Information Release, Innovation Diffusion, and Welfare Analysis: Evidence from Mandatory Disclosure of Clinical Trials

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Abstract

Using the Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA 801) that substantially increases the pressure for drug developers to disclose clinical trial plans and results publicly as identification, we provide novel evidence that increased information transparency accelerates innovative activities. Specifically, we find that the amount of time to proceed to the next phase decreases but the project suspension probability increases following the regulation policy change. These effects are stronger when there are more projects and firms targeting on similar indications. We also find evidence for information diffusion as firms' suspension decisions become dependent on their peers' after the FDAAA. Finally, we analyze the social welfare and policy implications with the evidence that the FDAAA 801 helped improve drug quality conditioning on project continuation but may decrease overall quantities available in the market and thus negatively affect mortality and morbidity.

Keywords: Mandatory Information Disclosure, Information Diffusion, Innovation Acceleration, Welfare Analysis
JEL Classification: G30, D80, O32

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1. Introduction

While the disclosure of ones' progress in innovative activities is often costly due to the imitation and learning of potential competitors (Arrow, 1972; Horstmann et al., 1985; Levin, Klevorick, Nelson, and Winter, 1987; Cohen et al., 2000; Anton and Yao, 2004; Guo et al., 2004; Gill, 2008; Jansen, 2011; Pajak, 2012; Hughes and Pae, 2015), it has social welfare implication due to spillovers and positive externalities. Entrepreneurs and inventors sometimes need to offer some information about their innovative activities to potential investors to mitigate information asymmetries and raise capital (Leland and Pyle, 1977; Bhattacharya and Ritter, 1983, Ferreira et al., 2014).[1] On the other hand, the spillovers of innovations spread new knowledge, inspire subsequent innovative activities, and enhance the aggregate productivity for the society (Solow, 1957; Romer, 1986; Jaffe, 1989). As spillovers have social welfare implications, governments may choose to play an active role in the creation and commercialization of innovations produced by the private sector. The patent system exemplifies such an intervention by encouraging individuals or organizations to share their inventions with the public in exchange for exclusive usage rights of their inventions for a certain period (e.g., Arora, 1995; Arora et al., 1998; Merges, 2005; Hellmann, 2007; Elfenbein, 2007). Prior studies document the impact of patent disclosure on the knowledge diffusion and innovations (e.g., Aoki and Spiegel, 1998; Johnson and Popp, 2001; Budish et al., 2015; Graham and Hegde, 2015; Hedge and Luo, 2017), but very few studies empirically examine how pharmaceutical firms react to public disclosures in terms of the opportunity to learn from peers, and update their beliefs about market and technological promise (e.g., Krieger, 2017; Krieger et al. 2018).

The development of new drugs is one of the most costly innovative activities in many dimensions: it involves a huge amount of research investments, long hours of laboratory experiments, a large number of animal lives, and many human subjects. Thus, pharmaceutical firms have strong incentive to keep the information related to clinical trials of new drugs as business secrets. In the past, these firms only need to file their clinical trial plans and data to the U.S. Food and Drug Administration (FDA) for regulation and approval. Nevertheless, the development of new drugs is also to the public's interest to a great extent. Timely and accurate information about the outcomes of clinical trials is important for researchers, patients and the public as it facilitates scientific knowledge accumulation, fosters scientific discovery processes, and advocates patient rights — all with the ultimate goal of enhancing public health (Lehman and Loder, 2012).

[1] Also, disclosure of innovations can have a strategic value in deterring rivals' R&D investment and innovation competition, which is sometimes socially inefficient (James 2011; Graham and Hegde, 2015; Hughes and Pae, 2015).

The interest of the public has imposed great pressure on the government and administrative bureaus (FDA and NIH). Patient advocacy groups had long lobbied for access to up-to-date information about potentially life-saving therapies (Gill, 2012). In addition, medical journals, industry associations, and international policies all urge more disclosure of clinical trials (Tse and Zarin, 2009; Zarin et al., 2016; Lassman et al., 2017). As a response to these requests, the Congress passed and enacted the Food and Drug Administration Amendments Act (FDAAA) in 2007, in which Section 801 made substantial advancement in information disclosure requirement in new drug development.

This Act has a great impact on the pharmaceutical industry in three ways: first, the Act established legal requirements for sponsors and designated principal investigators to report specified information of certain applicable clinical trials to ClinicalTrials.gov, a website that was established to open drug information to the general public.[2] Second, it imposes civil penalties on noncompliance (Tse et al., 2009; Tse and Zarin, 2009). Third, it also increases pressure on clinical trials those are uncovered by the Act to disclose their outcomes to the public. Indeed, prior studies have shown significantly more registrations in the ClinicalTrials.gov since 2007 (Gill, 2012) – which we also find a similar pattern in our sample based on the BioMedTracker (BMT) database. More importantly, industry-sponsored trials have a much higher registration rate than academics-sponsored trials after the enactment of the FDAAA (dos Santos and Atallah, 2015). Our review of the literature confirms the pervasive impact of the FDAAA on enhancing the disclosure of information about clinical trials to the research society and the general public.

