcomes

	ihs(Duration Per Trial (Years))	Share of Trials Completed	Share of Trials Reporting Results Within 1 Year
	(1)	(2)	(3)
$\mathbf{1}\{GDPR\} \times \mathbf{1}\{EUSiteShare\}$	0.111***	-0.0422*	-0.0133*
	(0.0407)	(0.0246)	(0.00693)
Mean of Dep. Var.	1.584	0.579	0.0127
Observations	6,308	8,106	8,106
Firm FEs	Yes	Yes	Yes
Year FEs	Yes	Yes	Yes

Notes. This table presents coefficients from firm-year regressions that regresses the outcome on an indicator for after the GDPR interacted with an indicator for whether a firm has an above median share of phase II trial sites in the EU prior to 2018. Estimates are based on OLS regressions with year fixed effects and firm fixed effects. Standard errors are clustered at the firm level and reported in parentheses, with *** p<0.01, ** p<0.05, * p<0.1.

Data Privacy Regulation and Innovation: Evidence from GDPR

Online Appendix

Appendix A Comparison of Data Privacy Regulations

The GDPR is part of a broader global trend toward strengthening data protections. This appendix compares the GDPR to two prominent U.S. regulations: the California Consumer Privacy Act (CCPA) and the Health Insurance Portability and Accountability Act (HIPAA).

California Consumer Privacy Act (CCPA)

The CCPA was passed on June 28, 2018, and became effective on January 1, 2020. Its subsequent amendment, the California Privacy Rights Act (CPRA), took effect on January 1, 2023. The CCPA grants California residents the right to know what personal data is collected about them, request deletion of their data, and opt out of the sale of their data (Jia et al., 2021; Peukert et al., 2022).

The CCPA differs from the GDPR in several important ways. First, the CCPA follows an opt-out approach: firms can set the default to allow data collection and then provide consumers an option to change this default. In contrast, the GDPR requires affirmative opt-in consent. Second, the CCPA applies only to for-profit businesses that meet at least one of the following criteria: gross annual revenue exceeding $25 million, collecting or sharing the data of more than 50,000 consumers, or deriving at least 50 percent of annual revenue from selling consumer data. These thresholds exclude most small businesses and startups (Jia et al., 2021). The GDPR, by contrast, applies broadly to any organization processing the personal data of EU residents, regardless of firm size or revenue.

Third, the CCPA's geographic scope is narrower. While it can apply to firms located outside California if they serve California residents, the GDPR's doctrine extends European privacy standards to any firm that offers goods or services to EU residents or monitors their behavior, regardless of where the firm is located (Peukert et al., 2022). Finally, the CCPA's penalties are lower than the GDPR's. CCPA penalties can reach up to $2,500 per unintentional violation and $7,500 per intentional violation. In contrast, the GDPR permits fines of up to €20 million or 4 percent of global annual revenue, whichever is greater.

Health Insurance Portability and Accountability Act (HIPAA)

HIPAA was enacted in 1996 and amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act in 2009, which added breach notification requirements for covered entities (Adjerid et al., 2016; Acquisti et al., 2016). HIPAA governs the use and disclosure of protected health information by covered entities, which include healthcare providers, health plans, and healthcare clearinghouses.

HIPAA differs from the GDPR in scope, consent requirements, and enforcement. First, HIPAA is sector-specific, applying only to healthcare-related entities and their business associates. The GDPR applies broadly across all industries. Second, HIPAA permits certain disclosures of health information without explicit patient consent. For example, healthcare

providers may share protected health information for treatment, payment, and healthcare operations without obtaining patient authorization (Adjerid et al., 2016). In contrast, the GDPR requires explicit consent for processing personal data, including health data, which it classifies as a special category warranting additional protections.

Third, HIPAA's penalties are substantially lower than the GDPR's. HIPAA penalties are tiered based on the level of culpability, ranging from $100 to $50,000 per violation, with an annual maximum of $1.5 million per violation category. The GDPR's maximum fines can reach up to €20 million or 4 percent of global revenue, whichever is higher.

