Information Disclosure and Peer Innovation: Evidence from Mandatory Reporting of Clinical Trials

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ABSTRACT

Using the Food and Drug Administration Amendments Act of 2007 (FDAAA) that requires drug developers to disclose detailed clinical study results publicly, we examine the effect of information disclosure on subsequent innovation in drug development. We find significantly more suspensions of ongoing drug projects and fewer new project initiations after the FDAAA. These results have a causal interpretation based on difference-in-differences analyses that exploit different information environments before the FDAAA. We highlight a learning mechanism for the negative impact on innovation. We also present several consequences of enhanced information disclosure; while the FDAAA helps improve drug quality, it leads to more suspensions of potential new drugs that could have reduced mortality and morbidity.

Keywords: Innovation, New Drug Development, Mandatory Information Disclosure, Information Diffusion, Peer Effects, Divestment, Welfare Analysis

JEL Classification: I18, M40, G30, D80, O32

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1 Introduction

The development of new drugs is one of the most costly innovative activities. It involves significant research investment, long hours of laboratory experiments, a large number of animal lives, and many human subjects. Thus, pharmaceutical firms have strong incentives to not publicly disclose the details of clinical trials because of the associated proprietary costs in the first place. Nevertheless, the development of new drugs greatly serves the public interest. Hence, timely and accurate disclosure of information about on-going clinical trials is important, because it facilitates scientific knowledge accumulation and discovery processes and advocates patient rights, all of which seek to enhance public health (Lehman and Loder (2012)). Therefore, public interest has imposed great pressure on the government and administrative bureaus (FDA and NIH) regarding the detailed information disclosure of clinical trials. In 2007, Congress enacted the Food and Drug Administration Amendments Act (FDAAA), in which Section 801 heightened information disclosure requirements with respect to new drug development (we offer more detail in Appendix A). This Act basically mandates the disclosure of the detailed designs and outcomes of clinical trials and the literature confirms substantially enhanced disclosure afterward (Gill (2012) and Dos Santos and Atallah (2015)).

Such mandatory information disclosures may influence pharmaceutical firms' investment decisions through two different channels: competition and learning (Krieger (2021)). First, when pharmaceutical firms compete to develop new drugs for the same disease, the first new drug to be approved may enjoy market advantages and preempt others. Therefore, the disclosures about failure outcomes of a drug project, albeit with no detail, increases other firms' expected profits and increases their incentives to continue related projects (Scherer (1967), Dasgupta and Stiglitz (1980a), and Dasgupta and Stiglitz (1980b)). Second, the learning effect refers to the externalities of clinical trial information that spills over to other firms. When pharmaceutical firms learn more from the details about others' failed clinical trials, some may decide not to continue their projects dealing with similar experimental problems.

Since most clinical trials end up unsuccessfully, we propose that the FDAAA positively (negatively) influences pharmaceutical firms' drug investments through a competition (learning) effect.[1] Moreover, the learning effect may be amplified by financial constraints, as firms without sufficient resources are more likely to suspend their projects upon failure news from peers.

While these two opposing effects triggered by the FDAAA may coexist in reality, which effect plays a dominating role is an intriguing and important research question for the following reasons: (i) a statistical analysis based on the FDAAA enables us to infer an *aggregate* effect of the trade-off between the two effects from enhanced information disclosures on firms' innovation activities;[2] and (ii) our empirical evidence has policy implications and offers new insights to the economic consequences of mandatory disclosures in high-tech industries.

We use the enactment of the FDAAA in 2007 as a quasi-natural shock that changed information environments for drug developers and the general public by mandating the disclosure of the details of clinical trials. While, during the pre-FDAAA period, drug developers still have information on the existence of all relevant ongoing projects in the market, they did not have comprehensive information about the clinical trial designs and experimental outcomes of those projects.[3] Therefore, the essence of the changes in information environments through the FDAAA is a transformation of information types from a mere binary format of initiations and terminations to the detailed clinical trial outcomes in all stages of on-going projects. The disclosure requirement by the FDAAA is unique and distinct from other disclosure requirements studied in the literature. Most financial information disclosures mandated

[1] Our proposition is consistent with the model implication of Krieger (2021), in which competitors' successful outcomes influence a drug developer's continuation of investment through two opposite effects: a positive effect from knowledge learned from competitors' successful outcomes and a negative effect from the reduction in expected market profits due to competition.

[2] From the perspective of a focal firm, the disclosure of its investment information is often considered detrimental to its value due to proprietary costs and would harm the firm's investment and innovation activities (e.g., Bhattacharya and Ritter (1983) and Cohen et al. (2000)). From another perspective, the focal firm's peers can learn from its disclosure to make more efficient investment decisions and can thus improve their values.

[3] Under FDA regulations, any research involving human subjects must receive an approval by Institutional Review Boards (IRB) to assure the protection of the rights and welfare of the human subjects. Therefore, the information on the existence (not the details) of a clinical trial in the market could be collected even before the FDAAA.

by the SEC are not directly associated with the details of innovation activities. Although patent publications are directly associated with detailed innovation activities, they are only related to completed and successful innovation activities. The FDAAA requires firm disclosures on ongoing innovation with both successful and *unsuccessful* experimental outcomes, which offers us a good empirical setting where we can test both positive and negative externalities of learning to innovation, without allowing firms' self-selection of disclosing good news only as in patenting activities.

We use the BioMedTracker (BMT) database that covers progresses of a broad scope of clinical trials both before and after the FDAAA, based on multiple sources of information such as medical conferences, proprietary or public databases, press releases, company websites, earnings conference calls, and the ClinicalTrials.gov database. In particular, we focus on industry-sponsored clinical trials for new drugs ("projects") that exist between 2002 and 2012 as a ten-year event window around the FDAAA in 2007.[4]

We first examine whether the FDAAA leads to higher or lower innovation by all drug developers, which reflects the aggregate effect of enhanced information disclosures. We test this using the suspension of a project as a proxy for *divestment* because suspending a project is firms' decision. This proxy is different from other innovation measures in the prior literature in that project suspension represents the discontinuation or failure of ongoing projects. We find that the project suspension likelihood increases by 12.6% following the enactment of the FDAAA. We control for many factors that may affect suspension decisions,[5] as well as fixed effects for firms, clinical trial phases, and project indications (i.e., the target disease, illness, or symptom to be treated). As supplementary evidence, we also consider new project initiation as an alternative proxy that reflects investment and find that project initiations decreases by 19.6% after the enactment of the FDAAA.

[4]Non-industry-sponsored (henceforth, academic, or academic-sponsored) clinical trials are projects with principal investigators from non-profit organizations such as universities and hospitals supported by federal (NIH), states, and non-profit foundations. Academic-sponsored clinical trials may have different incentives and funding constraints and thus we limit our sample to industry-sponsored clinical trials.

[5]Our control variables include the existence of a partner for a given project, a given drug developer's total number of projects, project diversification, percentage of matured projects, and firm-level percentage of projects with partners, and a given indication's total number of competitors and percentage of matured projects.

These findings support that peer learning dominates the competition effect with an introduction of a comprehensive learning environment, particularly concerning innovation failures. In this regard, our findings complement the evidence of positive externalities in the previous literature that focuses on the information disclosure of only successful innovation (e.g., patent publications in Fetter et al. (2018), Hegde et al. (2018), and Kim and Valentine (2021)) by showing that strong negative externalities exist as well when unsuccessful innovation outcomes are also disclosed.

To strengthen a causal interpretation of the result, we employ a difference-in-differences (DID) test by exploiting a difference in compliance timing with mandatory disclosure requirements between industry-sponsored vs. academic-sponsored clinical trials. In September 2004 (about three years before the FDAAA was enacted), the joint editorial of the International Committee of Medical Journal Editors (ICMJE) announced a new policy that requires submitters to register their projects in a comprehensive and publicly available database before their submissions (DeAngelis et al. (2005a) and DeAngelis et al. (2005b)).[6] Given academics' greater incentive to publish papers based on clinical trials (regardless the outcomes being successful or failed), we expect that clinical trial details of most academic-sponsored projects have been disclosed under the ICMJE policy.

Under the ICMJE policy, a company developing a project in an indication with many academic-sponsored projects (i.e., an academic-dominated indication) would have received more information before the FDAAA than another company developing a project in an indication with fewer academic-sponsored projects (i.e., an industry-dominated indication). As a result, the amount of information disclosed by academic-sponsored projects would have not changed as much as that by industry-sponsored projects in compliance with the FDAAA in 2007. Our DID test shows a significant increase in the suspension rate of industry-sponsored projects in industry-dominated indications (the treated group) relative to that of industry-sponsored projects in academic-dominated indications (the control group) after the FDAAA. Additional DID test also shows significantly fewer project initiations in the treated group relative to those in the control group after the FDAAA.

[6]For a list of journals that follow the ICMJE recommendations, refer to: http://www.icmje.org/.

We reinforce the causal interpretation of our results by additionally implementing within-indication DID tests that consider firm heterogeneity *within* indication.[7] Our DID results thus confirm that it is the FDAAA that increases drug developers' suspension rates and further support that peer learning dominates competition after the trade-off between the two effects was introduced by enhanced disclosures. While prior studies advocate the positive spillover and accumulation of technologies based on innovation disclosures, we provide a new insight that enhanced information environments can stifle innovation.

Additional robustness checks suggest that, before the FDAAA, the treated and control firms have similar success probabilities in new drug development and the FDAAA does not cause the two groups to differ in their external financing activities. We also ensure that our findings are not driven by the financial crisis in 2008-2009, project age and phase age, and the sample selection excluding phases inapplicable to the FDAAA.

Further analyses support the learning effect as follows. In our full sample, we find that a project's suspension likelihood increases with the incidence of suspended peer projects but is unrelated to the incidence of advanced peer projects, which is consistent with the learning effect but not the competition effect. In the pre- (post-) FDAAA periods, we find that a project's suspension likelihood decreases (increases) with the incidence of suspended peer projects, which confirms the emergence of the learning effect due to the disclosures of clinical trial details. Moreover, we show that the association between a project's and its peer projects' suspensions increases after the FDAAA, especially for low-quality firms and firms without partners. We implement additional tests to examine the role of financial

[7]These additional DID tests address a potential self-selection concern that projects in academic-dominated indications may be fundamentally different from those in industry-dominated indications. We consider three additional DID tests: We conjecture that, among all firms in the same indication group, i) those that are inexperienced (i.e., new to a certain disease group) or ii) younger in the pre-FDAAA period are affected by the FDAAA to a greater extent because they are more dependent on information disseminated from peer firms. We indeed find that inexperienced or younger firms before the FDAAA are more likely to suspend their new drug projects after the FDAAA. We also examine iii) whether the demand for information is different across firms within indication by considering another dimension of learning asymmetry. We define information providers as firms posting detailed study results on Clinicaltrials.gov before the FDAAA; other firms are defined as information receivers expected to be more sensitive to information disseminated from peer firms. We find that, relative to information providers, information receivers show a greater increase in suspension rate after the FDAAA.

constraints. We find that among financially constrained firms, their suspension likelihood increases with news about peer failures but is unrelated to news about peer successes. On the other hand, among unconstrained firms, their suspension likelihood is unrelated to news about peer failures but is negatively associated with news about peer successes. This finding is intuitive because unconstrained firms have resources to continue their projects when they receive positive signals about project prospects. All these results are thus consistent with the argument that the learning effect is amplified by financial constraints.

In our last set of empirical tests, we examine the economic consequences of the FDAAA. First, we find that the frequency of adverse patient events of a drug significantly reduces by about 43% after the FDAAA. This result is consistent with the interpretation that firms are more likely to suspend projects with a high possibility of undesirable patient outcomes due to their increased efficiency in making suspension decisions with enhanced information environments. Nevertheless, there are also downsides associated with the FDAAA. The enhanced information disclosure reduces first-movers' information advantage, which prevents firms from initiating new drug projects.[8] Also, the greater diffusion of information about the difficulty of ongoing new drug development may motivate firms to give up some projects earlier and more easily, which is rational for firms but may not be optimal for social welfare.[9] For example, our evidence shows that the annual growth rate of active projects is approximately 25% before the FDAAA but becomes negative after the FDAAA.

To interpret the health loss due to the decline in active drug projects, we compare Disability-Adjusted Life Years (DALYs, the number of years lost due to a given disease) from World Health Organization (WHO) between the two indication groups that experience high and low growth in the number of clinical trials around the FDAAA. We find that if

[8]When firms must disclose their innovative activities, they reduce their investment due to the loss of proprietary knowledge and rents from potential imitation and learning by their competitors (Scotchmer and Green (1990), Anton and Yao (1994), Fetter et al. (2018), and Kim and Valentine (2021)). However, the literature has highlighted the necessity and associated costs for entrepreneurs when they disclose their innovations to raise external funding and to mitigate information asymmetries (Leland and Pyle (1977), Bhattacharya and Ritter (1983), García-Meca et al. (2005), and Ferreira et al. (2014)). Also, some studies discuss firms' voluntary disclosure of their patenting activities for strategic reasons (Anton and Yao (2004), Guo et al. (2004), Gill (2008), and James (2011)).

[9]It is common in the literature that individual firms' profit-maximizing decisions may not be socially optimal (Hall and Lerner (2010) and Budish et al. (2015)).

the low-growth group receives the same investment as the high-growth group does, then the DALY of the low-growth group may also drop by the same magnitude (8.27%), which is 7.6 million years. These possible drawbacks call for further analysis of the optimal degree of information disclosure for the FDA's regulations over the pharmaceutical industry particularly and all mandatory disclosure regulations overall.[10]

Our paper contributes to the literature in several important ways. First, our study provides new evidence for the causal effect of enhanced information disclosure on investment in innovation. Previous empirical evidence of the effect is mainly based on the patent system which covers technical details of successful innovation (see, for example, Williams (2017)),[11] and little is known about the impacts of mandatory disclosure of new drugs' clinical trial outcomes. The enactment of the FDAAA mandates disclosures of ongoing innovation activities with both successful and unsuccessful outcomes and is found to have a greater negative effect on subsequent innovation than positive. Peer effects from unsuccessful innovation disclosure have not been examined in the prior literature, and thus our analyses using the FDAAA regulation make a unique contribution to the literature.

Second, we highlight the roles of learning and financial constraints in pharmaceutical firms' decisions in drug development. Our analysis on how a firm learns from its peers' disclosure of clinical trial details adds to the emerging literature on pharmaceutical firms' reactions to public disclosures (Krieger (2021) and Krieger et al. (2021)).[12] Our study differs from Krieger (2021) as follows: (i) we focus on a policy shock—the FDAAA—to offers a

[10]Prior studies have examined the optimal design for patent protection (see e.g., Gilbert and Shapiro (1990), Matutes et al. (1996), Goh and Olivier (2002), and Hall (2007)).

[11]Williams (2013), Hegde and Luo (2018), Hegde et al. (2018), Furman et al. (2018), and Kim and Valentine (2021) have proposed different ways to utilize law or regulation changes to establish a causal interpretation.

[12]Prior studies have shown how firms learn from their rivals' successes and failures (Madsen and Desai (2010), Baum and Dahlin (2007), Kim and Miner (2007), Ingram and Baum (1997), Haunschild and Sullivan (2002), Magazzini et al. (2012), Garzon-Vico (2012), and Bustamante and Frésard (2021)). Prior studies, in general, show that information disclosure in competitive environments has positive effects on subsequent innovation (Henderson and Cockburn (1994), Ederer (2016), Boudreau and Lakhani (2015), and Boudreau and Lakhani (2015)). However, there are also studies showing negative effects on subsequent innovation: (i) disclosure in technological advance deters R&D competition as rivals are less likely to develop and patent competing innovations (James (2011) and Glaeser and Landsman (2021)); (ii) firms react to news about competition and technological failure with an increase in project exit rates (Krieger (2021)); and (iii) negative shocks to a competitor's drug lead competing firms to move resources away from affected areas and into more exploratory projects (Krieger et al. (2021)).

causal interpretation for the learning effect; (ii) our evidence suggests that, in an almost fully transparent information environment, the learning effect dominates the competition effect for drug developers; and (iii) our results present unintended consequences of enhanced disclosures. On the other hand, we introduce the moderating effect of financial constraints in drug developers' learning, which complements Mace (2019) and Krieger et al. (forthcoming).