Different from most prior studies on the effects of the FDAAA that are conducted by medical researchers and focus on the disclosure contents and the frequency of compliance of individual firms, we aim to understand how the Act alters the firms' project choices and development plans due to information disclosure. The updates on the progress of a new drug are not only critical for patients and academic researchers but are also important to other firms who plan on or have been working on similar indications (i.e., a symptom that requires certain medical treatment). Since the Act triggered a policy shock that changes the information disclosure requirement for pharmaceutical companies, the effects of this shock on these companies' reactions are worth investigation.

In our empirical study, we use BioMedTracker (BMT) database that covers a broad scope of drug projects (i.e., clinical trials) based on multiple sources of information (e.g., ClinicalTrial.gov, press releases, company websites, earning conference calls). In particular, we focus on industry-sponsored

[2] The website also accepts the voluntary submission of clinical trial plans and outcomes.

clinical trials for new drugs that were initiated between 2002 and 2012.[3] We exclude the following clinical trials from our sample: (i) clinical trials for generic drugs, which follow different clinical process than new drugs and are of low uncertainty; (ii) clinical trials that are not sponsored by industry (i.e., pharmaceutical firms), which may have different incentive and pressure in disclosure and compliance; (iii) phase 1 trials, which are not subject to the FDAAA; and (iv) clinical trials that initiated after or terminated before the FDAAA. Differently from prior studies published in medical journals that focus on various types of drugs and different operational definitions for "applicable clinical trials" (ACT) of the FDAAA, we do not restrict our sample by focusing on trials that are likely ACT because the literature has found the definition of ACT unclear and relies on discretion and conjecture in selecting ACT samples.[4] As the FDAAA has created both mandatory requirement and ongoing pressure on the (possible) disclosure, we present the time-series pattern of the number of clinical trials of our main sample in Figure 1.

[Insert Figure 1 Here]

Figure 1-(a) shows that the total number of clinical trials has been continuously increasing over time. However, the average number of clinical trials per firm had a similar increasing trend before the FDAAA but the growth has slowed down to flat after the FDAAA. With regards to disclosures, Figure 1-(b) shows that the total number of progress updates (disclosures) continuously increases over time and more strongly so in more recent years. 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 regulation change.

We are particularly interested in how firms change their innovation strategies in reaction to the FDAAA. In particular, we examine the following characteristics of trials as they best capture firms' reactions: the project duration and the project suspension. The former is measured as the length (in days) of a clinical trial from its initiation date to its completion date, and measures the speed of a clinical trial. The project suspension, on the other hand, is an indicator variable that equals one if the firm suspends the clinical trial.[5]

We propose that when the pharmaceutical firm is required to disclose more information to the public, it is subject to greater time pressure as it can neither hide the adverse outcomes nor delay the information

[3] We focus the five-year periods before and after the FDAAA to reduce the possibility for other changes in regulation or industry environment to influence our statistical inference. Such design also mitigates the possibility of the impact of the FDAAA on the initiation and selection of new projects (i.e., endogeneity concerns), which may also bias our statistical inference on the effect of information disclosure due to the FDAAA.

[4] This also explains why the NIH and FDA have to announce the "Final Rule" in 2016 to clearly specify the coverage of the FDAAA. For more details, please see Zarin et al. (2016).

[5] The BMT database defines the suspension of a clinical trial by firm announcements and other public and private sources.

release for too long. It will thus accelerate the process and shorten project duration. In addition, it is more likely to suspend a project because the adverse outcomes and failures of its clinical trials are now better observed by the public and its reputation costs become higher. These arguments are supported by the first set of our empirical analysis based on multivariate regressions: the project duration is shortened by about 9% to 12% after the FDAAA when we use control for many other factors including the percentage of matured projects, the percentage of projects with partner, the number of competitors, the industry average failure rate, the industry total number of matured projects, indicator variable for private pharmaceutical firms, and fixed effects for firm, project indication (Industry), and clinical trial phases. Moreover, the project suspension likelihood increases by 5% to 13% after the FDAAA.

We further confirm the information diffusion channel by examining how firms react to their peers' trial outcomes, and find that firms' suspension decision depends on peers' failures after the FDAAA. This finding confirms the existence of information spillovers to peer firms, which allow firms to learn from peers' successful experience or fundamental difficulty and complication that cause peers' failure as well as market prospects. In addition, in comparison with low-quality firms, high-quality ones rely less on peers' experience, which is consistent with the information spillovers channel and suggests different learning behaviors among firms.

We then examine the role of existent information diffusion in the impact of information disclosure pressure on pharmaceutical firms. Specifically, we measure the information diffusion of a clinical trial by using the number of firms that have drug projects in the same indication in a given year.[6] We propose that when there are more drug projects and firms targeting on similar indications, the outcomes of one project will be learned by more other firms, which facilitate all participants' experiment designs and decisions. Thus, we expect the FDAAA effect on project duration and suspension increases with information diffusion. This proposition is also supported by our empirical evidence. When we split our sample into high- and low-information diffusion groups, we find that the post-FDAAA project duration in the high group is 13% to 15% shorter than that in the low group. Moreover, the post-FDAAA project suspension in the high group is 8% higher than that in the low group. We also verify the parallel trend assumption necessary for such difference-in-differences test: the project duration and suspension rate are not significantly different between the two groups in the pre period, suggesting that the treated and control groups do not differ in those dependent variables before the FDAAA.

[6] A trial is defined be to in a "high information diffusion" group if the total number of firms that have drugs (under development) in the same indication in a given year is greater than the sample median.