Fourth, enforcement under HIPAA has historically been less aggressive. The HITECH Act strengthened enforcement by requiring the Department of Health and Human Services to conduct periodic audits and by enabling state attorneys general to bring civil actions. Nonetheless, HIPAA enforcement has been described as relatively limited compared to the active enforcement regime that has emerged under the GDPR, where data protection authorities across EU member states have levied over €3 billion in fines in the five years following implementation (Demirer et al., 2024).

Summary

Table 6 summarizes the key differences across these three regulations. The GDPR is the most comprehensive along several dimensions: it applies across industries, requires affirmative consent, imposes substantial penalties, and extends to any firm serving EU residents regardless of location. These features help explain why the GDPR has attracted significant attention from firms operating internationally and why compliance costs have been substantial.

Table 6: Comparison of Data Privacy Regulations

	GDPR	**CCPA**	**HIPAA**
Effective Date	May 2018	January 2020	1996
Scope	All industries	All industries (with thresholds)	Healthcare sector
Consent Approach	Opt-in	Opt-out	Permits disclosure without consent for treatment, payment, operations
Size Thresholds	None	Revenue >$25M, >$50K users, or >$50% revenue from data sales	Applies to covered entities
Maximum Penalties	€20M or 4% global revenue	$7,500 per intentional violation	$1.5M per violation category per year
Geographic Reach	Effects-based (applies to firms serving EU residents)	Applies to firms serving CA residents	US only

Appendix B Background on Drug Development

This appendix provides additional detail on the regulatory approval processes in the European Union and United States.

Regulatory Approval in the European Union

In the European Union, the centralized procedure is managed by the European Medicines Agency (EMA) and yields a single marketing authorization valid across all EU and EEA member states (European Parliament and Council of the European Union, 2004). This procedure is mandatory for biotechnology-derived products, orphan drugs, advanced therapy medicinal products, and new active substances for treating cancer, HIV/AIDS, neurodegenerative disorders, diabetes, autoimmune diseases, and viral diseases. The EMA's Committee for Medicinal Products for Human Use (CHMP) evaluates applications within 210 active days; the European Commission then issues the final authorization within 67 days.

Drugs not required to use the centralized procedure may pursue the decentralized procedure, where drug developers can seek authorization of a drug for more than one member state at the same time (European Parliament and Council of the European Union, 2001). In this case, a Reference Member State conducts the primary review and notifies the other member states to which the application has been sent. Additional pathways include the mutual recognition procedure (a drug approved in one EU country can be approved for another country) and national authorization procedures (approval is sought within a single member state for use in that country only).