Lastly, our investigation highlights the intended and unintended consequences of the FDAAA.[13] Whereas more industry-sponsored projects are registered and their study details are disclosed in ClinicalTrials.gov after the FDAAA, increased project suspensions follow. This finding is novel to the literature and relevant for policy makers and the general public. We find that the FDAAA enhances the safety of new drugs but disincentivizes firms to continue or initiate new projects at the same time, and quantify potential loss of public health.[14]

2 Data and Variable Construction

2.1 Data sources and sample selection

We use the BMT database to obtain our primary sample. The BMT database covers project-level drug development progresses for all publicly and privately held firms in the drug industry sector. The database catalogues drug development events since the 1950s, drawing from multiple sources including the FDA approval database, company filings with the Securities Exchange Commission (SEC), conference calls, press releases, news articles, medical conferences, expert industry analysts, direct communication with companies, and the ClinicalTrials.gov database. Unlike the FDA approved-drug database, the BMT contains information on all current projects under development including the specific development status for each

[13] See also Aghamolla and Thakor (2019) for the effect of the FDAAA on private firms' propensity of going public.

[14] This result shows that the FDAAA might have unintended consequences and ought to draw attention from policy makers. A few recent studies examine the consequences of additional disclosure from the FDAAA but focus on an individual firm's information environment, such as reduced information asymmetry (Capkun et al. (2019)) and increased forecast accuracy (Hao et al. (2017)). However, none of them examines the consequences on aggregate innovative activities and social welfare implications.

project phase. The ClinicalTrials.gov database, one of the sources that the BMT collects data from, provides superb information on detailed study designs and outcomes of registered clinical trials but has a complete coverage only after the FDAAA. Although information from the BMT is limited to the occurrences of events as a binary form, it covers a much longer period from 1950. Also, the BMT covers mainly industry-sponsored clinical trials as the purpose of the BMT is to identify biotech and pharmaceutical investment opportunities. From BMT, we obtain the suspension variable and variables for phase advances, partnered projects, indications, and peer projects in the same indication.

Our final sample encompasses 16,916 industry-sponsored project-year observations covered by the BMT during the sample period from 2002 to 2012; this number includes 7,580 pre-FDAAA project-years and 9,336 post-FDAAA project-years. Our sample has 637 unique pharmaceutical firms with 3,590 unique new-drug projects. The relevant SIC codes for these firms are 2834 and 2836. We exclude the following from our sample: (i) clinical trials for generic drugs, which have low uncertainty and follow different FDA requirements; (ii) clinical trials that are not sponsored by industry (i.e., academic-sponsored drugs); and (iii) clinical trials in phase 1, which are not subject to the FDAAA.[15]

Figure 1 shows the time trends of the number of clinical trial projects and disclosure intensities of any event and detailed study reports. Figure 1(a) shows that the total number of clinical trials has been increasing over time but with a slowdown in the increase after the FDAAA. Figure 1(b) shows that the average number of progress updates per projects was around 1.2 before the FDAAA and has significantly increased in the more recent period after the FDAAA. Thus, after the FDAAA, the increasing trend of the number of projects has significantly abated while the disclosure frequency per project has increased. Relatedly, in our subsequent analyses of suspension decisions, we further exclude drug projects that

[15]We do not restrict our sample to "applicable clinical trials" (ACT) of the FDAAA, because the medical literature has found the definition of ACT, when the FDAAA was initially introduced in 2007, was unclear and thus selecting ACT samples relies on discretion and conjectures. Instead, we apply the clear rule that exempts phase-1 clinical trials and clinical trials for foreign-produced and foreign-marketed drugs from ACT to our sample selection procedure. The FDAAA Final Rule was issued in 2016 to clearly specify which clinical trials are subject to the mandatory reporting on the ClinicalTrials.gov (ACT). For more details, see Zarin et al. (2016)

were initiated after the FDAAA, because the initiation of these projects may have been also influenced by the enactment of the FDAAA.

Figure 1(c) shows the time trend of the fraction of clinical studies that accompany detailed reports of study results. The data on the submitted reports of study results are from the ClinicalTrials.gov database for both industry- and academic-sponsored projects. We find that the average submission rate of detailed study reports radically jumps up and reaches approximately 70% after the FDAAA. The moderate increase of the submission rate from 2004 until the FDAAA appears to be the effect the ICMJE in 2004. The essence of our empirical design is a change in the accessibility of detailed study reports from peer firms. Figure 1(c) validates that the FDAAA indeed altered information environments and the type of available information for pharmaceutical firms.

[Insert Figure 1 Here]

To study consequences of the FDAAA, we use the 1) FDA Adverse Event Reporting System (AERS) data and the 2) Disability-Adjusted Life Year (DALY) metric from the WHO Health statistics. The FDA uses the AERS to monitor adverse events and medication errors of all approved and marketed drugs under its own post-marketing safety surveillance program. The FDA receives reports about such events from health care professionals (e.g., physicians, pharmacists, and nurses) and consumers (e.g., patients, family members, and lawyers).[16] Appendix B shows examples of adverse event reports for a drug and how we classify different reporting cases. We use the number of adverse event reports (AER) for each approved and marketed drug as a proxy for drug quality. We classify reports as serious when the patient outcome is one of the following conditions: death, life-threatening illness, hospitalization, disability, congenital anomaly, or intervention required to prevent permanent impairment and damage. We classify reports as primary suspect when a given drug is identified as a primary suspect of the adverse case.

[16]Clinical reviewers in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) evaluate reports in AERS to monitor the safety of approved products. If reviewers identify a safety concern, the FDA may take regulatory actions that include updating a drug's labelling information, restricting use of the drug, communicating new safety information to the public, or removing a product from the market.

DALY is used to measure a burden of disease. DALY can be considered lost years of "healthy" life with a greater value of DALY indicating greater mortality and morbidity. DALY for a specific disease is calculated as the sum of the Years of Life Lost (YLL) due to premature mortality in the population and the Years Lost due to Disability (YLD) for people living with the condition or its consequences. We use two data points—DALYs for years 2000 and 2016—for the top 20 leading causes of DALY globally.[17] These two points are the nearest available data to the FDAAA enactment.

2.2 Variable construction

Our main dependent variable, Suspension, is a proxy for divestment defined as an indicator that equals one if an announcement of suspension is made for a project in a given year or no progress update is made for the duration longer than a threshold, and zero otherwise.[18] The latter condition is particularly important to mitigate the concern that drug developers might hide unsuccessful clinical trial outcomes from the public before the FDAAA. As the initiation of a clinical trial is known due to the FDAAA regulation of an IRB approval for any research involving human subjects, an unsuccessful project with no progress update for a long time will be considered as suspended under this condition. In Figure 2, we illustrate the time-series trend of average suspension rates for projects in each phase. The average suspension rate for each phase is calculated as the total number of suspended projects in a given year divided by the total number of projects in the year. We find in Figure 2 that suspension rates are stable in all phases before the FDAAA and increase significantly after the FDAAA, especially for phase 2.

[Insert Figure 2 Here]

[17]The DALY data are available at `https://www.who.int/healthinfo/global_burden_disease/estimates/en/index1.html` for 2000, 2010, 2015, and 2016. However, the indication-level DALYs are available only for 2000 and 2016.

[18]We use the 90th percentile of the sample duration for each phase as the threshold. The 90th percentile duration is 5 years for phase 2 and 3 projects and 4 years for post-phase 3 projects. For robustness, we also consider Disclosed Suspension, an indicator variable that equals one only if a suspension announcement is made for a project in a given year and zero otherwise. We find qualitatively similar results.

The main independent variable in our regression analyses is Post, which is one after the passage of the FDAAA in 2007 and zero otherwise. We are particularly interested in whether the passage of the FDAAA changes information environments for pharmaceutical firms' drug development. The major changes in information environments made by the FDAAA is disclosing study details (such as experimental designs and outcomes) of clinical trials to the public including competing drug developers. Appendix C shows an example of the detailed study report for a drug in phase 2 from ClinicalTrials.gov.

Panel A of Table 1 presents summary statistics of the variables used in our analyses. Suspension (Indicator) has the mean value of 0.13 indicating that 13% of the clinical trial projects are suspended in a year in the middle of the development process. The average firm in our sample additionally initiates 0.14 new projects every year (1.4 projects for ten years). On average, 54% of projects in our sample have partners (Project with Partner), and a firm carries 50% of its project portfolio with partners (Percent of Projects with Partner). The average of Log(1+Number of Projects) is 2.94, equivalent to 18 projects.[19]

[Insert Table 1 Here]

The following control variables are also included in regressions with detailed definitions provided in Appendix D. The diversification index of a firm's project portfolio has a mean of 0.52 (Project Diversification). Also, 9% of the projects in a firm's project portfolio are matured (i.e., in post-clinical trial phases and denoted by Percent of Matured Projects). The average total number of entities in each indication group in a given year is 17.73 (Log(1+Number of Competitors) = 2.93). Competing entities include both private and public pharmaceutical firms and academic drug developers. The average percentage of matured projects in an indication in a year is 12% (Percent of Indication Matured Projects).

In the analyses that explore possible mechanisms for our results, we consider the measures of peer suspensions and phase advances as well as the measures of competition and financial constraints. Peer Suspension is a dummy variable that takes one if at least one of peer

[19]The mean and median numbers of total projects per firm for a given year are 7.16 and 3, respectively. The numbers in Table 1, calculated at the project-year level, are greater than those calculated at the firm-year level due to greater weights on firms with a larger number of projects.

projects in the same indication as that of a given project is suspended in a given year. Peer Phase Advance is a dummy variable that takes one if at least one of peer projects in the same indication as that of a given project has advanced to the next phase in a given year. The peer suspension and the peer phase advance are both lagged with the averages of 60% and 70%, respectively, during our sample period. High Financial Constraint (Indicator) represents firms with the financial constraint index based on the KZ index (Kaplan and Zingales (1997)) or the WW index (Whited and Wu (2006)) being higher than the sample median during the pre-FDAA period, and this variable is used only for public firms.

For our analysis of social welfare, we consider the following variables based on adverse event reports (AER). The averages of the log of one plus the number of AER and the log of one plus the number of serious AER, Log(1+Number of AER) and Log(1+Number of Serious AER), are 2.84 and 2.39, respectively. These numbers are equivalent to 16 AER and 10 serious AER with a given drug being a primary suspect. Almost all approved drugs have at least one AER in a given year, and about 80% have at least one AER in a given year with the drugs being a primary suspect.

In Panel B of Table 1, we compare the variables between pre- and post-FDAAA periods. The suspension rate is significantly higher in the post-FDAAA period indicating that firms are more likely to suspend their ongoing projects after the FDAAA. Firms on average have greater numbers of total projects, smaller percentages of matured projects, fewer projects with partners, and greater numbers of competitors in the post-FDAAA period. We control for the effects of these variables in all of our analyses. The percentage of indication matured projects also has decreased from 14% to 10% on average after the FDAAA.

3 The Effect of Enhanced Disclosure on Drug Development

3.1 Baseline results: suspensions

In Table 2, we perform a baseline analysis of the effects of enhanced disclosures regarding clinical study details through the FDAAA on drug project suspensions. The sample is a project-year panel. The dependent variable is Suspension (Indicator) that equals one if the project has been suspended in a given year and zero otherwise.[20] We note that our definition of project suspension includes no progress update for a long time to mitigate a concern related to concealment and/or strategic delay of bad news. We estimate a linear probability model in Columns 1 and 2 and a probit model in Columns 3 and 4.

[Insert Table 2 Here]

In Columns 1 and 3, we regress Suspension (Indicator) on Post that indicates the post-FDAAA period starting in 2008 without controlling for any other variable except firm, indication, and trial-phase fixed effects. It is noteworthy that we cannot include project fixed effects in our models because projects that have never been suspended or have been approved will be dropped from our regression sample. The significantly positive coefficient of Post implies that the passage of the FDAAA is associated with an increased likelihood of suspension. In Columns 2 and 4, we show that the positive association is robust when we control for characteristics of drug developers and their industries. The effect of the FDAAA on project suspension is economically significant at 17.4% and 12.6% as estimated from the linear probability models in Columns 1 and 2, respectively.

[20] When a project is suspended or finally approved by the FDA in year t, it is dropped from our regression sample from year t+1.

3.2 Difference-in-differences regressions: suspensions

Next, we perform DID tests for causal interpretations of the increased suspensions after the FDAAA.

3.2.1 Industry-dominated vs. academic-dominated indications

In our primary DID test, we compare the heterogeneous effects of the FDAAA on project suspensions in industry-dominated vs. academic-dominated indications. We classify an indication as industry-dominated if more than 50 percent of projects in the indication during the sample period are industry-sponsored. Otherwise, we classify an indication as academic-dominated.[21] For this indication-classification purpose only, we append the academic-sponsored project data from ClinicalTrials.gov to our main sample. The average fraction of academic-sponsored projects is 12% for the industry-dominated group and 64% for the academic-dominated group.

Industry-sponsored projects in academic-dominated indications are suitable control observations for those in industry-dominated indications with regards to the changes in information environments due to the FDAAA. Such changes in information environments are expected to be smaller in academic-dominated indications than industry-dominated indications around FDAAA, because the details of academic-sponsored clinical trials may have been disclosed to the public to a greater extent before the FDAAA in compliance with the ICMJE issued in 2004. The ICMJE aims at promoting the disclosure of clinical study details conducted by academic investigators and explicitly mandates submitters to register their clinical trials beyond phase 1 in a comprehensive and publicly available database (such as ClinicalTrials.gov) before journal submissions. For this reason, the FDAAA may not affect disclosure practices of academic-sponsored projects as much as those of industry-sponsored projects. Therefore, we expect that projects in academic-dominated indications face smaller

[21] In Table IA.1 in Internet Appendix, we present the list of top 30 academic-dominated indications. Cancer is the indication with the largest fraction of academic projects (96%), and Metabolic – General (90%), Transplant Rejection (89%), and Alcohol Dependence (80%) follow. In terms of the number of projects, Cancer (137) and HIV/AIDS (110) have the most academic-sponsored projects.

changes in information environments at the time of the FDAAA enactment than projects in industry-dominated indications on average.

We use the sample of only industry-sponsored projects and divide it into the two groups of projects based on indications: industry-dominated (treated) and academic-dominated (control) indications. Table 3 reports results from the DID regressions. We focus on the linear probability model for the rest of our analyses because it generates a consistent (unbiased) estimate, even if the dependent variable does not follow a logistic or normal distribution (Wooldridge (2010)).

[Insert Table 3 Here]

In Column 1, we regress Suspension (Indicator) on the interaction term between Post and Industry-dominated Indication dummy variables and other control variables. DID regression analyses particularly allow us to include year fixed effects in addition to firm, phase, and indication fixed effects, mitigating the concern that year-specific economic situations such as a financial crisis drive our results. We find that the coefficients on the interaction term between Post and Industry-dominated Indication are significantly positive at the 1% level. This indicates that the effect of the increased disclosures on suspension rates is concentrated in the industry-dominated indication group. The economic interpretation of the effect is that projects in industry-dominated indications are 3.2 percentage-point more likely to be suspended than those in academic-dominated indications after the FDAAA.

In Column 2, we examine the dynamic DID effects of the FDAAA using year dummy variables: Year t-3, Year t-2, Year t-1, Year t, Year t+1, and Year [t+2 ,t+5] . Year t is the indicator for the year 2007, in which the FDAAA is enacted. We find insignificant coefficients on the interaction term of Industry-dominated Indication with Year t-3, Year t-2, Year t-1, and Year t. This result confirms that there is no pre-trend before the passage of the FDAAA and supports the parallel trend assumption underlying the DID test. In addition, the coefficient on the interaction term with Year [t+2 ,t+5] is significantly positive at the 5% level. This result suggests that the effect of the increased disclosures on suspension decisions starts after the enactment of the FDAAA for the industry-dominated group. The

magnitude of the effect is an approximately 5 percentage-point increase in suspension for the industry-dominated indication group after the FDAAA relative to the academic-dominated indication group.

Because there is a self-selection concern that industry-sponsored projects in academic-dominated indications are fundamentally different from those in industry-dominated indications, we also consider a more refined sample where projects in treated and control groups are similar across the control variables from Table 2 with propensity-score matching (PSM). In Panel A of Internet Appendix Table IA.2, we report pre-FDAAA summary statistics for the two groups of industry-sponsored projects in industry-dominated and academic-dominated indications and find that there are no significant differences in the observable characteristics (matching variables) between the two groups after the matching procedure. This mitigates the concerns about the fundamental differences between industry-sponsored projects in industry-dominated and academic-dominated indications. In Panel B of Internet Appendix Table IA.2, we report results from analogous tests to those in Table 4. We find consistent and even stronger results by using the propensity-score matched sample. The magnitude of the effect translates into projects in industry-dominated indications being 9.8 percentage-point more likely to be suspended than those in academic-dominated indications after the FDAAA. Also, the dynamic effect emerges right after the FDAAA with Year [t+1], and the coefficient on the interaction term with Year [t+2 ,t+5] is about five times larger than that in Table 4.