In our last set of empirical tests, we attempt to quantify the social welfare implications of the FDAAA. First, we find that the frequency of adverse event reports of clinical trials significantly reduces by 48% to 54% after enactment of the FDAAA.[7] Second, the likelihood of clinical trials in delivering any adverse event decreases by 13% to 16% after the enactment of the FDAAA. These results suggest that pharmaceutical firms pursue safer projects due to increased information disclosure pressure, which is fairly intuitive given that the costs of adverse events and bad outcomes are now transparent to the public.

Nevertheless, there are also downsides associated with enhanced information disclosure in drug development. The requirement and pressure of information disclosure reduce the expected NPV of some new drug projects in the future and thus prevent them from being adopted by pharmaceutical firms. Higher transparency in information about on-going new drug development may force pharmaceutical companies to give up some drugs that do not reveal good outcomes in the beginning, even though some of these projects may be revised and improved with more time. Moreover, the registration of adverse outcomes of clinical trials may impose extra reputation costs on institutes and individuals, which reduce their incentives to engage in new drug development. We find a significant drop in the number of projects targeting on the top 20 leading causes (diseases) in terms of Disability-Adjusted Life Years (DALYs) after the FDAAA. In addition, such slowdown in drug development is associated with substantial DALYs (estimated to be 19%) that could have been cured otherwise. These possible drawbacks call for further analysis on the optimal degree of information disclosure in new drug development.[8]

Our research contributes to the literature in the following ways: we use a unique policy change specific to information disclosure to understand the interplay between information disclosure and product market dynamics. Information has been a critical issue in innovation research, especially in promoting innovative activities and facilitating entrepreneurial activities by mitigating information asymmetries (Leland and Pyle, 1977; Bhattacharya and Ritter, 1983, Ferreira et al., 2014). Prior studies have shown how firms learn from their industry 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).[9] Our data of clinical trials (measuring product development) that target the same indication

[7] The frequency of adverse event reports is defined as the total number of reports in the Adverse Event Reporting System (AERS) that are designed to monitor drug safety for all approved drug and biologic products.

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

[9] Bustamante and Fresard (2017) show that firms under imperfect information environment use their peers' investment to update their estimation about the fundamentals. Prior studies in general show that information disclosure in a competitive dynamics have positive effects on innovation (Henderson and Cockburn, 1994; Ederer, 2013; Bloom et al., 2013; Boudreau and Lakhani, 2015). However, there are also studies showing negative effects on innovation: (i) disclosure in technological

allows us to analyse the peer effects from the increased disclosure requirements. The economic consequences and implications of on-going or unsuccessful innovations are not typically reflected in financial statements in a timely manner, and the non-financial information additionally disclosed after the passage of the FDAAA becomes a valuable information for peers, especially in assessing the feasibility of own innovation and the future economic performance.

Our investigation also has policy implications and highlights the intended and unintended consequences of the FDAAA, which are relevant for policy makers and the general public. We first show that, consistent with the literature (Gill 2012), more projects are registered in the ClinicalTrials.gov after the Act, which enhanced information disclosure. Moreover, we show accelerated clinical trials and increased suspension rates, which are novel findings for policy makers and deserve more considerations in future regulation changes. We also quantify the social welfare implications from the enhanced transparency of clinical trial outcomes: the frequency and likelihood of adverse event reports decrease by approximately 50% and 15%, respectively, after the enactment of the FDAAA. Nevertheless, we also show that the FDAAA may weaken the incentive of pharmaceutical firms to engage in new drug developments. Using disability-adjusted life year (DALY) lost measures from WHO, we find that, for the indication group that shows notably higher suspension rates after the FDAAA, DALYs increase by only approximately 2%, while the indication group with lower suspension rates after the FDAAA show a 19% decrease in DALYs on average. This result shows that the FDAAA might have unintended consequences of the FDAAA and ought to draw attentions from policy makers.[10]

2. Institutional Background

The Food and Drug Administration Modernization Act (FDAMA, Section 113) that was passed and enacted in 1997 establishes the ClinicalTrials.gov database,[11] a Web-based resource that provides patients, their family members, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and

advance deter R&D competition as rivals are less likely to develop and patent competing innovations (James, 2011); (ii) firms overreact to news about competition and technological failure with increase in project exit rates (Krieger, 2017); and (iii) negative shocks to a competitor's drug lead competing firms moving resources away from the affected area and into more exploratory projects (Krieger et al., 2018).

[10] A few prior studies examine the consequences of additional disclosure from the FDAAA but focus on an individual firm's information environment, such as reduced information asymmetry (Bourveau et al., 2017) and increased forecast accuracy (Hao et al., 2017). However, none of them examines the consequences on aggregate innovative activities following the increased information transparency and social welfare implications.

[11] The history and evolution of the ClinicalTrials.gov database: https://clinicaltrials.gov/ct2/about-site/history

conditions.[12] The website established the protocols of the records of clinical trials in order 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 the summary information about all publicly- and privately-funded clinical trials of investigational new drugs (and biological products) for serious or life-threatening diseases and conditions (Tse and Zarin, 2009). Voluntary reports from uncovered trials are also accepted.