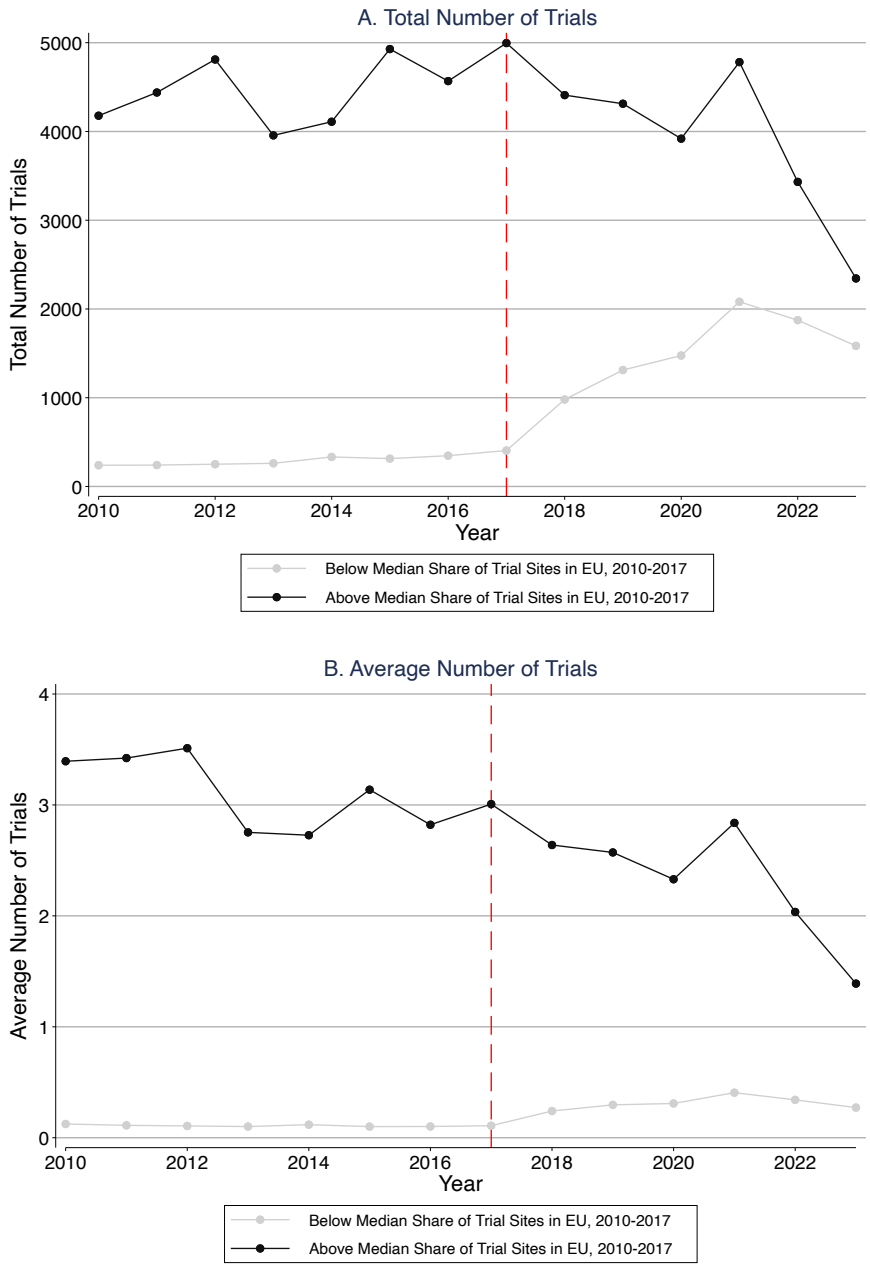
Clinical trial conduct in the EU is governed by the Clinical Trials Regulation (Regulation EU No 536/2014), which harmonizes procedures across member states (European Medicines Agency, 2014). Sponsors may also conduct trials outside the EU for subsequent EU marketing authorization as long as those trials meet equivalent standards.

Regulatory Approval in the United States

In the United States, the Food and Drug Administration (FDA) governs the drug approval process (U.S. Food and Drug Administration, 2023). Before conducting clinical trials, sponsors must file an Investigational New Drug (IND) application containing preclinical data demonstrating sufficient safety for human testing. Following successful trials, sponsors submit a New Drug Application (NDA) for small-molecule drugs or a Biologics License Application (BLA) for biologics. The FDA typically reviews both application types within 10 months (or 6 months under priority review).

Appendix C Additional Descriptives

Figure B1: Trends in Trials



Notes. This figure plots the total number of clinical trials across (i) firms with a below medians share of trial sites in the EU before 2017 (light gray) and (ii) firms with an above median share of trial sites in the EU before 2017 (dark gray). Panel A shows the total number of trials across firms. Panel B shows the average number of trials across firms. The dotted vertical line represents the year before the GDPR.