In Figure 3, we visualize the dynamic effects over each year from year t-3 to year t+3. We do not see any significant difference from year t-3 to year t, suggesting that there is no evidence of a pre-existing trend. Moreover, we find significantly more suspensions in year t+2 for the full sample and since year t+1 for the PSM sample. All these figures confirm our regression results.

[Insert Figure 3 Here]

Overall, the results with this DID approach mitigate concerns that our findings are driven by any commingled factor unrelated to the increased information disclosure after the

FDAAA. We find that industry-sponsored projects in industry-dominated indications make suspension decisions differently from those in academic-dominated indications. Thus, these findings especially support a causal interpretation that changes in information environments following the passage of the FDAAA significantly influence the investment decisions of pharmaceutical companies.

3.2.2 Learning asymmetry across firms within indication

In the previous DID test, we use treated and control groups based on indication characteristics. This approach that resorts to indication characteristics is especially suitable for our purpose, as we examine the effects of enhanced information for firms that mutually influence each other in the same information environment (i.e., indication). However, there is also a separate concern that indications are fundamentally different in their original environments for information, investments, and financing. To reinforce a casual interpretation of our finding, we further perform three additional DID tests by considering treated and control groups divided by firm heterogeneity within indication focusing on learning asymmetry across firms. We only brief the ideas in this section and leave all details in Section A of Internet Appendix and all results in Internet Appendix Table IA.3.

In the first alternative DID, we divide projects in our sample into two groups based on whether a project is from a firm that has any previous projects in the same disease code. In the second alternative DID, we divide firms in our sample into two groups based on firm age because younger firms are also less experienced in drug development and thus will be more dependent of information provided by their peers (Awaya and Krishna (2021)). Our test results suggest that a project initiated by a firm that has no previous experience or is young is more likely to be suspended after the FDAAA. In the third alternative DID, we divided the sample into two groups based on firms' average number of study-result reports per project during the pre-FDAAA period because firms that choose to disclose detailed study results before the FDAAA are less likely to be sensitive to information provided by peers (i.e., information providers). We find that firms that disclose less before the FDAAA

(i.e., information receivers) indeed suspend more projects after the mandate. Overall, these alternative DID test results not only mitigate the concerns regarding fundamental differences across indication groups but also strongly support the conclusion that the FDAAA has altered information environments disproportionally more for the firms that are in need of more information or are likely more dependent on information disseminated from peer firms.

3.3 Robustness

In this section, we conduct multiple robustness tests. First, in Table IA.4 of Internet Appendix, we consider an alternative definition of project suspension. We replace Suspension (Indicator) with Disclosed Suspension (Indicator) that equals one only if a suspension announcement is made for a project in a given year and zero otherwise.[22] Our results are robust to this alternative definition. Consistent results using both measures of suspension alleviate the concern that our result can be driven by strategic delay of reporting or the increased duration between progress updates.

Importantly, we note that there is a particular concern that the enactment of the FDAAA in 2007 is adjacent to the 2008-2009 financial crisis and our results may be driven by financial distress during the crisis period. We first address this concern by using a refined sample that completely excludes observations in the five-year event window, [-2, +2], that contains the financial crisis period (i.e., observations in 2005, 2006, 2007, 2008, and 2009). Panel A of Table IA.5 in Internet Appendix report the results. Throughout all columns, we find consistent results. Although these results suggest that the financial crisis is not the main driver of our results, we further examine firm financing activities directly in Panel B of Table IA.5. We use the following three variables to measure firms' financing activities: Equity issuance, Debt issuance, and Venture capital financing. If our DID results are driven by the possibility that firms in treated groups have greater financial distress relative to those in the control groups, we expect to find significantly more deteriorated financing activities

[22]Previously, Suspension (Indicator) is defined as an indicator that equals one if an announcement of suspension is made for a project in a given year or no progress update is made for the duration longer than a threshold (the duration in the 90th percentile), and zero otherwise. Thus, Disclosed Suspension (Indicator) differs from Suspension (Indicator) in the sense that the former only considers firms' announcements.

for firms in the treated groups. The results in Panel B of Table IA.5 indicate that there is no significant difference in firms' financing activities between the treated and control groups with respect to equity and debt issuances as well as venture capital financing for firms in our sample. Overall, our results suggest that the increase in suspension cannot be simply attributed to the financial distress.[23]

Our results could be also driven by M&A waves that possibly coincide with the FDAAA in the pharmaceutical industry. For example, Cunningham et al. (2021) suggests that pharmaceutical firms have an incentive to acquire industry rivals to terminate targets' projects and capture the preemptive advantages in competition. Thus, the increase in project suspensions after the FDAAA can be caused by such "killer acquisitions" rather than changes in information environments. To rule out this alternative explanation, we limit our sample to projects of firms that experience no M&A transaction in the concurrent year either as an acquirer or target. Table IA.6 in Internet Appendix presents the results.[24] We find that our results remain robust to using a sample free of M&A transactions. These results indicate that our findings are unlikely to be driven by strategic project terminations involving M&A activities in the pharmaceutical industry.

We exclude phase 1 projects from our main sample because the FDAAA does not require phase 1 information to be disclosed in ClinicalTrials.gov (i.e., not included in ACT) although firms can voluntarily do so. Also, we exclude projects initiated after the FDAAA from our sample, because firms would have different incentives in choosing projects to initiate after the FDAAA. However, the FDAAA could potentially affect divestment decisions of phase 1 projects as post-phase 1 trial outcomes may be correlated with phase 1 investment. Similarly, not taking into account the changes in initiations of projects after the FDAAA could generate

[23]One may be concerned that firms in the treated and control groups have different success potentialities and thus show different suspension rates of projects after the FDAAA. We directly examine overall firm success rates between treated and control groups in our DID analyses in the pre-FDAAA period. A firm's success rate is its total number of phase advances minus its total number of phase suspension scaled by the total number of projects. In unreported results, we find no evidence that firms in our treated and control groups show different pre-FDAAA success rates. This effectively alleviates concerns related to different firm performance between the treated and control groups.

[24]We consider the comprehensive global M&A transactions from the SDC Platinum database where more than 50% (majority) of equity stakes are acquired.

a systematic sample bias. To alleviate all these concerns, we expand our sample to include clinical trials in all phases and clinical trials that are initiated after the FDAAA. Table IA.7 in Internet Appendix shows the results using this extended sample with 21,309 project-year observations. Results in the table are consistent with our findings so far, suggesting that our main findings are not sensitive to the inclusion or exclusion of specific phases or projects.

Lastly, in Table IA.8 in Internet Appendix, we consider variables for project age and phase age. Project suspensions are likely to be associated with project maturity. It is possible that firms give up relatively less matured projects easily or that more matured projects with no success for a long time are more likely to be suspended. We address the concern that our results are driven by the difference in project maturity by including project age and phase age as additional control variables. We find that phase age has a significantly positive effect on project suspension decisions while the effect from phase age has a negative effect. More importantly, we find that our results are intact after controlling for the two age variables.

3.4 Tests for project initiations

In Table 4, we further examine the possibility that effects of the FDAAA can manifest in project initiation decisions. We replace the dependent variable of Table 2 with a measure of project initiation. Different from project level suspension variable in Table 2, the dependent variable of project initiation is a firm-indication level variable at best. Thus, the sample is a firm-year or a firm-indication-year panel. The sample for this test additionally includes pre-clinical trials, phase-1 trials, and also projects that are initiated after the FDAAA, as the FDAAA could potentially affect initiation decisions of all-phase trials. We consider two sets of regressions; one at the firm-year level with the total number of new projects initiated by a firm as the dependent variable, and the other at the firm-indication-year level with the number of new projects for each indication initiated by a firm as the dependent variable. In all columns, coefficient estimates for Post are negative and statistically significant at the 1% level. For example, Column 4 of Table 4 shows that after the FDAAA the fraction of newly initiated projects within indication drops by 19.6%. These results suggest that firms

cut back their investments significantly by not only suspending existing projects but also avoiding new project initiations.

[Insert Table 4 Here]

We also run analogous DID tests for the heterogeneous effects of the FDAAA on new project initiations by splitting all sample into industry-dominated vs. academic-dominated indications. We report the results in Table 5. In Column 1, we regress Log(1+Number of New Initiated Projects) on the interaction term between Post and Industry-dominated Indication dummy variables and other control variables. We find that firms in industry-dominated indications are significantly less likely to initiate new drug projects than those in academic-dominated indications after the FDAAA. The economic interpretation of the effect is that projects in industry-dominated indications are 5.3 percentage-point more likely to be suspended than those in academic-dominated indications after the FDAAA. In Column 2, we examine the dynamic DID effects of the FDAAA using year dummy variables, and find insignificant coefficients on the interaction term of Industry-dominated Indication with Year t-3, Year t-2, Year t-1, and Year t. In addition, the coefficient on the interaction term with Year [t+2 ,t+5] is positive and marginally significant. These results support a causal interpretation for a negative effect of the FDAAA on new project initiations.

[Insert Table 5 Here]

4 Mechanisms

4.1 Competition effects vs. learning effect

As discussed earlier and shown in the Appendix B, the FDAAA enhances the disclosure of study details of clinical trials. Before the FDAAA, firms have the information only on the existence of a clinical trial in the market. Such binary type of information that includes peer firms' project initiations and terminations could be used in a focal firm's investment decision. Specifically, the disclosures about failures of other firms' drug projects would

have increased the focal firm's expected profits and thus its incentives to continue related projects. We expect this competition effect to be strong before the FDAAA. With the enactment of the FDAAA, enhanced learning environments were additionally introduced. Thus, afterwards, a firm can make more informed investment decisions by learning from detailed clinical trial contents in peer project suspensions (bad news) and peer phase advances (good news) beyond mere progress updates. This argument suggests that the suspension likelihood will be associated with a trade-off between competition and learning and differently so for good vs. bad news. With these predictions, we examine the effects from competition and learning by contrasting the periods before and after the FDAAA in Table 6.

[Insert Table 6 Here]

We measure peer disclosures on suspensions (Peer Suspension) based on the incidence of suspended peer projects in the same indication as that of a given project's indication in a given year. Analogously, we measure peer disclosures on phase advances (Peer Phase Advance) based on the incidence of advanced peer projects in the same indication. These variables are lagged for one year to allow sufficient time for the focal firm to learn.

In Column 1 of Table 6, we first find that the overall effect of the trade-off regarding peer suspension for the full sample period is positive and significant. The economic interpretation of the coefficient on Peer Suspension is that the focal firm's suspension likelihood increases by 2.6 percentage points with the news that a peer in the same indication suspends its projects in the prior year. Conversely, we do not find any effect from peer firms' phase advancements. In Columns 2 and 3, we split the full sample into the pre-FDAAA period and the post-FDAAA period, respectively. In Column 2 for the pre-FDAAA period, we find that the coefficient on Peer Suspension is significantly negative, indicating that the focal firm is less likely to suspend its projects when peer firms in the same indication suspend their projects. This result supports the competition effect before the FDAAA. On the other hand, in Column 3 for the post-FDAAA period, the coefficient on Peer Suspension flips its sign and turns into significantly positive. This result is consistent with the peer learning effect dominating the competition effect. The increased details of disclosed study contents in compliance

with the FDAAA enable firms to learn from their peers' experiences and make investment decisions in the same direction. We note that the learning effect is especially pronounced for negative outcomes of peer projects because suspension events are more common in drug development and can reveal some fundamental difficulties and potential complications for drug development in the indication.

In the same spirit, we interact Peer Suspension and Peer Phase Advance with Post in Table 7. In Column 1 of Table 7, we find that the coefficient estimate for Peer Suspension $\times$ Post is positive and significant. The economic magnitude of the effect is comparable to the effect in Column 3 of Table 6 at a 2.9 percentage-point increase in the focal firm's suspension likelihood.[25]

[Insert Table 7 Here]

In Columns 2 and 3 of Table 7, we further split the sample into low-quality and high-quality firm groups based on drug development progresses and examine the differential effects between the two groups. We define high-quality firms as firms with the total number of phase advances in the past three years greater than the sample median; other firms are assigned as low-quality firms. The coefficient estimate for Peer Suspension $\times$ Post is still positive and statistically significant at the 10% level for low-quality firms in Column 2, whereas that is no longer significant for high-quality firms in Column 3. These results suggest that suspensions increase only for low-quality firms after their peer firms disclose suspensions. On the other hand, high-quality firms are less likely to respond to information revealed by peer suspension events because they might already have sufficient information for their project's prospect and a good progress to continue.

In Columns 4 and 5 of Table 7, we consider the differential effects by the existence of partners as Lerner et al. (2003) show that biotechnology firms rely on the partnership

[25]Figure 4 graphically displays the dynamic effects of peer suspensions on a focal firm's suspension decision after the FDAAA. We consider a setting (based on Column 1 of Table 7) that resembles an event study with peer suspension occurring at year t. We then examine a focal firm's response to any peer suspension at year t over time for the extended time window of [t-2, t+3]. This figure particularly informative about the timing of the responses. Overall, we find that the effects on focal firm suspensions exist only after peer suspensions occur at year t+1 and year t+3.

with large companies. The coefficient estimate for Peer Suspension × Post is positive and statistically significant at the 5% level only for firms without external partners in Column 4. This is consistent with one of the roles of outside partners being to provide information and guidance on the prospect of a project.

Collectively, the results in Tables 6 and 7 provide strong evidence that the FDAAA introduced an important trade-off between competition and learning to pharmaceutical firms' investment decision-making process and that the peer learning effect dominates the competition effect in the trade-off.

4.2 Financial constraints

As drug development is a costly investment and takes long time to deliver (if it ever succeeds), financial constraints play an important role (Mace (2020) and Krieger et al. (forthcoming)). We propose that the learning effect is amplified by financial constraints because news about peers' failure is more likely to trigger the suspension of a project by firms short of financial resources. On the other hand, good news about peers' advance is also likely to encourage unconstrained firms to continue their investments.

To test these propositions, we separate sample firms into two subsamples based on measures of financial constraints. We consider both the KZ index (Kaplan and Zingales (1997)) and the WW index (Whited and Wu (2006)). The financially constrained subsample includes firms with KZ (WW) indexes above the sample median in the pre-FDAAA period, and the unconstrained subsample includes all the rest. We then estimate the same regression as in Column 1 of Table 7 within each subsample and report the estimation results in Table 8. In Column 1 for financially constrained firms, we find that the coefficient on Peer Suspension × Post is significantly positive, while the coefficient on Peer Phase Advance × Post is insignificant. These results suggest that news about peer failures significantly increases a financially constrained firm's suspension likelihood but news about peer success does not affect such firm. This finding strongly supports the conclusion in the previous section that the learning effect dominates the competition effect in the following sense: if the competition

effect dominates, then news about peer success should be bad news to financially constrained firms and make them suspend more.

[Insert Table 8 Here]

On the other hand, in Column 2 for unconstrained firms, we find that the coefficient on Peer Suspension × Post is insignificant, while the coefficient on Peer Phase Advance × Post is significantly negative. These results suggest that news about peer success encourages an unconstrained firm to continue its projects, and news about peer failures does not affect the firm's suspension likelihood. Again, this finding is consistent with the learning effect dominating the competition effect, in which news about peer failures should be good news to unconstrained firms and make them suspend less. This finding is especially intuitive because unconstrained firms have resources to continue their projects when they receive positive signals about project prospects.

5 Analyses of Consequences

In this section, we examine the consequences of the higher suspension likelihood driven by the FDAAA. We examine both quality and quantity aspects of drug development before and after the FDAAA. We do not analyze price effects, however, due to the lack of individual drug price data. Although a final conclusion for social welfare implications is hard to be drawn without knowing price effects, our analysis on quality and quantity of drug development offers new evidence and insight to public health policies.