The most significant changes to the disclosure of drug development is Section 801 of FDAAA (FDAAA 801), which was passed and enacted in 2007 (Tse et al., 2009; Tse and Zarin, 2009).[13] This act can be regarded as an advancement in information disclosure, following FDAMA, the International Committee of Medical Journal Editors (ICMJE) joint editorial, 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).[14] It responds to the call from patient advocacy groups which had lobbied to help patients gain access to up-to-date information about possible life-saving therapies and the loss of the public's trust in medical literature due to publication bias (Gill, 2012; dos Santos and Atallah, 2015).

The Act amends the Public Health Service (PHS) Act to require the FDA (i) to mandate the *expanded* scope and additional information of "applicable clinical trial" to be registered in the ClinicalTrials.gov database within 21 days of enrolling the first patient;[15] in addition, the summary results are required to be

[12] https://clinicaltrials.gov/ct2/about-site/background

[13] https://www.congress.gov/bill/110th-congress/house-bill/3580 Title VIII: Clinical Trials Databases - (Sec. 801) Amends the Public Health Service (PHS) Act to require the Secretary, acting through the Director of NIH, to expand the clinical trials registry data bank. 1. Requires the Director to ensure that the data bank is made publicly available through the Internet. Specifies information required to be submitted for an applicable clinical trial and included in the data bank. 2. Requires the Secretary to ensure that the data bank includes links to results information for those clinical trials that form the primary basis of an efficacy claim or are conducted after the drug or device involved is approved or cleared. 3. Requires the Secretary to further expand the registry and results data bank to provide more complete results information and enhance patient access to and understanding of the results of clinical trials within three years after enactment of this Act. 4. Prohibits the failure to submit required clinical trial information or the submission of false or misleading clinical trial information to the data bank. Sets forth civil penalties for violations. 5. Prohibits a state or political subdivision from establishing or continuing in effect any requirement for the registration of clinical trials or for the inclusion of information relating to the results of clinical trials in a database after the required expansion of the data bank three years after enactment of this Act.

[14] The ICMJE policy is a new policy published by several important medical journals in 2004 that requires submitters to register their projects in any comprehensive, publicly available database before the enrollment of the first patient (De Angelis et al., 2004, 2005).

[15] 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. Source: https://clinicaltrials.gov/ct2/manage-

filed within a year of clinical trial completion date,[16] (ii) to make the database publicly available through the Internet, and (iii) to establish civil penalties for failure to submit required clinical trial information or the submission of false or misleading clinical trial information to the database. The Act required sponsor, sponsor-investigator, or sponsor-designated principal investigator of clinical trials to submit information about a clinical study to ClinicalTrials.gov and update that information on ClinicaTrials.gov. The penalties for noncompliance include the withholding of NIH grant funding and civil monetary penalties of up to $10,000. Moreover, the submission of adverse events information to the website also becomes mandatory by law in September 2009.[17]

Overall, the literature suggests that the FDAAA enhanced the information disclosure of clinical trials. Using a sample of 243 clinical trials of specific biological products, dos Santos and Atallah (2015) find that the rate of ClinicalTrials.gov registration increases from 13.6% before the Act 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). The literature has also observed a substantial increase in the number of registered trials in the ClinicalTrials.gov since 2007 (Gill, 2012).

Some studies suggested that the coverage of the database is not comprehensive or updated timely. Using a sample of 317 industry-sponsored trials that are completed in 2009 and are likely subject to the FDAAA 801, Prayle et al. (2012) find that only 126 (40%) of these had submitted their results to ClinicalTrials.gov on time (i.e., within the one-year period from the completion date). However, the FDA has disagreed with the results reported by Prayle et al. (2012) and pointed out methodological flaws in that study, such as including trials that are not covered by FDAAA or only tracking the on-time registrations (Hawkes, 2012). In responding to this dispute, the U.S. National Institutes of Health (NIH) implemented an unofficial analysis and reported that 52% of industry-sponsored trials have filed results on time. In addition, Nguyen et al. (2013) examine a sample of 646 cancer-related trials and find that 31% of them posted results in ClinicalTrials.gov within three years after the completion date. Anderson et al. (2015) construct a sample of 8,736 industry-funded trials that are completed after 2008 and are highly likely subject to the FDAAA and find that 41.5% of them reported results at ClinicalTrials.gov by

recs/fdaaa#WhichTrialsMustBeRegistered. For more details definition of applicable clinical trials, see: https://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf

[16] 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 marketing approval of novel products. A certification to delay submission or an extension request must be provided (http://www.atlantclinical.com/compliance-with-fdaaa801).

[17] https://www.nlm.nih.gov/pubs/techbull/so08/so08_clinicaltrials.html

September 2013 (but only 17.0% were reported on-time). Reexamining the data of Miller et al. (2012), Lassman et al., (2017) focus on 15 novel drugs that were sponsored by big firms and were approved in 2012 and find that almost all of them fully complied with the FDAAA. All these studies collectively indicate a substantial albeit imperfect coverage of the results of industry-sponsored clinical trials after the enactment of the FDAAA.

On the other hand, the fact that the registration rate of industry-sponsored trials is not close to 100% can be attributed to several reasons (Miller et al., 2012; Lassman et al., 2017): first, the collaborations 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.