Table B1: Pre-GDPR Differences Across Low and High Exposure Firms

	Low Exposure		High Exposure		
	Mean	SD	Mean	SD	p-value
	(1)	(2)	(3)	(4)	(5)
Research Levels					
# Trials	0.15	0.80	3.31	20.08	0.00***
Research Processes					
Share of Trials with Pre-specified Plans for Sharing Participant Data	0.03	0.16	0.05	0.18	0.00***
# Trials with EU Site	0.04	0.54	3.10	19.25	0.00***
# Trials with Non-EU Sites	0.11	0.53	0.22	1.16	0.00***
# Multicountry Trials	0.05	0.30	1.02	3.71	0.00***
# Patients Per Trial	102.12	161.08	127.46	145.08	0.00***
# Diseases	0.09	0.34	0.45	1.27	0.00***
# Trials with Collab.	0.03	0.39	0.32	2.45	0.00***
# Trials with New Collab.	0.03	0.26	0.24	1.86	0.00***
# Trials with Established Collab.	0.01	0.26	0.11	1.50	0.00***
Research Outcomes					
Duration Per Trial (Years)	2.31	1.80	3.10	2.12	0.00***
Share of Trials Completed	0.77	0.40	0.75	0.38	0.08*
Share of Trials Reporting Results Within 1 Year	0.01	0.11	0.03	0.13	0.00***
Firm Characteristics					
0/1: Old Firm	0.42	0.49	0.51	0.50	0.00***
0/1: Large Firm	0.10	0.30	0.52	0.50	0.00***

Notes. This table compares summary statistics of key research characteristics before the GDPR across firms with low and high exposure. Column 5 presents p-values from t-tests comparing the difference of means. *** p<0.01, ** p<0.05, * p<0.1

Table B2: Pre-GDPR Differences Across Firms Without and With Collaborators

	No Collaboration		Any Collaboration		
	Mean	SD	Mean	SD	p-value
	(1)	(2)	(3)	(4)	(5)
Research Levels					
# Trials	0.27	1.54	3.89	22.19	0.00***
Research Processes					
Share of Trials with Pre-specified Plans for Sharing Participant Data	0.03	0.17	0.08	0.25	0.00***
# EU Trials	0.20	1.47	3.49	21.45	0.00***
# Non-EU Trials	0.06	0.33	0.40	1.32	0.00***
# Multicountry Trials	0.21	0.70	0.98	4.15	0.00***
# Patients Per Trial	105.26	140.83	131.42	191.15	0.00***
# Diseases	0.10	0.35	0.55	1.37	0.00***
Trial Outcomes					
Duration Per Trial (Years)	2.34	1.68	3.10	2.35	0.00***
Share of Trials Completed	0.55	0.47	0.57	0.45	0.05*
Share of Trials Reporting Results Within 1 Year	0.01	0.09	0.01	0.10	0.00***
Firm Characteristics					
0/1: Old Firm	0.39	0.49	0.38	0.48	0.00***
0/1: Large Firm	0.15	0.35	0.39	0.49	0.00***

Notes. This table compares summary statistics of key research characteristics across firms with and without any collaborators. Column 5 presents p-values from t-tests comparing the difference of means. *** p<0.01, ** p<0.05, * p<0.1

Appendix D Robustness Checks and Heterogeneity Analyses

Table C1: Impact of GDPR on Trial Levels, Firm-Disease-Year Analysis

	Dependent variable: ihs(# Trials)			
	(1)	(2)	(3)	(4)
$\mathbf{1}\{GDPR\} \times \mathbf{1}\{EUSiteShare\}$	-0.00975***	-0.00823***	-0.00823***	-0.00823***
	(0.00161)	(0.00159)	(0.00160)	(0.00160)
Mean of Dep. Var.	0.00694	0.00694	0.00694	0.00694
Observations	807,375	807,375	807,375	807,375
Firm FEs	No	Yes	Yes	Yes
Year FEs	No	No	Yes	Yes
Disease FEs	No	No	No	Yes

Notes. This table presents coefficients from a firm-disease-year level regression that regresses the outcome on an indicator for after the GDPR interacted with an indicator for whether a firm has an above median share of phase II trial sites in the EU prior to 2018. Diseases are measured at the 3-digit MeSH code level. Estimates are based on OLS regressions. Standard errors are clustered at the firm level and reported in parentheses, with *** p<0.01, ** p<0.05, * p<0.1.