5.1 Drug quality

We first examine whether the overall quality of drugs has changed after the increased disclosures of clinical trial details through the FDAAA. We use adverse event reports (AER) from the FDA to analyze the quality changes of FDA-approved drugs. We focus our analysis on the safety side of drug quality but not on the efficacy side of drug quality due to the absence

of drug effectiveness data. We expect the quality of drugs to improve after the FDAAA because firms have better knowledge to discontinue projects without promising outcomes that could send bad signals to the market and to continue and improve projects with promising outcomes. Table 9 examines this prediction based on annual observations of AER for approved drugs. The main variable of interest is Project Initiation After FDAAA that is one if the drug project is initiated after the passage of the FDAAA and zero otherwise.

[Insert Table 9 Here]

For the analysis in Table 9, we merge the approved and marketed drugs from our main sample with the Adverse Event Reporting System (AERS) data provided by the FDA by drug names. The sample period of the AERS data starts in 2004, and thus the sample in Table 9 covers the period from 2004 to 2017.[26] In Columns 1 and 2, we use the total number of AER that a drug has received as a primary suspect in a given year for an inverse measure of the drug's quality. We consider an alternative measure in Columns 3 and 4 by focusing on serious patient outcomes. Appendix C illustrates how we classify different AER cases. Columns 1 and 3 only control for Years from Approval and firm, indication, and year fixed effects. In Columns 2 and 4, we control for characteristics of drug developers and their industries.

Throughout all columns in Table 9, the coefficient estimates of Project Initiation After FDAAA are significantly negative, consistent with our prediction. These effects translate into approximately a 43% decrease in the number of AER if the clinical trial of a drug project is initiated after the passage of the FDAAA.[27] Considering the average numbers of total AER and serious AER per year of 16 and 10, respectively, from Table 1, this 43% decrease is equivalent to receiving 7 and 4 less total AER and serious AER per drug per year. It is worth noting that the inclusion of Years from Approval and year fixed effects in our regressions alleviates the concern that older drugs could be widely adopted and are thus

[26]The Adverse Event Reporting System (AERS) data start in 2004, and we restrict our sample to FDA-approved industry-sponsored drugs that are initiated and approved in and after 1990. If an approved drug in our main sample has no match with the AERS data for a given year, we assume the number of AER received in that year is zero.

[27]For example, in Column 2, the coefficient estimate of -0.563 is equivalent to exp(-0.563)-1=-0.431.

more likely to receive a larger number of AER than newer drugs in a year, or conversely that older drugs are safer and thus likely to receive fewer AER.

The results in Table 9 suggest that drugs developed under the enhanced disclosures due to the FDAAA show a lower frequency of adverse outcomes on the intensive margin. These results are consistent with our prediction: Firms discontinue projects without promising outcomes due to the better knowledge on on-going projects and the higher costs of bad outcomes under more transparent information environments.

5.2 Burden of Disease

We now examine the quantity effect, specifically whether the FDAAA has any implication on the Burden of Disease.[28] The previous evidence in Sections 3 and 4 indicates that the increased disclosures from the FDAAA lead to greater suspensions of active projects mainly through peer learning mechanism. Also, the FDAAA is associated with a decrease in new project initiations. The society may lose potential remedies for critical diseases if firms give up their projects earlier or more often or avoid taking risk in initiating new projects. Therefore, we expect that such a decrease in drug development activities can result in greater Burden of Disease and, thus, negatively influence social welfare.

To test this prediction, we first calculate annual growth rates of active projects numbers (i.e., the number of total projects minus the number of suspended projects) for each indication. Figure 5 plots the average numbers and growth rates of active projects over time. We find that the average number of active projects continuously increases in the pre-FDAAA period, but the increase suddenly stops with the FDAAA. The time trend for growth rates also confirms that the FDAAA in 2007 appears to slow down the growth significantly. The pre-FDAAA growth rate is approximately 25%, but this growth collapses to nearly zero after the FDAAA. Together with prior results, Figure 5 points to a significant drop in drug development activities after the FDAAA.

[28]The Burden of Disease is the impact of a health problem as measured by financial costs, mortality, morbidity, or other indicators, and is often quantified with Disability-Adjusted Life Years (DALY), which means the number of years lost in disability or death due to a given disease.

[Insert Figure 5 Here]

We then focus on indications that intend to take care of the top 20 leading causes (diseases) of the globally measured Disability-Adjusted Life Years (DALY). We use the two snapshots of 2000 and 2016 by the WHO. These two years are the closest data points available around the FDAAA with detailed indication information. A disease's DALY combines the years lived with disability and the years of life lost due to that disease (i.e., the greater DALY, the more illness). To further quantify the social welfare loss in DALY due to the slowdown in drug development activities for those critical conditions, we compare reductions in DALY between high-growth and low-growth indication groups and use the difference as social loss due to the slowdown.

Using the difference between average growth rates before and after the FDAAA (Post-Pre), we split indications into two groups: (a) the low-growth indication group if the difference is less than the sample median and (b) the high-growth indication group otherwise. Panel A of Table 10 shows the average differences of projects' growth, suspension rates, and newly initiated project numbers between pre- and post-FDAAA periods for the two groups. Because the division of groups is based on the first set of statistics presented in Row 1, we see the clear difference between the two groups. In the low-growth group, growth rates of active projects decreased by 46% after the FDAAA, while those increased by 5% in the high-growth group. We attribute this decrease in growth rates to the increased suspensions and the decrease in new project initiations due to the enactment of the FDAAA. We confirm this conjecture with the statistics presented in Rows 2 and 3. We find that in the low-growth group, the increase in suspension rates is 7.0%, which is 3.8% higher than that in the high-growth group (3.1%) and that the decrease in the average number of initiated projects within indication is significantly greater for the low-growth group at approximately 3 fewer projects.

[Insert Table 10 Here]

In Panel B, we then quantify the public health loss associated with the decrease in the

number of active projects based on DALY. In Rows 1 and 2, we first show DALY statistics for the two groups for the pre-FDAAA period. As we discussed previously, the detailed indication-level DALY are only available from the WHO for two years, 2000 and 2016. We therefore use the former for the statistics representing the pre-FDAAA period and the latter for the post-FDAAA period.

In Row 1, we find that DALY for low- and high-growth groups are 91.900 and 100.542 million years, respectively, in 2000. The difference between the two groups is not statistically significant. Results are similar for the other measure of DALY that uses % in Row 2. DALY (%) represents the fraction of DALY attributable to a given disease in the entire DALY. Next, in Rows 3 and 4, we show the difference between 2000 and 2016 for the same statistics. We find that the decrease in DALY from 2000 to 2016 is significantly greater for the high-growth group than the low-growth group with both measures. The difference is 18.68 million years in Row 3.

In sum, as shown in Row 5, average percentage changes in DALY from 2000 to 2016 are -8.27% for the high-growth group and +4.21% for the low-growth group. These final statistics suggest that if the low-growth group received the same level of aggregate investment as that in the high-growth group, then the DALY of the low-growth group would have dropped by the same magnitude (8.27%, or 7.6 million years).[29] This finding, together with our previous findings, suggests that the increased disclosure requirements result in more frequent suspensions of active projects and, in turn, possibly an increase in the Burden of Disease for our society. These results reflect potential unintended consequences of the FDAAA and thus have important policy implications.

6 Conclusion

To better understand the effects of information disclosures in the pharmaceutical industry, we use a unique policy change, the enactment of Section 801 of the Food and Drug Ad-

[29]The potential decline in DALY is estimated at 7.6 million years based on the mean DALY for the low-growth group of 91.9 million years in 2000.

ministration Amendments Act in 2007 (FDAAA), to examine how mandatory disclosure of pharmaceutical firms' clinical trial details influences peer innovation as captured by drug developers' suspensions of on-going projects and initiations of new projects. The model of Krieger (2021) suggests that news about peers' clinical trial outcomes have two opposite effects, learning and competition, on drug developers' investment decisions. Which effect dominates under a transition to a transparent information environment is an important question calling for empirical investigation. In addition, due to the costly investment and high uncertainty in new drug development, the role of financial constraints in the transition also deserves exploration.

Specifically, we find higher suspension rates of on-going projects after the FDAAA, suggesting that increased information transparency reduces pharmaceutical firms' innovative investments and that the learning effect dominates the competition effect at the aggregate level. This relation has a causal interpretation based on several difference-in-differences analyses showing that projects are suspended more often after the FDAAA when they are in less transparent pre-FDAAA information environments or with the higher demand for peer information. We also find fewer new project initiations of on-going projects after the FDAAA, which is also supported by a difference-in-differences test and thus has a causal interpretation.

Additional mechanism tests support the learning effect by showing that a project's suspension likelihood increases with the incidence of suspended peer projects but is unrelated to the incidence of advanced peer projects (which reflects the competition effect). In addition, we find that a firm's suspension decision is positively associated with peers' detailed suspension disclosures after the FDAAA and that this relation is more pronounced for low-quality firms and firms without partners. Therefore, the enhanced disclosure after the FDAAA indeed appears to create negative externalities to peer firms and lead to a reduction of subsequent innovation in the pharmaceutical industry sector.

Further analysis also shows that the learning effect is amplified by financial constraints. The suspension likelihood of resource-constrained firms increases with their peers' failures

but is unrelated to their peers' success. On the other hand, the suspension likelihood of unconstrained firms decreases with their peers' success but is unrelated to their peers' failures.

To provide policy and social welfare implications, we further quantitatively analyze the intended and unintended consequences of the FDAAA. On the one hand, the original goal of enhancing transparency and safety has been achieved – we find fewer adverse patient outcomes in the use of FDA-approved new drugs after the FDAAA, suggesting an improvement with respect to drug quality. On the other hand, as unintended consequences of enhanced information disclosure, pharmaceutical firms become less motivated to initiate and more likely to cut risky on-going projects. Such risk-averse approaches result in fewer new drug projects, which lowers the life quality of the public in the long run.

Our findings can extend to innovation investments in any innovation-intensive industries and speak to the discussion on how disclosure mandates of innovation progresses can have negative externalities on innovation investments of peer firms and social welfare of the public.

Appendix A Institutional Background of the FDAAA

The Food and Drug Administration Modernization Act (FDAMA Section 113) that was enacted in 1997 established the ClinicalTrials.gov database, a website that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately funded clinical trials.[30] The website established the protocols for recording clinical trials to disclose design, methods, objectives, relevant scientific background, and statistical information and is maintained by the National Library of Medicine (NLM) at the National Institutes of Health (NIH). FDAMA Section 113 requires summary information about clinical trials of investigational new drugs only for serious or life-threatening diseases and conditions (Tse and Zarin (2009)). Voluntary reports from uncovered trials are also accepted.

The most significant change to the disclosure of drug development is Section 801 of FDAAA, which was enacted in 2007 (Tse and Zarin (2009) and Tse et al. (2009)).[31] This act is regarded as an advancement in information disclosure, following the FDAMA, the ICMJE joint editorial, the Joint Position on the Disclosure of Clinical Trial Information issued by four pharmaceutical industry associations worldwide, and other relevant U.S. and international policies (Tse and Zarin (2009), Zarin et al. (2016), Lassman et al. (2017)). The FDAAA amends the Public Health Service (PHS) Act to require the FDA (i) to mandate the expanded scope and additional information of an "applicable clinical trial" (ACT)[32] to be registered in the ClinicalTrials.gov database within 21 days of enrolling the first patient; in addition, the summary results are required to be filed within a year of a clinical trial's completion date,[33] (ii) to make the database publicly available, and (iii) to establish civil penalties for failure to submit required clinical trial information or for the submission of false

[30]The history and evolution of the ClinicalTrials.gov database are available at `https://clinicaltrials.gov/ct2/about-site`.

[31]The details of Section 801 can be found at `https://www.congress.gov/bill/110th-congress/house-bill/3580`.

[32]Registration is required for studies that meet the definition of an "applicable clinical trial" (ACT) and either were initiated after September 27, 2007 or initiated on or before that date and were still ongoing as of December 26, 2007. ACTs, as defined in section 402(j) of the PHS Act, include (i) controlled clinical investigations (other than phase 1 investigations) of any FDA-regulated drug or biological product for any disease or condition, and (ii) certain studies of FDA-regulated medical devices, excluding small clinical trials to determine feasibility and certain clinical trials to test prototype devices, but including FDA-required pediatric postmarket surveillances of a device product. For more detailed definition of applicable clinical trials, see: `https://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf`.

[33]The completion date is the date of the last clinical trial visit of the last patient enrolled in the clinical trial. This deadline, however, can be extended up to 2 years under certain circumstances related to the market's approval of novel products. See `http://www.atlantclinical.com/compliance-with-fdaaa801`.

or misleading information to the database (Tse and Zarin (2009) and Tse et al. (2009)). The FDAAA requires sponsors, sponsor-investigators, or sponsor-designated principal investigators of clinical trials to submit information about a clinical study to ClinicalTrials.gov and update that information accordingly. The penalties for noncompliance include the withholding of NIH grant funding and civil monetary penalties of up to $10,000.

Overall, the literature suggests that the FDAAA significantly enhanced the information disclosure of clinical trials. Dos Santos and Atallah (2015) find that the rate of ClinicalTrials.gov registration increases from 13.6% before the FDAAA to 70.2% for trials subject to the mandatory reporting under the FDAAA (and 35.6% of trials that are not subject to the FDAAA).[34] Gill (2012) confirms a substantial increase in the number of registered trials in ClinicalTrials.gov since 2007. On the other hand, some studies suggested that the database may not be updated in a timely manner; however, such a criticism is denied by the FDA (Hawkes (2012), Lassman et al. (2017)).[35] All these studies collectively indicate a substantial albeit imperfect coverage of the results of industry-sponsored clinical trials after the enactment of the FDAAA. In fact, all the discussions (including criticisms) on the efficacy and consequence of the FDAAA suggest that the FDAAA and its impact on information disclosure were well-perceived and widely discussed among participants.

The FDAAA was refined in 2016 with the issuance of 42 CFR Part 11 for Clinical Trials Registration and Results Information Submission (i.e., the "Final Rule"), which took effect in January 2017. The Final Rule aims to clarify the requirements for the regulated parties, interpret ambiguous important statutory provisions, and make decisions about additional reporting requirements necessary (Zarin et al. (2016)). In sum, FDAAA 801 essentially

[34]The fact that the registration rate of industry-sponsored trials is not close to 100% can be attributed to several reasons (Miller et al. (2015), Lassman et al. (2017)). First, the collaboration among different institutes and the occurrences of mergers and acquisitions make it difficult for the FDA to hold any party responsible for the registration. Second, the coverage of applicable clinical trials of the FDAAA is not well-defined and some descriptions about the registration obligation and deadlines are ambiguous. Third, the delay penalty has not been imposed.

[35]Prayle et al. (2012) find that only 126 (40%) of 317 industry-sponsored trials had submitted their results to ClinicalTrials.gov on time. The FDA has disagreed with the results reported by Prayle et al. (2012) and pointed out methodological flaws in that study (e.g., including trials not covered by FDAAA, only tracking the on-time registrations) (Hawkes (2012)). In responding to this dispute, the NIH implemented an unofficial analysis and reported that 52% of industry-sponsored trials had filed results on time. Nguyen et al. (2013) find that 31% of 646 cancer-related trials posted results in ClinicalTrials.gov within three years after the completion date. Anderson et al. (2015) find that 41.5% of 8,736 industry-funded trials that are completed after 2008 and are highly likely subject to the FDAAA reported their results at ClinicalTrials.gov by September 2013. Reexamining the data of Miller et al. (2015), Lassman et al. (2017) find that almost all of the 15 novel drugs that were sponsored by big firms and approved in 2012 fully complied with the FDAAA.

requires all clinical trials of new drugs that are under the FDA jurisdiction to be registered on ClinicaTrials.gov within 21 days of enrolling the first patient and also requires summary results (including adverse events) to be reported within a year of clinical trial completion date (Fassbender (2018)).

Appendix B Examples of the FDA Adverse Event Reports

This appendix presents examples of the FDA adverse event reports for a drug named Androgel. Androgel is a supplement for testosterone. The field, Outcomes, in the table indicates whether the reported outcome is Serious. The outcome categories include congenital anomaly/birth defect (CA), death (DE), disability (DS), hospitalization (HO), life-threatening (LT), other serious important medical event (OT), and required intervention to prevent permanent impairment/damage (RI). A report can state multiple outcomes. If the field is missing, the report is classified as Non-serious. The field, Role, indicates whether the reported drug is Primary Suspect. Suspect (S) identifies products that the initial reporter deemed most likely to be associated with the event, and Concomitant (C) identifies products taken at the same time with the suspect product but not deemed as being associated with the event. The Suspect field can be further classified as Secondary Suspect when needed. In the four adverse event reports shown, for Androgel being a primary suspect, the Number of AER are four, and the Number of Serious AER are three. For Zocor which is reported as a concomitant drug, both the Number of AER and the Number of Serious AER are zero.