Despite the aforementioned criticisms, researchers do observe a significant increase in the registration and reported results of industry-sponsored clinical trials after FDAAA. In fact, all the discussions (including criticism) on the efficacy and consequence of FDAAA suggest that the Act and its impact on the information disclosure were well-perceived and widely discussed among participants; such attention to and awareness of regulation changes naturally increase the pressure to prepare for the disclosure that is currently mandatory or may become necessary in the future.

A noteworthy event that occurred close to the FDAAA is the joint editorial of the International Committee of Medical Journal Editors (ICMJE) in September 2004. The new policy of the ICMJE aimed at promoting the disclosure of all clinical trials and explicitly mandated submitters to register their clinical trials beyond phase 1 in one comprehensive and publicly available database before journal submissions. We deliberately focus on the effect of the FDAAA on drug development in 2007 rather than that of the ICMJE joint editorial for two reasons: First, the ICMJE joint editorial may not affect pharmaceutical firms those do not encourage scientists to submit to academic journals. Second, the literature has pointed out that the registration rate of NIH-funded (thus likely academic-sponsored) trials is substantially and significantly lower than that of industry-sponsored trials, even after the FDAAA (Prayle et al., 2012; Nguyen et al., 2013; Anderson et al., 2015). Thus, the incentive of compliance for academic researchers may be low in general, especially for failed trials. Third, due to the high investments and expected payoffs from successful new drugs, pharmaceutical firms have a much stronger incentive to comply with the FDA and bear much higher reputation costs for losing the public's trust.

The FDAAA was refined in 2016 with the issuance of 42 CFR Part 11 for Clinical Trials Registration and Results Information Submission — known as the "Final Rule" that takes effect in January 2017.[18] 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 a nutshell, the FDAAA 801 basically requires all clinical trials of new drugs that are in Phases 2 to 4 and are under the FDA jurisdiction to be registered on ClinicaTrials.gov within 21 days of enrolling the first patient, and reporting the summary results (including adverse events) within a year of clinical trial completion date (Fassbender, 2018).

3. Data and Variable Construction

3.1.Main sample

We use the BioMedTracker (BMT) database to obtain our primary sample. To measure pharmaceutical firms' innovation activities, especially the development of new drugs, we use two different empirical measures; the amount of time to proceed to the next phase of the drug development and the project suspension. We obtain these two variables and other variables related to drug development such as phase advances, partnered projects, and peer projects in the same indication from the BMT database that covers detailed project-level drug development processes including clinical trials for all publicly and privately held firms in the drug industry sector. The BMT database tracks pharmaceutical and biotech investment opportunities by analyzing drug pipelines and future catalysts. The database catalogues drug developments and related events since the 1950s, drawing from sources that include the FDA approval database, company filings with the Securities Exchange Commission (SEC), conference calls, press releases, news articles, medical conferences, direct communication with companies, and the ClinicalTrials.gov database. Thus, our sample naturally includes a greater breadth of drug project related events than using ClinicalTrial.gov only. The FDA does publish comprehensive information about approved drugs, including the approval date, but it does not provide in-process information for current individual projects which are under development. Unlike the FDA approval database, the BMT contains information on all drug pipelines, including the specific development phase and outcome for each project phase.

Drug development is regulated by the FDA requirements. The process is divided into parts: pre-clinical research on micro-organisms and animals, and clinical trials—which include phases 1, 2, and 3—on

[18] For details, see Zarin et al. (2016).

humans. During the pre-clinical stage, laboratories pinpoint new compounds and companies perform safety testing for phase 1. An Investigational New Drug (IND) application is then submitted to the FDA; this application details the effects of the active ingredients and toxicities of the drug. After the IND receives approval, the development advances to the three clinical phases. During phase 1, safety and dosing concerns are addressed with healthy volunteers. During phase 2, the drug's effectiveness is tested in a relatively small sample of people up to several hundred with a certain disease or condition. During phase 3, large-scale trials are conducted to determine the safety and effectiveness of a drug, with 300 to 3,000 people. At the conclusion of phase 3, a New Drug Application (NDA) or Biologic License Application (BLA) is submitted for FDA review and final approval. The FDA reviews all of the data presented with an NDA or BLA and ultimately approves or denies a new drug for the market.

At times, though, a drug's development can be suspended in the middle of clinical trial phases, for various reasons. Firms can voluntarily suspend or terminate their trials at any point, if their results aren't demonstrating the expected effectiveness, for example. Likewise, firms are not allowed to continue to the next trial phase if trial results are not successful. Further, if regulatory agencies believe that a clinical trial is not meeting applicable regulatory requirements or that the trial poses an excessive safety risk to participants—including significant side effects—they can suspend the project. Although suspended trials can be resumed with a new or revised clinical trial design, the data indicate that resumption is not a common event.

We use FDA project-level clinical trial phase data that have been covered by the BMT during the sample period from 2002 to 2012 as our main dataset. In particular, we focus on industry-sponsored clinical trials and *exclude* the following clinical trials from our sample: (i) clinical trials for generic drugs, which have low uncertainty and follow different FDA requirements than new drug development; (ii) clinical trials that are not sponsored by industry (i.e., academic-sponsored drugs rather than pharmaceutical firms), which may have different incentives and pressure in disclosure and compliance; (iii) clinical trials in phase 1, which are not subject to the FDAAA; and (iv) drug projects that initiated after or terminated before the FDAAA.