Table C2: Impact of GDPR: Alternative Outcome and Samples

	Dep. Var: $\mathbf{1}\{AnyTrial\}$	Dep. Var: ihs(# Trials) Sample: Years before 2020	Dep. Var: ihs(# Trials) Sample: Multinational firms
	(1)	(2)	(3)
$\mathbf{1}\{GDPR\} \times \mathbf{1}\{EUSiteShare\}$	-0.112***	-0.140***	-0.212***
	(0.00700)	(0.0173)	(0.0289)
Mean of Dep. Var.	0.134	0.230	0.494
Observations	73,253	45,289	18,675
Firm FEs	Yes	Yes	Yes
Year FEs	Yes	Yes	Yes

Notes. This table reports coefficients from firm-year regressions that regresses the outcome on an indicator for after the GDPR interacted with an indicator for whether a firm has an above median share of phase II trial sites in the EU prior to 2018. The outcome in column 1 is an indicator for whether there is any phase II trial conducted in the firm-year. Column 2 restricts firm-years to those before 2020. Column 3 restricts firm-years to multinational firms. Multinational firms are defined as those whose pre-2018 share of EU trials is between 0 and 1. In all regressions, we include year fixed effects and firm fixed effects. Estimates are from OLS regressions. Standard errors are clustered at the firm level and reported in parentheses, with *** p<0.01, ** p<0.05, * p<0.1.

Table C3: Impact of GDPR on Trial Levels by Firm Age and Size

	Dependent variable: ihs(# Trials)			
	Firm Age		Firm Size	
	Younger Firm (1)	Older Firm (2)	Smaller Firm (3)	Larger Firm (4)
$\mathbf{1}\{GDPR\} \times \mathbf{1}\{EUSiteShare\}$	-0.239***	-0.172***	-0.104***	-0.0605
	(0.0206)	(0.0230)	(0.0111)	(0.0349)
Mean of Dep. Var.	0.206	0.267	0.116	0.656
Diff. Wald Test $-value$	0.03		0.23	
Observations	42,236	26,938	59,326	14,265
Firm FEs	Yes	Yes	Yes	Yes
Year FEs	Yes	Yes	Yes	Yes

Notes. This table presents coefficients from firm-year regressions that regresses the outcome on an indicator for after the GDPR interacted with an indicator for whether a firm has an above median share of phase II trial sites in the EU prior to 2018. Estimates are from seemingly unrelated regressions. Outcomes are transformed with the inverse hyperbolic sine transformation. The "Wald Test p-value" is the p-value comparing the $GDPR \times HighExposure$ coefficient in columns 1 vs. 2 and columns 3 vs. 4. Standard errors are clustered at the firm level and reported in parentheses, with *** p<0.01, ** p<0.05, * p<0.1.

Table C4: Impact of GDPR Across Trial Phases

	ihs(# Phase I Trials) (1)	ihs(# Phase II Trials) (2)	ihs(# Phase III Trials) (3)
$\mathbf{1}\{GDPR\} \times \mathbf{1}\{EUSiteShare\}$	-0.0298***	-0.205***	-0.0163
	(0.00861)	(0.0147)	(0.0163)
Mean of Dep. Var.	0.131	0.219	0.190
Observations	73,253	73,253	73,253
Firm FEs	Yes	Yes	Yes
Year FEs	Yes	Yes	Yes

Notes. This table reports coefficients from firm-year regressions that regresses the outcome on an indicator for after the GDPR interacted with an indicator for whether a firm has an above median share of phase II trial sites in the EU prior to 2018. In all regressions, we include year fixed effects and firm fixed effects. Estimates are from OLS regressions. Standard errors are clustered at the firm level and reported in parentheses, with *** p<0.01, ** p<0.05, * p<0.1.