FDA Adverse Event Reporting System (FAERS)
Freedom of Information Act (FOIA)
Detailed Report

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Feb-2010	7271740	EXPEDITED (15-DAY)	Y	DE	US-SOLVAY-00310000680		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myocardial infarction	ANDROGEL	S	TRANSDERMAL	Daily dose: unknown	1 YR	
Off label use	UNKNOWN DIABETIC MEDS	C	ORAL	Daily dose: unknown		
	ZOCOR	C	ORAL	Daily dose: unknown		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
05-Feb-2010	7271758	EXPEDITED (15-DAY)	N	OT	US-SOLVAY-00210000660	59 YR	Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Prostate cancer	ANDROGEL	S	TRANSDERMAL	Daily dose: 5 gram(s)		
Cataract	METOPROLOL TARTRATE	C	ORAL	Daily dose: unknown		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
17-Feb-2010	7195451	EXPEDITED (15-DAY)	N		US-SOLVAY-00209007046	53 YR	Female	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Hirsutism	ANDROGEL	S	TRANSDERMAL	Daily dose: 2.5 gram(s)	19 MTH	
	VIVELLE DOT	C	OTHER	Daily dose: unknown, As used: 0.075 milligram, frequency: Twice a week, route: transdermal		

FDA Received Date	Case #	Case Type	Health Professional	Outcomes	Manufacturer Control #	Age	Sex	Country
22-Feb-2010	7252209	EXPEDITED (15-DAY)	Y	DE	US-SOLVAY-00210000159		Male	USA

Preferred Term	Product	Role	Route	Dosage Text	Duration	Manufacturer
Myocardial infarction	ANDROGEL	S	TRANSDERMAL	Daily dose: 5 gram(s)	16 MTH	
	ZOCOR	C	ORAL	Daily dose: unknown		
	UNKNOWN DIABETIC MEDS	C	ORAL	Daily dose: unknown		

Appendix C An Example of Study Details from ClinicalTrials.gov

This appendix presents an example of the detailed study report for a suspended clinical trial of a drug named Lumicitabine. Lumicitabine is a treatment for Respiratory Syncytial Viruses. We present Table of Contents of the study report only to conserve space and show how detailed the report is. The entire report is available at `https://clinicaltrials.gov/ProvidedDocs/73/NCT02935673/Prot_000.pdf`.

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Appendix D Variable Definitions

- Suspension (Indicator): An indicator that is one if the project is suspended in a given year or has no progress update for the duration longer than the 90th percentile of the sample duration with the same phase and zero otherwise.
- Disclosed Suspension (Indicator): An indicator that is one if a suspension announcement is made for the project in a given year and zero otherwise.
- Post (Indicator): An indicator that is one after the passage of the FDAAA in 2007 and zero otherwise.
- Project with Partner (Indicator): An indicator that is one if the project has partners in a given year and zero otherwise.
- Log(1+Number of Projects): The log of the total number of drug projects for the firm in a given year.
- Project Diversification: The firm-year level diversification index calculated as one minus the sum of the squared project shares of the disease groups in the firm's pipeline in a given year.
- Percent of Matured Projects: The percentage of matured projects (post-phase 3) in the firm's pipeline in a given year.
- Percent of Projects with Partner: The percentage of the projects in the firm's pipeline that have partners in a given year.
- Log(1+Number of Competitors): The log of one plus the total number of drug developers in each indication in a given year. The entire industry-sponsored (both public and private) and academic-sponsored projects from the preclinical stage to the final FDA approval stage are considered for the variable construction.
- Percent of Indication Matured Projects: The average percentage of matured projects (post-phase 3) in a given year for each indication. The entire industry-sponsored and academic-sponsored projects from the preclinical stage to the final FDA approval stage are considered for the variable construction.
- Industry-dominated indication (Indicator): An indicator that is one if more than 50 percent of projects in the indication during the sample period are industry-sponsored and zero otherwise (e.g., funded by universities, hospitals, and the NIH).
- Information Receiver (Indicator): An indicator that is one if the firm's average number of study-result reports submitted to Clinicaltrials.gov per project during the pre-FDAAA period is lower than the indication median and zero otherwise.
- Low Firm Age (Indicator): An indicator that is one if the firm's age during the pre-FDAAA period is lower than the indication median and zero otherwise.
- High Quality (Indicator): An indicator that is one if a firm's total number of phase advances in the past three years is greater than the sample median and zero otherwise.
- Partner (Indicator): An indicator that is one if the project has partners and zero otherwise.
- High (Low) Financial Constraint (Indicator): An indicator that is one if a firm's measure for financial constraints (the KZ index or the WW index) is higher (lower) than the sample median in the pre-FDAAA period and zero otherwise.
- KZ index: The Kaplan-Zingales index based on the five-factor model in Kaplan and Zingales (1997).
- WW index: The Whited-Wu index from Whited and Wu (2006).
- Equity Issuance: The log one plus the total amount of equity issuances for the full sample including both initial and seasoned public equity offerings from SDC.

- Debt Issuance: The log of one plus the total amount of debt issuances for public firms including public debt from SDC and bank loans from Dealscan.
- VC Funding: The log of one plus the total amount of venture capital financing for private firms from VentureXpert.
- Firm Size: The log of total assets of the firm in a given year from the Compustat database.
- R&D Expense/Assets: R&D expenses scaled by total assets of a firm in a given year from the Compustat database.
- Log(1+Total VC Funding): The log of one plus the cumulative amount of VC funding up to a given year from VentureXpert.
- Years from Approval: The difference between a given year and the FDA approval year of the drug.
- Log(1+Number of New Initiated Projects) (Firm-Year Level): The log of one plus the total number of new projects initiated by the firm in a given year.
- Log(1+Number of New Initiated Projects) (Firm-Indication-Year Level): The log of one plus the total number of new projects in each indication initiated by the firm in a given year.
- Firm Success Rates: A firm's total number of phase advances minus its total number of suspensions scaled by the total number of projects.
- Project Age: The difference between a given year and the drug project's initial year of a preclinical trial.
- Phase Age: The difference between a given year and the drug project's most recently updated phase year.
- Peer Phase Advance (Lagged): An indicator that is one if at least one of peer projects in the same indication as the project's indication has advanced to a next phase in a given year, excluding the own project's advancement.
- Peer Suspension (Lagged): An indicator that is if at least one of peer projects in the same indication as the project's indication is suspended in a given year, excluding the own project's suspension.
- Project Initiation After FDAAA (Indicator): An indicator that is one if the project is initiated after the passage of the FDAAA in 2007 and zero otherwise.
- Log(1+Number of AER): The log of one plus the total number of AER in which the drug is reported as a primary suspect in a given year.
- Log(1+Number of Serious AER): The log of one plus the total number of AER in which the patient outcome is one of the serious conditions (death, life-threatening, hospitalization, disability, congenital anomaly, or required intervention to prevent permanent impairment and damage) and the drug is reported as a primary suspect in a given year.
- Primary Suspect in AER (Indicator): An indicator that is one if the approved drug is identified as a primary suspect in any AER in a given year and zero otherwise.
- Primary Suspect in Serious AER (Indicator): An indicator that is one if the approved drug is identified as a primary suspect in any AER with serious patient outcomes in a given year and zero otherwise.
- Disability-Adjusted-Life-Years (DALY) (years): Sum of the years lived with disability and the years of life lost due to that disease.
- Disability-Adjusted-Life-Years (DALY) (%): The fraction of DALY (years) attributable to a given disease in DALY (years) for any disease.

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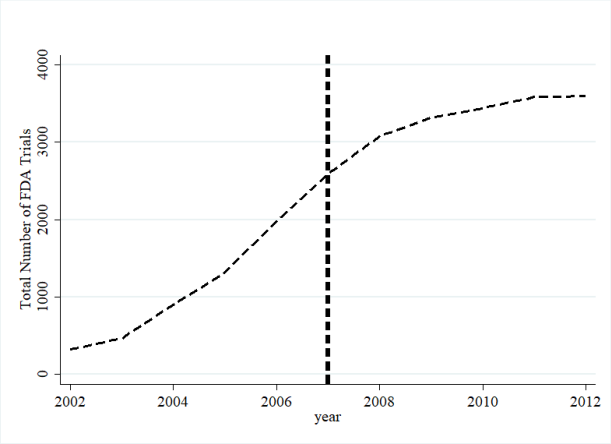
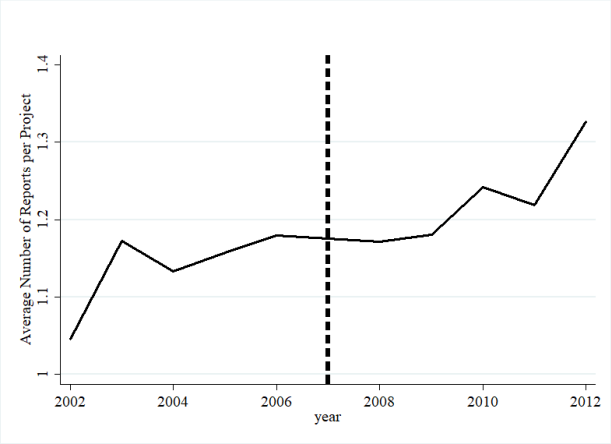
Figure 1: Pre- and Post-FDAAA Trends of Clinical Trials and Disclosures

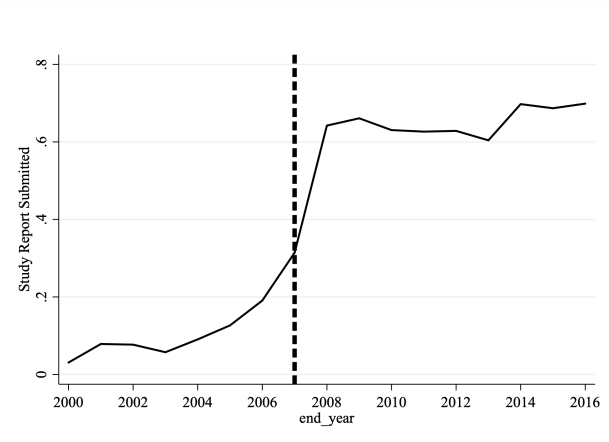
The figures present the time trends of clinical trials from 2002 to 2012. Figure (a) shows the total number of clinical trials. The number of clinical trials includes all ongoing projects that are not suspended. A suspended project is a project that is publicly disclosed as suspended or has no progress update for the duration longer than the 90th percentile of the sample duration for each clinical trial phase. Figure (b) shows the average number of progress updates (e.g., trial initiation, progress update, trial progressing, and updated results) per project. The frequency of progress updates can vary across trials. Figure (c) shows the average fraction of clinical trials with a detailed study-result report. We use the ClinicalTrials.gov data for submitted study results after excluding clinical trials in phase 1 which are not subject to the FDAAA.



(a) The number of clinical trials



(b) The average number of progress reports



(c) The fraction of projects with detailed study reports

Figure 2: Pre- and Post-FDAAA Trends of Project Suspension Rates

The figure presents the time trends of clinical trial suspensions from 2002 to 2012. Each line shows the average suspension rate (i.e., the total number of suspended projects divided by the total number of projects in a given year) for each phase. FDAAA covers clinical trials other than phase 1 investigations of any U.S. FDA-regulated drug or biological product.

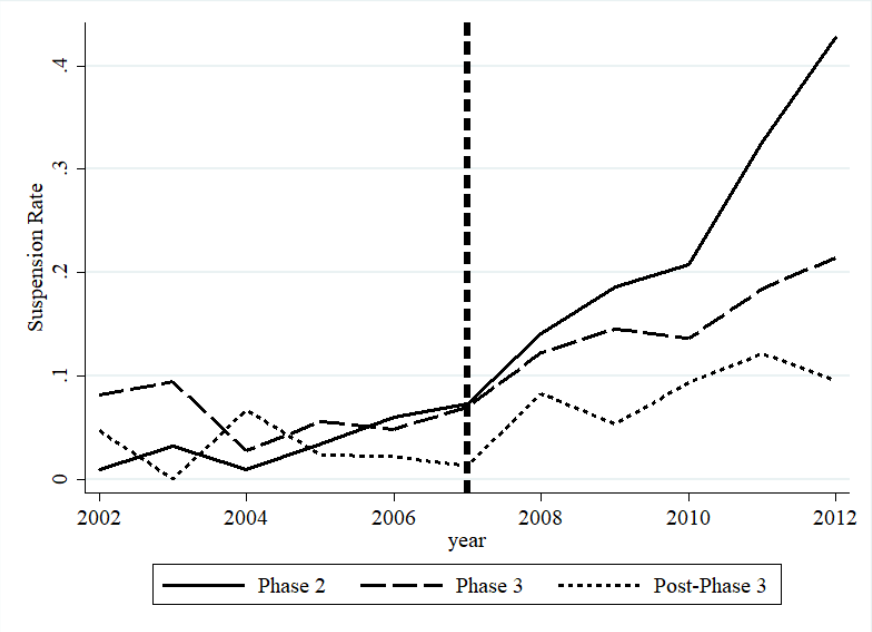
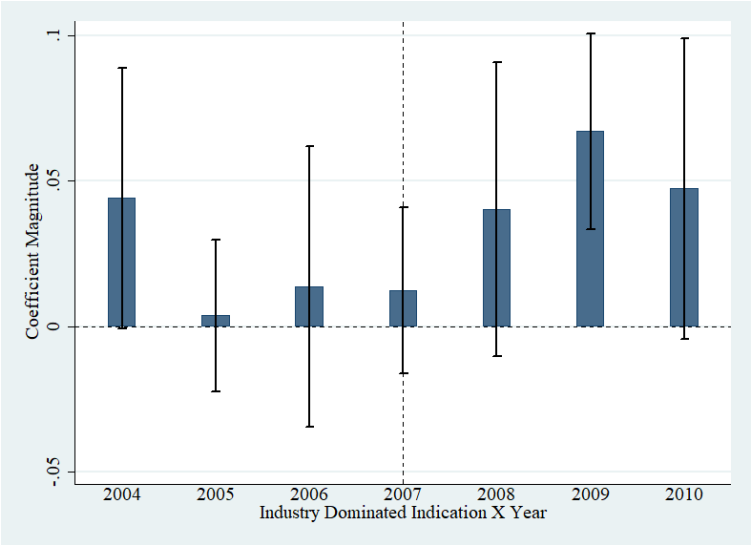
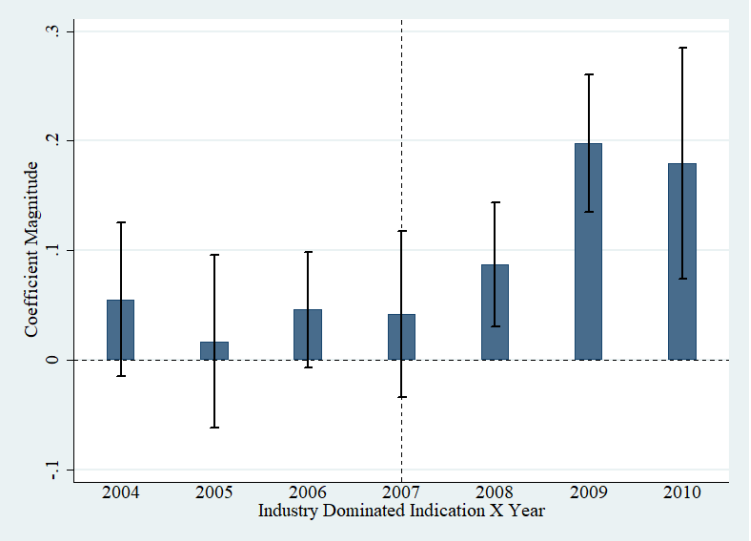


Figure 3: Difference-in-Differences Effects on Project Suspension Rates

The figure presents the difference-in-differences (DID) effects between treated and control groups over time. We use industry-dominated vs. academic dominated indication groups as the treated and control groups, respectively. Each bar represents the magnitude of the DID effect with a capped spike showing the 90 percent confidence interval.