Our final sample encompasses 25,212 new drug project phase-year observations; this number includes 11,066 clinical trial phase-years pre-FDAAA and 14,146 clinical trial phase-years post-FDAAA. It is a subset of firms in the biotech and pharmaceutical industries that includes new drug development only, especially excluding development of generic drugs. We have 593 unique pharmaceutical firms with 3,597 unique drug projects in our sample. The relevant SIC codes for these firms are 2834 and 2836. Previous

studies published in medical journals focus on various types of drugs and different operational definitions for "applicable clinical trials" (ACT) of the FDAAA; unlike these studies, we do not additionally restrict our sample by focusing on trials that are likely ACT, because the literature has found the definition of ACT unclear and relies on discretion and conjectures in selecting ACT samples.

To study social welfare and policy implications, we use data from the FDA Adverse Event Reporting System (AERS). Appendix A shows examples of adverse event reports for a drug and how we classify different reporting cases. The FDA uses the AERS database to support its own post-marketing safety surveillance program for all approved drugs and therapeutic biologic products, monitoring new adverse events and medication errors that might occur with these products. The FDA receives reports about such events from both health care professionals (such as physicians, pharmacists, nurses, etc.) and consumers (such as patients, family members, lawyers, etc.). Health professionals and consumers can also send adverse event reports to manufacturers, who must then forward the report to the FDA, as specified by regulations. Clinical reviewers in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) then evaluate the reports in AERS to monitor the safety of products after they have been approved by the FDA. If reviewers identify a potential safety concern, the FDA may take regulatory action based on an assessment of the concern, to improve product safety and protect the public health; such actions might 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. Studying information provided by the AERS database, we consider the number of adverse event reports (AER) for each 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, intervention required to prevent permanent impairment and damage. We classify reports as *suspect* when the drug is reported as a primary or secondary suspect in an adverse case. This information is found in data fields "ROLE_COD" and "OUTC_COD" of the AERS.

To further examine social welfare and policy implications, we use the Disability-Adjusted Life Year (DALY) metric from the WHO Health statistics and information systems. This measure quantifies the burden of disease from mortality and morbidity. One DALY can be considered one lost year of "healthy" life. DALYs for a specific disease or health condition are 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 health condition or its consequences. We use two data points—DALYs from 2000 and

2016—for the top 20 leading causes of DALY globally.[19] These two points are the nearest available data to the FDAAA shock. We compare the two groups of indications with high-growth of active projects and low-growth of active projects following the FDAAA disclosure shock; thus, we can examine how the shock changes the DALYs between the two data points (2000 and 2016).

3.2. Variable construction

Our two main variables of interests are the amount of time to proceed to the next phase of the drug development and the project suspension. We are interested in these two variables as they can capture pharmaceutical firms' innovation activities, which are specifically development cycles of new drugs. *Duration of Phase Change* denotes the amount of time to proceed to the next phase measures the length in days of one clinical trial phase, which is a proxy for the speed of the clinical trial from its initiation to completion. We use the log of one plus the duration in days between the end date of the previous phase and that of the current phases, which is denoted as *Log(1+Duration of Phase Change)*. On the other hand, *Suspension* is an indicator variable that equals one if a project (i.e., clinical trial) is suspended in a given year and zero otherwise. A project is regarded as suspended if an announcement of suspension is made.[20] This measure captures the likelihood of suspension during clinical trials.

In Figure 2, we illustrate the time-series trends of aggregate project duration and suspension rates of projects. We measure project duration and suspension rates across all projects for each year – the former is calculated if there is a phase advance in the year, and the latter is calculated as the total number of suspensions in a year divided by the total number of projects in the same year. In Figure 2, the average project duration of phase changes has decreased after the FDAAA while suspension rates have increased and become stable after the FDAAA. We also observe the pre-trends of increases in progress updates of suspensions in the same figure, which is likely to be related to other policies before the FDAAA that promote disclosures (e.g., the ICMJE's policy primarily for academic-sponsored projects).

[Insert Figure 2 Here]

[19] The DALY estimates 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.

[20] There are non-active projects with no progress update for a long period of time, often referred to "zombie projects." We define a project with no progress update for more than 7 years as a zombie project and conduct a robustness test excluding these non-active projects. Our choice of 7 years to define these projects is based on the distribution of the length between a progress update and the next update. Approximately 90% of firms in our sample have a progress update in less than 7 years.

Our main independent variable in regression analysis is *Post*, which is an indicator variable that takes one after the passage of the FDAAA in 2007 and zero otherwise. What we are interested in is whether the passage of the FDAAA changes information environment, more so under intensive information diffusion, and thus affects pharmaceutical firms' innovation activities. Thus, we also need variables that measure intensity of the diffusion of information related to drug development. We use four different measures for information diffusion, *Number of Peers*, *Number of Drugs*, *Fluidity*, and *Non-Expedited Drugs*.[21] We define our main information diffusion measure, *Number of Peers*, as the total number of firms that have drug projects in the same indication in a given year, and indicator variable, *High Number of Peers*, that takes the value of one if *Number of Peers* is greater than the sample median from the entire sample and zero otherwise.[22] *Number of Drugs* is the total number of drug projects in the same indication in a given year, and *High Number of Drugs* is an indicator variable that takes the value of one if *Number of Drugs* is greater than the sample median and zero otherwise. *Fluidity* is the product market fluidity variable from Hoberg, Phillips and Prabhala (2014), and *High Fluidity* is an indicator variable that takes the value of one if *Fluidity* is greater than the sample median and zero otherwise.[23] Moreover, *Non-Expedited Drugs* is an indicator that takes the value of one if the drug project are not designated as the FDA expedited programs including fast track, breakthrough therapy, and orphan drug that are treated differently by the FDA for any development and review. The expedited program is designed to incentivize the development of new drugs to fill an unmet medical need for a serious condition, and thus drug projects covered by the program is generally considered to be unique. These measures capture how much a firm can learn from its peers about drug development, experiment designs, and market prospects to improve its drug development decisions.