Table C5: Impact of GDPR on Levels Across Diseases with Varying Levels of Prior Research Activity

	Dependent variable: ihs(# Trials)		
	Diseases with Low Research Activity (1)		Diseases with High Research Activity (2)
$\mathbf{1}\{GDPR\} \times \mathbf{1}\{EUSiteShare\}$	-0.00195		-0.0150***
	(0.00106)		(0.00308)
Mean of Dep. Var.	0.007		0.007
Diff. Wald Test p-value		0.00	
Observations	807,375		807,375
Firm FEs	Yes		Yes
Year FEs	Yes		Yes
Disease FEs	Yes		Yes

Notes. This table reports DID estimates of the effect of GDPR across diseases with low vs. high level of prior research activity. A disease is considered as having a low (high) level of prior research activity if the total number of clinical trials before 2010 is below (above) the median. The unit of observation is the firm-disease-year level. Diseases are measured at the 3-digit MeSH code level. Estimates are from seemingly unrelated regressions. The "Wald Test p-value" is the p-value comparing the $GDPR \times HighExposure$ coefficient in columns 1 vs. 2. Standard errors are clustered at the firm level and reported in parentheses, with *** p<0.01, ** p<0.05, * p<0.1.

Appendix E Additional Collaboration Analyses

Table D1: Impact of GDPR on Trial Collaboration: Alternative Time-Horizon for Measuring New and Existing Collaborations

	Dependent variable: ihs(# Trials)		
	With New Collab.		With Established Collab.
	(1)		(2)
$\mathbf{1}\{GDPR\} \times \mathbf{1}\{EUSiteShare\}$	-0.0236**		0.00808*
	(0.00736)		(0.00370)
Mean of Dep. Var.	0.044		0.006
Diff. Wald Test p-value		0.00	
Observations	73,591		73,591
Firm FEs	Yes		Yes
Year FEs	Yes		Yes

Notes. This table presents coefficients from firm-year regressions that regresses the outcome on an indicator for after the GDPR interacted with an indicator for whether a firm has an above median share of phase II trial sites in the EU prior to 2018. The outcome in column 1 is the number of trials conducted by research partners with no prior collaboration or collaborations that began within five years of the focal trial. The outcome in column 2 is the number of other trials conducted by research partners. Outcomes are transformed with the inverse hyperbolic sine transformation. Estimates are from seemingly unrelated regressions. The "Wald Test p-value" is the p-value comparing the $GDPR \times HighExposure$ coefficient. Standard errors are clustered at the firm level and reported in parentheses, with *** p<0.01, ** p<0.05, * p<0.1.

Table D2: Impact of GDPR on Trial Collaboration: Alternative Phases for Measuring New and Existing Collaborations

	Dependent variable: ihs(# Trials)	
	With New Collab.	With Established Collab.
	(1)	(2)
$\mathbf{1}\{GDPR\} \times \mathbf{1}\{EUSiteShare\}$	-0.0228**	0.00618
	(0.00731)	(0.00373)
Mean of Dep. Var.	0.044	0.005
Diff. Wald Test p-value	0.00	
Observations	73,591	73,591
Firm FEs	Yes	Yes
Year FEs	Yes	Yes

Notes. This table presents coefficients from firm-year regressions that regresses the outcome on an indicator for after the GDPR interacted with an indicator for whether a firm has an above median share of phase II trial sites in the EU prior to 2018. The outcome in column 1 is the number of trials conducted by research partners with no prior phase III collaboration or phase III collaborations that began within three years of the focal trial. The outcome in column 2 is the number of other trials conducted by research partners. Outcomes are transformed with the inverse hyperbolic sine transformation. Estimates are from seemingly unrelated regressions. The "Wald Test p-value" is the p-value comparing the $GDPR \times HighExposure$ coefficient. Standard errors are clustered at the firm level and reported in parentheses, with *** p<0.01, ** p<0.05, * p<0.1.