(a) Full sample



(b) Propensity-score matched sample

Figure 4: Responses to Peer Suspensions

The figure presents dynamic effects of peer suspensions on a focal firm's suspension decisions given the peer suspensions occur at year t. We consider a regression similar to Column 1 of Table 6 but additionally consider lags, the contemporaneous value, and leads of Peer Suspension interacted with Post. Peer Suspension is one if any peer project is suspended in the same indication as that of a focal firm's project. Post is one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. Each diamond marker represents the magnitude of the effect of peer suspensions (t) on the focal firm suspension over time in the post-FDAAA period relative to that in the pre-FDAAA period. A capped spike shows the 90 percent confidence interval.

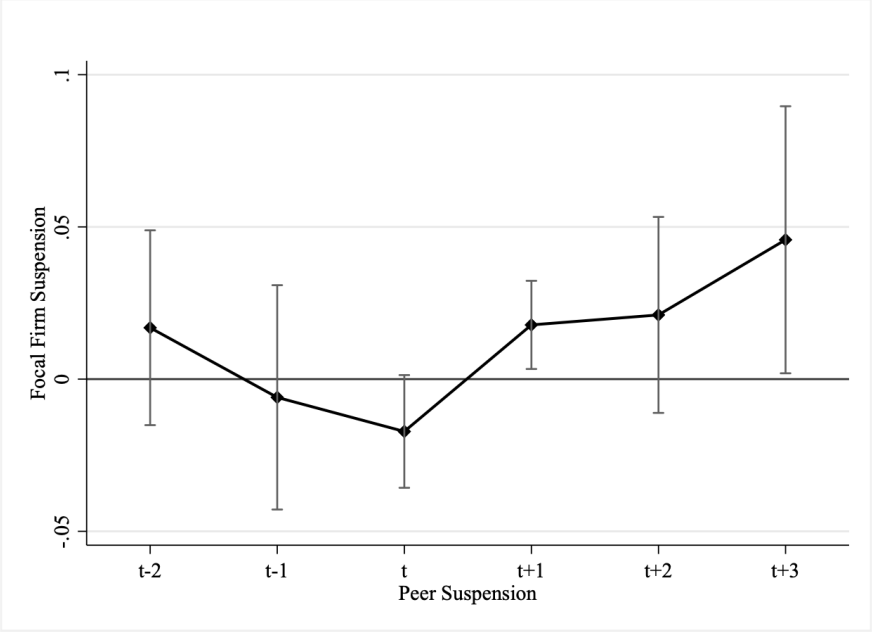


Figure 5: Pre- and Post-FDAAA Number and Growth of Active Projects

The figure presents the time trends of the average number and growth rate of active projects within indication from 2002 to 2012. The number of active projects is the total number of projects including new project initiations minus the number of suspended projects in a given year for a given indication. The active project growth rate is the percentage growth in the number of active projects for a given indication, which is the number of active projects in a given year divided by the number of active projects in the prior year minus one.

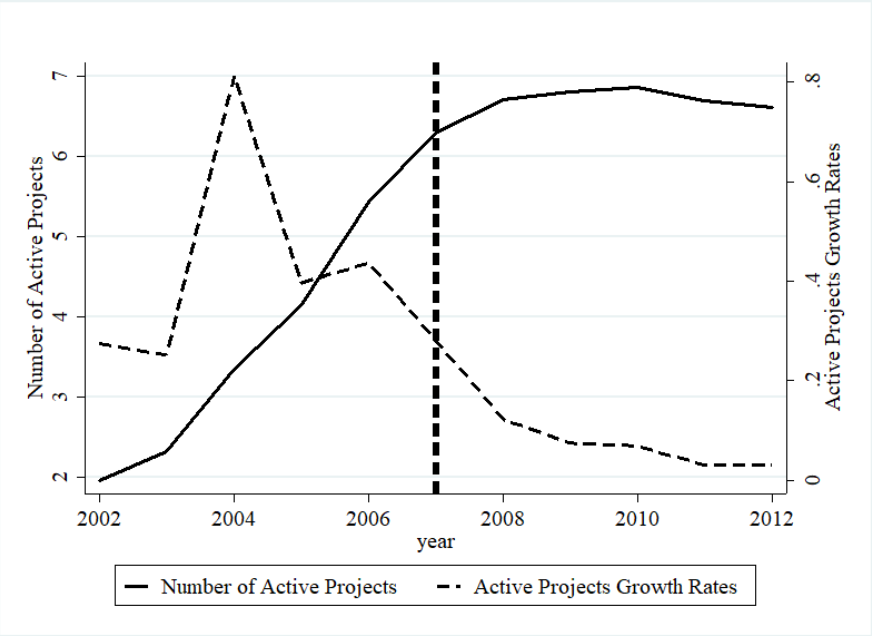


Table 1: Descriptive Statistics

The table presents summary statistics for our main sample in Panel A and compares variables used in regressions between the pre- and post-FDAAA periods in Panel B. The sample consists of 16,916 project-year observations from the BioMedTracker database for our sample period from 2002 to 2012. We exclude the following clinical trials from our sample: (i) clinical trials for generic drugs; (ii) clinical trials that are not sponsored by industry (i.e., academic-sponsored drugs); (iii) phase 1 trials, which are not subject to the FDAAA; and (iv) trials initiated in the post-FDAAA period. Suspension (Indicator), our main dependent variable, is one if the project is suspended in a given year or has no progress update for the duration longer than the 90th percentile of the sample duration for each clinical trial phase and zero otherwise. The detailed descriptions of other variables are available in Appendix D.

Panel A. Summary Statistics

	Mean	SD	Min	Median	Max	Obs.
Suspension (Indicator)	0.13	0.33	0.00	0.00	1.00	16,916
Log(1+Number of New Initiated Projects)	0.13	0.29	0.00	0.00	1.10	12,040
Project with Partner (Indicator)	0.54	0.50	0.00	1.00	1.00	16,916
Log(1+Number of Projects)	2.94	1.44	0.69	2.77	5.61	16,916
Project Diversification	0.52	0.31	0.00	0.63	0.90	16,916
Percent of Matured Projects	0.09	0.16	0.00	0.04	1.00	16,916
Percent of Projects with Partner	0.50	0.30	0.00	0.50	1.00	16,916
Log(1+Number of Competitors)	2.93	1.10	0.69	3.04	5.19	16,916
Percent of Indication Matured Projects	0.12	0.18	0.00	0.05	1.00	16,916
Peer Suspension (Lagged)	0.60	0.49	0.00	1.00	1.00	12,808
Peer Phase Advance (Lagged)	0.70	0.46	0.00	1.00	1.00	12,808
High Financial Constraint (Indicator, Public Sample, KZ)	0.50	0.50	0.00	0.00	1.00	7,916
High Financial Constraint (Indicator, Public Sample, WW)	0.49	0.50	0.00	0.00	1.00	7,651
Log(1+Number of AER)	2.84	2.32	0.00	2.56	10.30	7,593
Log(1+Number of Serious AER)	2.39	2.18	0.00	1.95	9.95	7,593

Panel B. Univariate Analysis

	Pre-FDAAA			Post-FDAAA			
	Mean	Median	Obs,	Mean	Median	Obs.	Diff
Suspension (Indicator)	0.05	0.00	7,580	0.19	0.00	9,336	-0.14***
Log(1+Number of New Initiated Projects)	0.23	0.00	5,276	0.05	0.00	6,764	0.17***
Project with Partner (Indicator)	0.55	1.00	7,580	0.52	1.00	9,336	0.03***
Log(1+Number of Projects)	2.73	2.64	7,580	3.10	2.94	9,336	-0.37***
Project Diversification	0.53	0.64	7,580	0.52	0.63	9,336	0.00
Percent of Matured Projects	0.13	0.09	7,580	0.06	0.03	9,336	0.08***
Percent of Projects with Partner	0.54	0.54	7,580	0.48	0.48	9,336	0.06***
Log(1+Number of Competitors)	2.51	2.56	7,580	3.27	3.40	9,336	-0.76***
Percent of Indication Matured Projects	0.14	0.05	7,580	0.10	0.06	9,336	0.04***

Table 2: Effects of the FDAAA on Project Suspension

The table presents results from the linear probability model regressions in Columns 1 and 2 and the probit regressions in Columns 3 and 4 that test the effects of the FDAAA on project suspension. The sample consists of 16,916 project-year observations from the BioMedTracker database for our sample period from 2002 to 2012. The dependent variable is Suspension (Indicator) that is one if the project is suspended in a given year or has no progress update for the duration longer than the 90th percentile of the sample duration for each clinical trial phase and zero otherwise. Post (Indicator) is one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. The detailed descriptions of other variables are available in Appendix D. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Suspension (Indicator)			
	(1)	(2)	(3)	(4)
	Linear Probability Model		Probit Model	
Post (Indicator)	0.174***	0.126***	1.049***	0.627***
	(0.005)	(0.006)	(0.039)	(0.062)
Project with Partner (Indicator)		-0.039***		-0.213***
		(0.009)		(0.048)
Log(1+Number of Projects)		-0.042***		-0.181*
		(0.010)		(0.099)
Project Diversification		0.075**		0.602***
		(0.034)		(0.184)
Percent of Matured Projects		-0.024		-0.369**
		(0.021)		(0.183)
Percent of Projects with Partner		-0.012		-0.116
		(0.028)		(0.179)
Log(1+Number of Competitors)		0.096***		0.811***
		(0.007)		(0.063)
Percent of Indication Matured Projects		0.059		-0.337
		(0.035)		(0.498)
Firm Fixed Effects	Yes	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes	Yes
Observations	16,888	16,888	14,883	14,883
R-squared	0.119	0.128		
Adjusted R-squared	0.062	0.072		
Pseudo R-squared			0.144	0.165

Table 3: Project Suspension: Difference-in-Differences using Industry- vs. Academic-dominated Indications

The table presents results from the DID regressions on project suspensions using industry-dominated and academic-dominated indications. The sample consists of 16,916 project-year observations from the BioMedTracker database for the sample period from 2002 to 2012. We divide the sample into two groups of industry-dominated and academic-dominated indications, and projects in industry-dominated indications are considered as treated. Industry-dominated Indication (Indicator) is one if more than 50 percent of projects in the indication during the sample period are industry-sponsored and zero otherwise (e.g., funded by universities, hospitals, and the NIH). The dependent variable is Suspension (Indicator) that is one if the project is suspended in a given year or has no progress update for the duration longer than the 90th percentile of the sample duration for each clinical trial phase and zero otherwise. Post (Indicator) is one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. Year t represents the year of FDAAA adoption. The detailed descriptions of other variables are available in Appendix D. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Suspension (Indicator)	
	(1)	(2)
Industry-dominated Indication (Indicator) × Post	0.032***	
	(0.009)	
Industry-dominated Indication (Indicator) × Year t-3		0.044
		(0.026)
Industry-dominated Indication (Indicator) × Year t-2		0.004
		(0.015)
Industry-dominated Indication (Indicator) × Year t-1		0.014
		(0.028)
Industry-dominated Indication (Indicator) × Year t		0.013
		(0.017)
Industry-dominated Indication (Indicator) × Year t+1		0.041
		(0.030)
Industry-dominated Indication (Indicator) × Year [t+2, t+5]		0.049**
		(0.020)
Control Variables	Yes	Yes
Year Fixed Effects	Yes	Yes
Firm Fixed Effects	Yes	Yes
Phase Fixed Effects	Yes	Yes
Indication Fixed Effects	Yes	Yes
Observations	16,888	16,888
R-squared	0.158	0.158
Adjusted R-squared	0.103	0.103

Table 4: Effects of the FDAAA on New Project Initiation

The table presents results from the tests that examine the effects of the FDAAA on new project initiations. In Columns 1 and 2, the dependent variable is the log of one plus the total number of new projects initiated by the firm in a given year. In Columns 3 and 4, the dependent variable is the log of one plus the total number of new projects in each indication initiated by the firm in a given year. Post (Indicator) is one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. The detailed descriptions of other variables are available in Appendix D. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Log(1+Number of New Initiated Projects)			
	(1)	(2)	(3)	(4)
	Firm-Year level		Firm-Indication-Year level	
Post (Indicator)	-0.115***	-0.354***	-0.207***	-0.196***
	(0.015)	(0.031)	(0.004)	(0.009)
Project with Partner		0.060		-0.025***
		(0.055)		(0.006)
Log(1+Number of Projects)		0.738***		0.036**
		(0.033)		(0.016)
Project Diversification		0.010		-0.163***
		(0.063)		(0.029)
Percent of Matured Projects		-0.033		-0.021
		(0.067)		(0.032)
Percent of Projects with Partner		-0.063		0.020
		(0.041)		(0.019)
Log(1+Number of Competitors)		-0.114***		-0.037***
		(0.012)		(0.008)
Percent of Indication Matured Projects		-0.049		-0.025
		(0.089)		(0.021)
Firm Fixed Effects	Yes	Yes	Yes	Yes
Indication Fixed Effects	No	No	Yes	Yes
Observations	4,275	4,275	14,636	14,636
R-squared	0.605	0.718	0.199	0.204
Adjusted R-squared	0.539	0.670	0.139	0.144

Table 5: New Project Initiation: Difference-in-Differences using Industry- vs. Academic-dominated Indications

The table presents results from the DID regressions on new project initiations using industry-dominated and academic-dominated indications. The sample consists of 12,040 firm-indication-year observations from the BioMedTracker database for the sample period from 2002 to 2012. We divide the sample into two groups of industry-dominated and academic-dominated indications, and projects in industry-dominated indications are considered as treated. Industry-dominated Indication (Indicator) is one if more than 50 percent of projects in the indication during the sample period are industry-sponsored and zero otherwise (e.g., funded by universities, hospitals, and the NIH). The dependent variable is the log of one plus the total number of new projects in each indication initiated by the firm in a given year. Post (Indicator) is one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. Year t represents the year of FDAAA adoption. The detailed descriptions of other variables are available in Appendix D. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Log(1+Number of New Initiated Projects)	
	(1)	(2)
Industry-dominated Indication (Indicator) × Post	-0.053***	
	(0.017)	
Industry-dominated Indication (Indicator) × Year t-3		-0.110
		(0.156)
Industry-dominated Indication (Indicator) × Year t-2		-0.168
		(0.102)
Industry-dominated Indication (Indicator) × Year t-1		-0.092
		(0.063)
Industry-dominated Indication (Indicator) × Year t		-0.112
		(0.105)
Industry-dominated Indication (Indicator) × Year t+1		-0.165*
		(0.094)
Industry-dominated Indication (Indicator) × Year [t+2, t+5]		-0.166*
		(0.091)
Control Variables	Yes	Yes
Year Fixed Effects	Yes	Yes
Firm Fixed Effects	Yes	Yes
Indication Fixed Effects	Yes	Yes
Observations	12,040	12,040
R-squared	0.241	0.241
Adjusted R-squared	0.175	0.175

Table 6: Competition vs. Learning around the FDAAA

The table presents results from the tests that examine competition effects vs. learning effects on suspension decisions around the FDAAA. The sample consists of 16,916 project-year observations from the BioMedTracker database for the sample period from 2002 to 2012. The dependent variable is Suspension (Indicator) that is one if the project is suspended in a given year or has no progress update for the duration longer than the 90th percentile of the sample duration for each clinical trial phase and zero otherwise. We consider the full sample in Column 1, the pre-FDAAA sample in Column 2, and the post-FDAAA sample in Column 3. Peer Suspension (Lagged) is one if any peer project is suspended in the same indication as that of a given project in the prior year. Peer Phase Advance (Lagged) is one if any peer project advances to the next phase in the same indication as that of a given project in the prior year. The detailed descriptions of other variables are available in Appendix D. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Suspension (Indicator)		
	(1)	(2)	(3)
	Full Sample	Pre-FDAAA	Post-FDAAA
Peer Suspension (Lagged)	0.026**	-0.008**	0.036**
	(0.012)	(0.004)	(0.017)
Peer Advance (Lagged)	-0.003	0.003	0.008
	(0.008)	(0.008)	(0.013)
Project with Partner (indicator)	-0.046***	-0.030***	-0.063***
	(0.011)	(0.007)	(0.016)
Log(1+Number of Projects)	-0.032	0.007	0.246***
	(0.022)	(0.020)	(0.054)
Project Diversification	0.125***	0.024	0.137**
	(0.033)	(0.078)	(0.054)
Percent of Matured Projects	-0.018	0.004	-0.149**
	(0.024)	(0.045)	(0.068)
Percent of Projects with Partner	-0.014	-0.002	-0.052
	(0.032)	(0.064)	(0.045)
Log(1+Number of Competitors)	0.175***	0.039**	0.352***
	(0.011)	(0.015)	(0.024)
Percent of Industry Matured Projects	0.188	-0.005	-0.148
	(0.110)	(0.107)	(0.167)
Firm Fixed Effects	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes
Observations	12,763	4,034	8,589
R-squared	0.121	0.184	0.155
Adjusted R-squared	0.053	0.052	0.060