Table 1 presents summary statistics of the variables used in our analyses. The sample is from the FDA clinical trial phase-level data that have been covered by the BMT from 2002 to 2012. The sample consists of 25,212 new drug project phase-year observations with our screening procedures discussed previously. We have 1,588 observations for the length of each clinical trial phase change. The average of *Duration of Phase Change* is 533.56, which means that on average it takes about 17.5 months to complete each clinical trial phase conditioning on the event of phase advance. *Suspension* (indicator) is an indicator variable that

[21] For the definition of information diffusion measures, we also include clinical trials that are sponsored by non-industry or academic institutions.
[22] Our results are robust to using sample median from each year.
[23] We thank Gerard Hoberg and Gordon Phillips to make their product market fluidity data available on their website. The product market fluidity measure is from 10-K filings for public firms. Therefore, when we consider the fluidity as an alternative measure, the analysis excludes all private firms in our sample.

equals one if the project is suspended and zero otherwise; it has the mean value of 0.05, which means that on average 5% of the clinical trial projects are suspended in the middle of the clinical trials. This mitigates a possible concern that our results are driven by different project choices after the FDAAA, and our results come more from a firm's reaction to the FDAAA during the development of a new drug.

The averages of *Number of Peers*, *Number of Drugs*, and *Fluidity* are 13.84, 20.27, and 11.57, respectively. Because the observations are at the project phase-year level, the mean values of the first three indicator variables for information diffusion (*High Number of Peers*, *High Number of Drugs*, and *High Fluidity*) are not exactly 0.5, although the cutoffs are median values. 87% of the drug projects in our sample are not designated as the FDA expedited programs.

[Insert Table 1 Here]

The following control variables from the BMT are also included in regressions (and their detailed definitions are provided in Appendix B): *Peer Phase Advance Rate* averages 14% with a standard deviation of 18%. *Peer Suspension Rate* averages 10% with a standard deviation of 15%. These two variables are lagged to account for potential time-lag for responding to information from peers' drug development progress because we need to ensure that peers' phase advance or suspension occurs before a given project's phase advance or suspension event. 51% of the projects have partners (which is measured by an indicator variable *Project with Partner*), and 49% of on-going projects a firm carries in its pipeline have partners (which is measured by a variable *Percent of Projects with Partner*). Firm have on average 0.3 preclinical projects (*Log (1+Number of Preclinical Projects)* = 0.25) and 40% of the projects in a firm's pipeline are matured (i.e., post-clinical trial phases) projects (denoted by *Percent of Matured Projects*). The average total number of both private and public firms with new drug development in each indication group in a given year is 150 (*Log (1+Number of Competitors* = 5.02)). *Industry Failure Rate* denotes the industry average of firm failure rate in a given year is 11% and *Industry Total Number of Matured Projects* denotes the industry average of the percentage of firms' matured projects in a given year is 32%.

We consider the following variables based on adverse event reports (AER) for our analysis of social welfare: The average total number of AER is 29 (*Log(1+Number of AER)* = 3.37). Log of one plus the number of AER Suspect, AER Primary Suspect, Serious AER, Serious AER Suspect, and Serious AER Primary Suspect are 3.01, 2.79, 3.03, 2.65, and 2.44 respectively. *Project Initiation After FDAAA*, denotes an indicator variable that is equal to one if the drug project is initiated after the passage of the FDAAA

(and zero otherwise) and averages 0.10. 69% of approved drugs have at least one serious AER and 66% of them are considered as primary suspect in AER.

Next, in Table 2, we compare our variables between pre- and post-FDAAA periods (Panel A) and between high and low information diffusion groups based on *High Number of Peers* =1 and 0, respectively (Panel B). The amount of time to successfully proceed to the next phase is shorter for the post-FDAAA period, which provides preliminary evidence that the effect of increased mandatory disclosure and ongoing pressure on possible disclosure through the FDAAA has increased the speed of clinical trials. This is also consistent with the comparison of *Peer Phase Advance Rate* variable, which becomes higher for the post period. However, the suspension rate is higher for the post-FDAAA period, which indicates that pharmaceutical firms are more likely to suspend their ongoing projects after the FDAAA regulation change. This is also consistent with the comparison of *Peer Suspension Rate* and *Industry Failure rate*, which are higher for the post period as well.

Information diffusion becomes severe in the post-FDAAA period as we find the following: *Number of Peers* increases from 12.42 in the pre-FDAAA period to 14.95 in the post-FDAAA period, *Number of Drugs* increases from 18.24 to 21.86, and *Fluidity* increases from 11.09 to 11.93. All these increases are significant. The percentage of non-expedited drug projects, the number of preclinical projects and the likelihood that a project has partners increase while the percentage of matured projects as well as the percentage of projects in a firm's pipeline with partners decrease for the post-FDAAA period. Moreover, the industry average of firm failure rates has increased in the post-FDAAA period while the industry average of matured projects has decreased.