Table D3: Impact of GDPR on Trial Collaboration by Firm Age and Size

	Dependent variable: ihs(# Collab. Trials)			
	Firm Age		Firm Size	
	Young Firm	Old Firm	Small Firm	Large Firm
	(1)	(2)	(3)	(4)
$\mathbf{1}\{GDPR\} \times \mathbf{1}\{EUSiteShare\}$	-0.0377***	-0.00129	-0.00601	0.0229
	(0.00805)	(0.0129)	(0.00453)	(0.0168)
Mean of Dep. Var.	0.041	0.061	0.025	0.139
Diff. Wald Test p-value	0.02		0.10	
Observations	42,236	26,938	59,326	14,265
Firm FEs	Yes	Yes	Yes	Yes
Year FEs	Yes	Yes	Yes	Yes

Notes. This table presents coefficients from firm-year regressions that regresses the outcome on an indicator for after the GDPR interacted with an indicator for whether a firm has an above median share of phase II trial sites in the EU prior to 2018. Estimates are from seemingly unrelated regressions. Outcomes are transformed with the inverse hyperbolic sine transformation. The "Wald Test p-value" is the p-value comparing the $GDPR \times HighExposure$ coefficient in columns 1 vs. 2 and columns 3 vs. 4. Standard errors are clustered at the firm level and reported in parentheses, with *** p<0.01, ** p<0.05, * p<0.1.

Table D4: Impact of GDPR on Deal-Based Research Collaboration

	Dependent variable: ihs(# Deals)	
	R&D Collab. Deals	Asset Transfer Deals
	(1)	(2)
$\mathbf{1}\{GDPR\} \times \mathbf{1}\{EUSiteShare\}$	-0.0136***	-0.0212***
	(0.00433)	(0.00461)
Mean of Dep. Var.	0.0547	0.0581
Observations	73,253	73,253
Firm FEs	Yes	Yes
Year FEs	Yes	Yes

Notes. This table presents coefficients from firm-year regressions that regresses the outcome on an indicator for after the GDPR interacted with an indicator for whether a firm has an above median share of phase II trial sites in the EU prior to 2018. The outcome in column 1 is the number of co-development deals. The outcome in column 2 is the number of asset transfer deals. Outcomes are transformed with the inverse hyperbolic sine transformation. Estimates are from OLS regressions. Standard errors are clustered at the firm level and reported in parentheses, with *** p<0.01, ** p<0.05, * p<0.1.

Table D5: Impact of GDPR on Trial Levels, by Geographic Distance of Collaborator Headquarters

	Dependent variable: ihs(# Trials)			
	Firm with EU HQ		Firm with Non-EU HQ	
	Collab. Firm with EU HQ	Collab. Firm with Non-EU HQ	Collab. Firm with EU HQ	Collab. Firm with Non-EU HQ
	(1)	(2)	(3)	(4)
$\mathbf{1}\{GDPR\} \times \mathbf{1}\{EUSiteShare\}$	-0.00321	0.00207	-0.00301	-0.00755
	(0.00494)	(0.00712)	(0.00480)	(0.00740)
Mean of Dep. Var.	0.00711	0.0155	0.00650	0.0152
Observations	17,309	17,309	54,430	54,430
Firm FEs	Yes	Yes	Yes	Yes
Year FEs	Yes	Yes	Yes	Yes

Notes. This table presents coefficients from firm-year regressions that regresses the outcome on an indicator for after the GDPR interacted with an indicator for whether a firm has an above median share of phase II trial sites in the EU prior to 2018. The outcome in column 1 is the number of co-development deals. The outcome in column 2 is the number of asset transfer deals. Outcomes are transformed with the inverse hyperbolic sine transformation. Estimates are from OLS regressions. Standard errors are clustered at the firm level and reported in parentheses, with *** p<0.01, ** p<0.05, * p<0.1.