Table 7: Peer Learning and Project Suspension

The table presents results from the tests that examine the effects of peer learning on suspension decisions after the FDAAA. The sample consists of 16,916 project-year observations from the BioMedTracker database for the sample period from 2002 to 2012. The dependent variable is Suspension (Indicator) that is one if the project is suspended in a given year or has no progress update for the duration longer than the 90th percentile of the sample duration for each clinical trial phase and zero otherwise. Post (Indicator) is one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. We consider full sample in Column 1, and subsamples of projects based on firm quality measured with drug development progresses in Columns 2 and 3 and based on the existence of partners in Columns 4 and 5. High Quality (Indicator) is one if a firm's total number of phase advances in the past three years is greater than the sample median and zero otherwise. Partner (Indicator) is one if the project has partners and zero otherwise. Peer Suspension (Lagged) is one if any peer project is suspended in the same indication as that of a given project in the prior year. Peer Phase Advance (Lagged) is one if any peer project advances to the next phase in the same indication as that of a given project in the prior year. The detailed descriptions of other variables are available in Appendix D. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Suspension (Indicator)				
	(1)	(2)	(3)	(4)	(5)
	Full Sample	Low Quality	High Quality	Without Partner	With Partner
Peer Suspension (Lagged) × Post	0.029**	0.052*	0.013	0.042**	0.017
	(0.011)	(0.030)	(0.008)	(0.020)	(0.014)
Peer Phase Advance (Lagged) × Post	-0.004	0.014	-0.019	-0.033**	-0.008
	(0.011)	(0.019)	(0.014)	(0.013)	(0.015)
Peer Suspension (Lagged)	-0.011	-0.042***	0.017	-0.013	0.004
	(0.008)	(0.013)	(0.014)	(0.009)	(0.011)
Peer Phase Advance (Lagged)	-0.002	-0.002	0.001	0.032**	-0.012
	(0.008)	(0.014)	(0.009)	(0.012)	(0.009)
Post (Indicator)	0.088***	0.092***	0.084***	0.124***	0.091***
	(0.012)	(0.027)	(0.010)	(0.017)	(0.016)
Project with Partner (Indicator)	-0.047***	-0.031*	-0.057***		
	(0.011)	(0.016)	(0.012)		
Log(1+Number of Projects)	-0.050***	-0.022	-0.054	-0.049	-0.071***
	(0.015)	(0.015)	(0.048)	(0.030)	(0.011)
Project Diversification	0.126***	0.088*	0.113*	0.157**	0.137***
	(0.035)	(0.047)	(0.057)	(0.060)	(0.037)
Percent of Matured Projects	-0.029	-0.062	-0.267*	-0.129**	-0.001
	(0.026)	(0.046)	(0.145)	(0.059)	(0.058)
Percent of Projects with Partner	0.008	0.006	-0.057	-0.106**	0.005
	(0.030)	(0.047)	(0.136)	(0.044)	(0.029)
Log(1+Number of Competitors)	0.130***	0.150***	0.118***	0.151***	0.145***
	(0.011)	(0.023)	(0.009)	(0.026)	(0.025)
Percent of Indication Matured Projects	0.078	0.121*	-0.014	0.090	0.099
	(0.054)	(0.066)	(0.056)	(0.071)	(0.065)
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes	Yes	Yes
Observations	12,763	6,068	6,329	5,896	6,841
R-squared	0.133	0.194	0.120	0.168	0.147
Adjusted R-squared	0.066	0.063	0.073	0.071	0.060

Table 8: Peer Learning and Financial Constraints

The table presents results from the tests that examine how drug developers' financial constraints affect the effects of peer learning on suspension decisions after the FDAAA. In Columns 1 and 2 (3 and 4), the sample consists of 7,916 (7,651) project-year observations from the BioMedTracker database for the sample period from 2002 to 2012. The dependent variable is Suspension (Indicator) that is one if the project is suspended in a given year or has no progress update for the duration longer than the 90th percentile of the sample duration for each clinical trial phase and zero otherwise. Post (Indicator) is one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. We use the KZ-index (the WW-index) during the pre-FDAAA period to divide the public firm sample into subsample of firms with high and low financial constraints in Columns 1 and 2 (3 and 4). Peer Suspension (Lagged) is one if any peer project is suspended in the same indication as that of a given project in the prior year. Peer Phase Advance (Lagged) is one if any peer project advances to the next phase in the same indication as that of a given project in the prior year. The detailed descriptions of other variables are available in Appendix D. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Suspension (Indicator)			
	(1) Financially Constrained (High KZ Index)	(2) Financially Unconstrained (Low KZ Index)	(3) Financially Constrained (High WW Index)	(4) Financially Unconstrained (Low WW Index)
Peer Suspension (Lagged) × Post	0.046**	-0.004	0.029*	0.017
	(0.021)	(0.011)	(0.017)	(0.009)
Peer Phase Advance (Lagged) × Post	-0.027	-0.062***	-0.041	-0.053***
	(0.020)	(0.014)	(0.029)	(0.009)
Peer Suspension (Lagged)	-0.002	0.026*	-0.001	0.034*
	(0.011)	(0.014)	(0.016)	(0.015)
Peer Phase Advance (Lagged)	-0.011	0.035***	-0.001	0.032***
	(0.020)	(0.004)	(0.019)	(0.006)
Post (Indicator)	0.082***	0.164***	0.097***	0.133***
	(0.021)	(0.018)	(0.027)	(0.010)
Project with Partner (Indicator)	-0.027**	-0.076***	-0.031**	-0.083***
	(0.009)	(0.015)	(0.013)	(0.012)
Log(1+Number of Projects)	-0.013	-0.059*	-0.025	-0.046
	(0.018)	(0.033)	(0.017)	(0.044)
Project Diversification	0.063	0.021	0.017	-0.085
	(0.045)	(0.105)	(0.034)	(0.053)
Percent of Matured Projects	0.012	-0.018	0.055	0.054
	(0.046)	(0.090)	(0.039)	(0.140)
Percent of Projects with Partner	0.011	-0.138*	-0.058	0.194
	(0.078)	(0.070)	(0.042)	(0.179)
Log(1+Number of Competitors)	0.131***	0.104***	0.110***	0.120***
	(0.017)	(0.018)	(0.015)	(0.019)
Percent of Indication Matured Projects	0.034	-0.018	0.004	-0.081
	(0.050)	(0.043)	(0.083)	(0.046)
Firm Fixed Effects	Yes	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes	Yes
Observations	3,923	3,927	3,713	3,911
R-squared	0.201	0.140	0.183	0.142
Adjusted R-squared	0.099	0.071	0.075	0.084

Table 9: Effects of the FDAAA on Drug Quality: Adverse Event Reports (AER)

The table presents results from the tests that examine the effects of the FDAAA on drug quality using adverse event reports from the FDA Adverse Event Reporting System (AERS) data for the drugs in our sample for the period from 2004 to 2017. The AERS data start in 2004. We restrict our sample to marketed drugs that are approved by the FDA in and after 1990 (1,303 unique drugs). Log(1+Number of AER) is the log of one plus the total number of adverse event reports (AER) for the drug in a given year in which the drug is reported as primary suspect. Log(1+Number of Serious AER) is the log of one plus the total number of AER in which the patient outcome is one of the serious conditions (death, life-threatening, hospitalization, disability, congenital anomaly, or required intervention to prevent permanent impairment and damage), and the drug is reported as a primary suspect. Project Initiation After FDAAA (Indicator) is an indicator variable that is one if the project is initiated after the passage of FDAAA in 2007 and zero otherwise. The detailed descriptions of other variables are available in Appendix D. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Log(1+Number of AER)		Log(1+Number of Serious AER)	
	(1)	(2)	(3)	(4)
Project Initiation After FDAAA	-0.541*	-0.563**	-0.536*	-0.544**
	(0.288)	(0.245)	(0.263)	(0.236)
Years from Approval	-0.073***	-0.127***	-0.061***	-0.103***
	(0.017)	(0.031)	(0.015)	(0.029)
Project with Partner (Indicator)		0.244**		0.231**
		(0.107)		(0.109)
Project Diversification		-0.256		-0.081
		(0.425)		(0.398)
Log(1+Number of Projects)		-0.335**		-0.253*
		(0.148)		(0.123)
Percent of Matured Projects		-0.481		-0.304
		(0.655)		(0.564)
Percent of Projects with Partner		0.662		0.612
		(0.508)		(0.455)
Log(1+Number of Competitors)		0.198		0.206
		(0.191)		(0.178)
Percent of Indication Matured Projects		1.021*		0.977*
		(0.546)		(0.506)
Firm Fixed Effects	Yes	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes
Observations	7,551	7,551	7,551	7,551
R-squared	0.519	0.532	0.535	0.546
Adjusted R-squared	0.489	0.502	0.506	0.518

Table 10: Effects of the FDAAA on Burden of Disease: Disability-Adjusted-Life-Years (DALY)

The table examines how the changes in active project growth rates and suspension rates before and after the FDAAA are associated with the changes in DALY at the indication level. We use the two points DALY data from the WHO for 2000 and 2016. We split indications into the two groups with (a) low and (b) high project growth before and after the FDAAA. The significance in the Difference (a)-(b) column is based on the t-tests for the equality of means in the two groups. Panel A shows the differences in average project growth rates, suspension rates, and initiated projects between the pre- and the post-FDAAA periods for the two groups. Suspension rate is defined as the mean of Suspension (Indicator) in a given indication. Initiated projects are defined as the number of new projects initiated by firms in a given indication. In Panel B, we quantify the indication-level changes in the Burden of Disease based on DALY for the two groups. DALY (million years) are the years lived with disability and the years of life lost due to that disease in millions. DALY (%) represents the fraction of the DALY (years) attributable to a given disease in the entire DALY (years) for any disease. ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

Panel A. Changes in Project Growth Rates and Suspension Rates

	Indications with low project growth	Indications with high vproject growth	Difference (a)–(b)	t-statistics (Difference)
Difference, Post – Pre:				
(1) Active projects growth rates	-0.462	0.049	-0.511***	-11.74
(2) Suspension rates	0.070	0.031	0.038**	2.39
(3) Initiated projects	-3.637	-0.585	-3.052***	-3.53
Observations	69	66		

Panel B. Changes in the Burden of Disease Based on DALY

	Indications with low project growth	Indications with high vproject growth	Difference (a)–(b)	t-statistics (Difference)
Pre-FDAAA period, 2000:				
(1) DALY (million years)	91.900	100.542	-8.643	-0.76
(2) DALY (%)	3.26%	3.57%	-0.31%	-0.76
Difference, 2016 – 2000:				
(3) DALY (million years)	-2.800	-21.483	18.683**	2.60
(4) DALY (%)	0.08%	-0.59%	0.67%***	2.63
Percentage Change:				
(5) (2016 DALY–2000 DALY)/2000 DALY	4.21%	-8.27%	12.48%**	2.08
Observations	69	66		

Information Disclosure and Peer Innovation: Evidence from Mandatory Reporting of Clinical Trials

Internet Appendix

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The Internet Appendix includes analysis and results of robustness tests that are referenced in the paper.

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1 Additional Difference-in-Differences Tests

In this section, we focus on firms' heterogeneous learning potential, specifically firms' experience in a specific group of disease, firm age, and the extent to which a firm was a previous information provider. All these characteristics capture the learning asymmetry of firms within the same indication. Table IA.3 of this Internet Appendix presents results from these alternative DID tests.

For the first within-indication DID analysis that uses a learning asymmetry proxy based on firm experience, we divide firms in our sample into two groups based on whether a project is from a firm that has any previous drug development projects in the same disease code. We use the disease code instead of indications to classify industry experience because clinical trial knowledge is transferable within disease code.[1] Learning Need High (Indicator) for this test is one if the project is the first one for the firm in a certain disease code and zero otherwise. We find in Column 1 that a project in a certain disease code that a firm has no previous experience is more likely to be suspended after the FDAAA. The economic magnitude is comparable to that in Table 3 in the paper as a 4.3-5.5 percentage-point increase in suspension rates. The dynamic DID test in Column 2 shows that the effect is concentrated in the years after the FDAAA enactment and thus that there is no pre-trend. The results in Columns 1 and 2 provide strong evidence that a project conducted by a relatively inexperienced firm for a specific category of disease is more likely to be suspended after the FDAAA.

As another industry experience measure, we consider firm age. We expect that younger firms are also less experienced in drug development and thus will be more dependent of information provided by their peers (Awaya and Krishna (2021)). We test for this prediction

[1]For example, the "Oncology" disease-code group includes "Breast Cancer" and "Prostate Cancer" as separate indications where clinical trial knowledge of one indication is highly likely to be useful for the other indication within a firm. Our results are also robust to use indications to define industry experience.

in Columns 3 and 4 and find qualitatively similar results to those in the first two columns.

We further consider another measure of learning asymmetry within indication. In particular, we utilize data in ClinicalTrials.gov regarding whether a firm has reported detailed study results for its clinical trials during the pre-FDAAA period. Firms that voluntarily report detailed study results before the reports are mandated are less likely to be in need of information from other firms. We denote those firms by information providers within indication and classify other firms as information receiver. This distinction between information providers and receivers serves as another measure for the extent to which peer information is useful. Specifically, Learning Need High (Indicator) for this case is one if the firm's average number of study result reports per project in ClinicalTrials.gov during the pre-FDAAA period is lower than the indication median and zero otherwise. Results for this DID test are presented in Columns 5 and 6. Column 5 shows that firms that are regarded as an information receiver suspend approximately 5 percentage-point more projects than information providers after the FDAAA. In Column 6, we also find that this effect manifests only after the FDAAA without a pre-trend.

Overall, the results in this section imply that even firms in one narrow indication can be significantly different in their learning needs. These results not only mitigate the concerns regarding fundamental differences across indication groups but also strongly support the conclusion that the FDAAA has altered information environments disproportionally more for the firms that are in need of more information and are likely more dependent on information disseminated from peer firms.

Table IA.1: List of Academic-Dominated Indications

The table presents the list of the top 30 academic-dominated indications. Academic-dominated indications are the ones with more than 50 percent of projects are funded by non-industry sponsors (e.g., universities, hospitals, and the NIH).

Indication	Ratio of Academic -sponsored Projects	Number of Industry -sponsored Projects	Number of Academic -sponsored Projects	Total Number of Projects
Cancer	96%	5	137	142
Metabolic – General	90%	2	19	21
Transplant Rejection	89%	2	16	18
Alcohol Dependence	80%	9	35	44
Esophageal Cancer	78%	7	25	32
End-Stage Renal Disease (ESRD)	76%	4	13	17
Urinary Incontinence	75%	1	3	4
Respiratory Distress Syndrome (RDS)	75%	2	6	8
Aplastic Anemia	75%	1	3	4
Myopic Macular Degeneration (MMD)	75%	2	6	8
Endometrial Hyperplasia	75%	1	3	4
Acute Promyelocytic Leukemia (APL)	75%	1	3	4
Coronary Artery Disease	74%	13	37	50
Fever	71%	2	5	7
Mild Cognitive Impairment (MCI)	71%	2	5	7
Cardiovascular Disease	71%	6	15	21
Preterm Labor	70%	3	7	10
Malaria	68%	12	26	38
Nasal Polyposis	67%	1	2	3
Vitiligo	67%	1	2	3
Turner Syndrome	67%	1	2	3
Panic Disorder	67%	2	4	6
Chronic Cough	67%	3	6	9
HIV / AIDS	66%	57	110	167
Traumatic Brain Injury (TBI)	64%	5	9	14
Liver Transplant Rejection	61%	7	11	18
Hepatitis B (HBV) Treatment (Antiviral)	61%	15	23	38
Allergy	60%	2	3	5
Smoking Cessation	59%	11	16	27
Anesthesia	59%	7	10	17

Table IA.2: Effects of the FDAAA on Project Suspension: Difference-in-Differences using a Propensity-score Matched Sample

The table presents results from the DID regressions between industry-dominated and academic-dominated indications using a propensity score matched sample. The propensity-score matched sample consists of 2,744 project-year observations from the BioMedTracker database for the sample period from 2002 to 2012. In Panel A, we divide the sample into two groups of industry-dominated and academic-dominated indications and compare summary statistics for the pre-FDAAA period for the propensity-score matched sample. Industry-dominated Indication (Indicator) is one if more than 50 percent of projects in the indication during the sample period are industry-sponsored and zero otherwise (e.g., funded by universities, hospitals, and the NIH). We use firm-year level project-portfolio characteristics as matching variables. We then match a treated project with a control project in the same year and phase that has the closest propensity score. The significance in the Difference column is based on the t-tests for equality of means in the two groups. In Panel B, we present estimates of the DID regressions using the propensity-score matched sample. The dependent variable is Suspension (Indicator) that is one if the project is suspended in a given year or has no progress update for the duration longer than the 90th percentile of the sample duration for each clinical trial phase and zero otherwise. Post (Indicator) is one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. Year t represents the year of FDAAA adoption. The detailed descriptions of other variables are available in Appendix D. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

Panel A. Pre-FDAAA Conditions for Propensity Score Matched (PSM) Sample

	Industry-dominated Indications (N = 401)		Academic-dominated Indications (N = 401)		Mean Difference	t-stat
	Mean	Median	Mean	Median		
Project with Partner (Indicator)	0.47	0.00	0.52	1.00	-0.04	-1.20
Log(1+Number of Projects)	2.53	2.40	2.54	2.40	-0.01	-0.08
Project Diversification	0.53	0.63	0.54	0.64	-0.02	-0.74
Percent of Matured Projects	0.15	0.09	0.17	0.09	-0.02	-1.11
Percent of Projects with Partner	0.53	0.52	0.54	0.53	-0.01	-0.37
Log(1+Number of Competitors)	1.92	1.95	1.97	1.95	-0.05	-0.78
Percent of Indication Matured Projects	0.20	0.09	0.23	0.15	-0.03	-1.61

Panel B. Difference-in-Differences Regression Analysis using a Propensity-score matched sample

	Suspension (Indicator)	
	(1)	(2)
Industry-dominated Indication (Indicator) × Post	0.098***	
	(0.016)	
Industry-dominated Indication (Indicator) × Year t-3		0.046
		(0.041)
Industry-dominated Indication (Indicator) × Year t-2		0.009
		(0.045)
Industry-dominated Indication (Indicator) × Year t-1		0.035
		(0.026)
Industry-dominated Indication (Indicator) × Year t		0.030
		(0.037)
Industry-dominated Indication (Indicator) × Year t+1		0.074*
		(0.042)
Industry-dominated Indication (Indicator) × Year [t+2, t+5]		0.153***
		(0.045)
Control Variables	Yes	Yes
Year Fixed Effects	Yes	Yes
Firm Fixed Effects	Yes	Yes
Phase Fixed Effects	Yes	Yes
Indication Fixed Effects	Yes	Yes
Observations	2,744	2,744
R-squared	0.256	0.258
Adjusted R-squared	0.121	0.121

Table IA.3: Effects of the FDAAA on Project Suspension: Difference-in-Differences using Within-Indication Heterogeneity

The table presents results from the within-indication DID regressions. For learning asymmetry across firms within indication, we consider the following three measures: A) firm-level drug development experience in a disease code group, B) voluntary study results reporting intensity, and C) firm age. Learning Need High (Indicator) in A is one if the project is the first one for the firm in a certain disease code and zero otherwise. Learning Need High (Indicator) in B is one if the firm's age during the pre-FDAAA period is lower than the indication median and zero otherwise. Learning Need High (Indicator) in C is one if the firm's average number of study results reporting per project in ClinicalTrials.gov during the pre-FDAAA period is lower than the indication median and zero otherwise. The sample consists of 16,916 project-year observations from the BioMedTracker database for the sample period from 2002 to 2012. In Columns 5 and 6, 1,498 observations are dropped for firms with no project before the FDAAA. The dependent variable is Suspension (Indicator) that is one if the project is suspended in a given year or has no progress update for the duration longer than the 90th percentile of the sample duration for each clinical trial phase and zero otherwise. Post (Indicator) is one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. Year t represents the year of FDAAA adoption. The detailed descriptions of other variables are available in Appendix D. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Suspension (Indicator)					
	(1)	(2)	(3)	(4)	(5)	(6)
	A. Industry Experience		B. Firm Age		C. Information Receiver	
Learning Need High (Indicator) × Post	0.043***		0.045***		0.047**	
	(0.010)		(0.010)		(0.021)	
Learning Need High (Indicator)	0.018***	0.023***	0.048***	0.016	-0.069***	-0.081***
	(0.004)	(0.008)	(0.013)	(0.016)	(0.015)	(0.023)
Learning Need High (Indicator) × Year t-3		-0.019		0.021		-0.016
		(0.012)		(0.026)		(0.025)
Learning Need High (Indicator) × Year t-2		-0.002		0.040		0.009
		(0.014)		(0.026)		(0.033)
Learning Need High (Indicator) × Year t-1		-0.009		0.019		0.020
		(0.014)		(0.032)		(0.021)
Learning Need High (Indicator) × Year t		0.000		0.048*		0.016
		(0.010)		(0.028)		(0.017)
Learning Need High (Indicator) × Year t+1		0.037**		0.053***		0.050**
		(0.015)		(0.015)		(0.024)
Learning Need High (Indicator) × Year [t+2, t+5]		0.039**		0.087***		0.063**
		(0.015)		(0.021)		(0.027)
Control Variables	Yes	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Observations	16,888	16,888	16,888	16,888	15,418	15,418
R-squared	0.160	0.160	0.162	0.162	0.178	0.178
Adjusted R-squared	0.105	0.105	0.107	0.107	0.124	0.124

Table IA.4: Effects of the FDAAA on Disclosed Project Suspension

The table presents results from OLS regressions in Columns 1 and 2 and the DID regressions for industry-dominated vs. academic-dominated indications in Column 3 that test the effects of the FDAAA on disclosed project suspension. In Column 3, projects in industry-dominated indications are considered as treated. The sample consists of 16,916 project-year observations from the BioMedTracker database for our sample period from 2002 to 2012. The dependent variable is Disclosed Suspension (Indicator) that is one if a suspension announcement is made for the project in a given year and zero otherwise. Post (Indicator) is one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. Industry-dominated Indication (Indicator) is one if more than 50 percent of projects in the indication during the sample period are industry-sponsored and zero otherwise (e.g., funded by universities, hospitals, and the NIH). The detailed descriptions of other variables are available in Appendix D. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Disclosed Suspension (Indicator)		
	(1)	(2)	(3)
Post (Indicator)	0.127***	0.097***	
	(0.006)	(0.006)	
Post (Indicator) × Industry-dominated Indication (Indicator)			0.034***
			(0.010)
Project with Partner (Indicator)		-0.046***	-0.048***
		(0.008)	(0.008)
Log(1+Number of Projects)		0.003	0.014***
		(0.007)	(0.005)
Project Diversification		0.035	0.041
		(0.042)	(0.041)
Percent of Matured Projects		-0.015	-0.026
		(0.016)	(0.018)
Percent of Projects with Partner		0.031	0.045
		(0.030)	(0.028)
Log(1+Number of Competitors)		0.041***	0.025***
		(0.005)	(0.009)
Percent of Indication Matured Projects		0.044*	0.008
		(0.023)	(0.022)
Year Fixed Effects	No	No	Yes
Firm and Institution Fixed Effects	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes
Observations	16,888	16,888	16,888
R-squared	0.120	0.126	0.133
Adjusted R-squared	0.064	0.069	0.076

Table IA.5: Effects of the FDAAA on Project Suspension: Excluding Financial Crisis and Effect on Financing Activities

The table presents results from the tests that examine the effects of the FDAAA on suspension decisions considering the financial crisis period and the effect of the FDAAA on financing activities. In Panel A, we use a refined sample that excludes observations in the five-year event window, [-2, +2], that contains the financial crisis period (i.e., observations in 2005, 2006, 2007, 2008, and 2009). Columns 1 and 2 show results from OLS regressions and Column3 shows results from the DID regressions for industry-dominated vs. academic-dominated indications. The sample consists of 16,916 project-year observations from the BioMedTracker database for our sample period from 2002 to 2012. The dependent variable is Suspension (Indicator) that is one if the project is suspended in a given year or has no progress update for the duration longer than the 90th percentile of the sample duration for each clinical trial phase and zero otherwise. In Panel B, we compare financing activities between treated and control groups for the original sample period. The dependent variable in Column 1 is the log of one plus the total amount of equity issuances for the full sample including both initial and seasoned public equity offerings from SDC. The dependent variable in Column 2 is the log of one plus the total amount of debt issuances for public firms including public debt from SDC and bank loans from Dealscan. The dependent variable in Column 3 is the log of one plus the total amount of venture capital financing for private firms from VentureXpert. Post (Indicator) is one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. Industry-dominated Indication (Indicator) is one if more than 50 percent of projects in the indication during the sample period are industry-sponsored and zero otherwise (e.g., funded by universities, hospitals, and the NIH). The detailed descriptions of other variables are available in Appendix D. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

Panel A: Excluding Financial Crisis Period

	Suspension (Indicator)		
	(1)	(2)	(3)
Post (Indicator)	0.218***	0.091**	
	(0.015)	(0.032)	
Post (Indicator) × Industry-dominated Indication (Indicator)			0.048*
			(0.027)
Project with Partner (Indicator)		-0.060***	-0.068***
		(0.010)	(0.009)
Log(1+Number of Projects)		-0.044***	-0.017
		(0.011)	(0.013)
Project Diversification		0.050	0.033
		(0.035)	(0.036)
Percent of Matured Projects		-0.046*	-0.051
		(0.026)	(0.030)
Percent of Projects with Partner		-0.012	0.010
		(0.027)	(0.023)
Log(1+Number of Competitors)		0.117***	0.050***
		(0.016)	(0.010)
Percent of Indication Matured Projects		0.060	0.011
		(0.061)	(0.066)
Year Fixed Effects	No	No	Yes
Firm and Institution Fixed Effects	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes
Observations	6,037	6,037	6,037
R-squared	0.210	0.220	0.262
Adjusted R-squared	0.077	0.087	0.135

Panel B: Financing Activities

	Suspension (Indicator)		
	(1) Equity Issuance (Full Sample)	(2) Debt Issuance (Public Firms)	(3) VC Funding (Private Firms)
Post (Indicator) × Industry-dominated Indication (Indicator)	-0.072	0.088	0.062
	(0.092)	(0.374)	(0.060)
Control Variables	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes
Firm and Institution Fixed Effects	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes
Observations	2,734	1,991	731
R-squared	0.499	0.660	0.301
Adjusted R-squared	0.407	0.591	0.078

Table IA.6: Effects of the FDAAA on Project Suspension: Excluding M&A

The table presents results from the tests that examine the effects of the FDAAA on suspension decisions after excluding firm-years that experience any M&A transactions (either as an acquirer or target). Columns 1 and 2 show the results from OLS regressions, and Column 3 shows results from the DID regressions for industry-dominated vs. academic-dominated indications. The sample consists of 12,826 project-year observations from the BioMedTracker database for our sample period from 2002 to 2012. The dependent variable is Suspension (Indicator) that is one if the project is suspended in a given year or has no progress update for the duration longer than the 90th percentile of the sample duration for each clinical trial phase and zero otherwise. Post (Indicator) is one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. Industry-dominated Indication (Indicator) is one if more than 50 percent of projects in the indication during the sample period are industry-sponsored and zero otherwise (e.g., funded by universities, hospitals, and the NIH). The detailed descriptions of other variables are available in Appendix D. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Suspension (Indicator)		
	(1)	(2)	(3)
Post (Indicator)	0.179***	0.125***	
	(0.005)	(0.006)	
Post (Indicator) × Industry-dominated Indication (Indicator)			0.041**
			(0.017)
Project with Partner (Indicator)		-0.033***	-0.036***
		(0.008)	(0.007)
Log(1+Number of Projects)		-0.039***	-0.022***
		(0.008)	(0.007)
Project Diversification		0.067*	0.059
		(0.033)	(0.037)
Percent of Matured Projects		-0.012	-0.020
		(0.021)	(0.024)
Percent of Projects with Partner		-0.013	0.013
		(0.028)	(0.025)
Log(1+Number of Competitors)		0.102***	0.037***
		(0.008)	(0.009)
Percent of Indication Matured Projects		0.078**	0.014
		(0.034)	(0.031)
Year Fixed Effects	No	No	Yes
Firm and Institution Fixed Effects	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes
Observations	12,826	12,826	12,826
R-squared	0.135	0.145	0.178
Adjusted R-squared	0.061	0.071	0.107

Table IA.7: Effects of the FDAAA on Project Suspension: Including Projects in All Phases and Initiated After FDAAA

The table presents results from the tests that examine the effects of the FDAAA on project suspension decisions using an expanded sample that includes phase 1 projects and projects initiated after the FDAAA. Columns 1 and 2 show the results from OLS regressions, and Column 3 shows results from the DID regressions for industry-dominated vs. academic-dominated indications. The sample consists of 21,309 project-year observations from the BioMedTracker database for our sample period from 2002 to 2012. The dependent variable is Suspension (Indicator) that is one if the project is suspended in a given year or has no progress update for the duration longer than the 90th percentile of the sample duration for each clinical trial phase and zero otherwise. Post (Indicator) is one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. Industry-dominated Indication (Indicator) is one if more than 50 percent of projects in the indication during the sample period are industry-sponsored and zero otherwise (e.g., funded by universities, hospitals, and the NIH). The detailed descriptions of other variables are available in Appendix D. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Suspension (Indicator)		
	(1)	(2)	(3)
Post (Indicator)	0.180***	0.130***	
	(0.005)	(0.005)	
Post (Indicator) × Industry-dominated Indication (Indicator)			0.031***
			(0.009)
Project with Partner (Indicator)		-0.036***	-0.040***
		(0.006)	(0.006)
Log(1+Number of Projects)		-0.039***	-0.018***
		(0.008)	(0.006)
Project Diversification		0.058	0.058
		(0.037)	(0.039)
Percent of Matured Projects		-0.021	-0.029
		(0.018)	(0.027)
Percent of Projects with Partner		-0.013	0.015
		(0.021)	(0.022)
Log(1+Number of Competitors)		0.098***	0.038***
		(0.006)	(0.007)
Percent of Indication Matured Projects		0.069**	-0.003
		(0.032)	(0.032)
Year Fixed Effects	No	No	Yes
Firm and Institution Fixed Effects	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes
Observations	21,309	21,309	21,309
R-squared	0.118	0.128	0.157
Adjusted R-squared	0.070	0.080	0.110

Table IA.8: Effects of the FDAAA on Project Suspension: Controlling for Project and Phase Age

The table presents results from the tests that examine the effects of the FDAAA on project suspension decision after controlling for project and phase ages. We include project age and phase age as additional control variables. Columns 1 and 2 show the results from OLS regressions, and Column 3 shows results from the DID regressions for industry-dominated vs. academic-dominated indications. The sample consists of 16,916 project-year observations from the BioMedTracker database for our sample period from 2002 to 2012. The dependent variable is Suspension (Indicator) that is one if the project is suspended in a given year or has no progress update for the duration longer than the 90th percentile of the sample duration with the same phase and zero otherwise. Post (Indicator) is one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. Industry-dominated Indication (Indicator) is one if more than 50 percent of projects in the indication during the sample period are industry-sponsored and zero otherwise (e.g., funded by universities, hospitals, and the NIH). The detailed descriptions of other variables are available in Appendix D. Standard errors reported in parentheses are robust and clustered by industry (disease code). ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Suspension (Indicator)		
	(1)	(2)	(3)
Post (Indicator)	0.078***	0.056***	
	(0.005)	(0.006)	
Post (Indicator) × Industry-dominated Indication (Indicator)			0.044***
			(0.010)
Project Age	-0.000	-0.003**	-0.016***
	(0.001)	(0.001)	(0.001)
Phase Age	0.051***	0.051***	0.052***
	(0.003)	(0.003)	(0.003)
Control Variables	Yes	Yes	Yes
Year Fixed Effects	No	No	Yes
Firm and Institution Fixed Effects	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes
Observations	16,888	16,888	16,888
R-squared	0.176	0.181	0.194
Adjusted R-squared	0.123	0.128	0.141