[Insert Table 2 Here]

In Panel B, the pre-FDAAA sample is divided into the two groups with high and low information diffusion based on the median *Number of Peers* from the entire sample to understand the effect of information diffusion on the project cycle. Other information diffusion-related measures are consistent with *Number of Peers* as their averages in the high group are higher than those in the low group. The duration of phase changes and the suspension rate are not significantly different between the two groups in the pre period, which confirms the parallel trend assumption because the treated and control groups do not differ in dependent variables of interest before the FDAAA. These statistics motivate our difference-in-differences analyses of the differential effects of the FDAAA on firms' drug development. The percentage of non-expedited drugs is higher for the high group. *Peer Phase Advance Rate* and *Peer Suspension Rate* are higher for the high group. Projects in the high information diffusion group are more

likely to have partners. Firms with projects in the high group have more preclinical projects and smaller percentages of matured projects. *Industry Failure Rate* is higher for the high group but the industry percentage of matured projects is higher for the low group.

4. The Effect of Enhanced Disclosure Pressure on Innovation Cycle

In the literature, information transparency is often regarded as a first-order concern when a new mandatory disclosure requirement is proposed. However, researchers have not arrived at a conclusion yet for the eventual effects of the improved transparency on innovation strategies of information providers and their peers as well. In this section, we first explore how the increased information transparency for clinical trials alters pharmaceutical firms' drug development, and then examine how such influence varies due to existent information diffusion intensity.

4.1. Main results: The effect of disclosure pressure

In Table 3, we present the results from our baseline regressions that examine the effects of increased mandatory disclosures (and ongoing pressure on possible disclosures) through the FDAAA on project duration and suspension rates. In Columns 1 to 3, we first examine the effect of project duration. For the first three columns, the dependent variable of the regressions is *Log(1+Duration of Phase Change)*, and the sample is project-phase observations conditioning on the events of phase advances.[24]

[Insert Table 3 Here]

In Column 1, we regress the project duration measure on the dummy variable, *Post*, that indicates the post-FDAAA period starting from 2008 without controlling any other variable in the regression except multiple fixed effects based on firms, indications, and clinical trial phases. The significant negative coefficient of *Post* indicates that the passage of the FDAAA is associated with a decrease in the project duration. In Column 2, we show that the negative association between the passage of the FDAAA and the project duration is robust when we control for characteristics of drug developers and their industries. For the control variables, we consider the number of preclinical projects, percentage of matured projects, whether the project has outside partners, percentage of projects that have outside partners for the firm, number of competitors in the same indication, industry failure rate, and percentage of matured projects in

[24] Phase advances are rare events in clinical trials for new drug development. In our data, the incidence rate of phase advances is estimated at approximately 5.35%. Therefore, the size of the sample for examining the duration of phase changes is much smaller (1,349) than the size of the entire phase-year sample (25,206) for examining the suspension likelihood.

the same industry as control variables (all defined in Appendix B). The negative effect of the passage of the FDAAA on the project duration is economically significant. The passage of the FDAAA decreases the length of phase advance in clinical trials by 9.5%. Considering the mean duration of the phase change (454 days) in Table 1, the 9.5% decrease translates into approximately 43 days on average.

In Column 3, we show the effect of the passage of the FDAAA on project duration dynamically by considering the year dummy variables, Year $_{t-2}$, Year $_{t-1}$, Year $_{t}$ and Year $_{t+1 \text{ to } 2}$, and Year $_{t+3 \text{ to } 5,}$ that indicate the annual pre- and post-FDAAA periods. Year $_{t}$ is the indicator for the year, 2007, when the FDAAA is enacted. While the coefficients on Year $_{t-2}$, Year $_{t-1}$, Year $_{t}$ and Year $_{t+1 \text{ to } 2}$ are insignificant, the coefficient on Year $_{t+3 \text{ to } 5}$ is negative and statistically significant at the 10% level. This indicates that the negative effect of the increased disclosure requirement is present about two years later than the enactment of the FDAAA. This mitigates a potential concern that our results can be merely driven by a mechanical effect from the increased number of disclosures. If so, right after the enactment of the FDAAA, firms might have filed and updated the over-due clinical trial results to comply with the regulation. Further, we do not find any pre-trend before the passage of the FDAAA as the coefficient estimates for Year $_{t-2}$, Year $_{t-1}$, Year $_{t}$ do not show significance.

In Columns 4 to 6 in Table 3, the dependent variable is *Suspension (Indicator)*, which equals one if the project has been reported as suspended in a given year and zero otherwise. We estimate a linear probability model instead of a logit or probit model because the former is able to generate a consistent (unbiased) estimate, even if the dependent variable does not follow a logistic or normal distribution (Wooldridge, 2002). In Column 4, we report the regression results of the suspension indicator on the dummy variable, *Post*, without other control variables but with firm, indication, and phase fixed effects. We find a significant and positive association between the dummy variable indicating the post-FDAAA period and the suspension likelihood. After we control for other variables for characteristics of drug-developing firms and their industries, we find a slightly stronger effect of the passage of the FDAAA on suspensions. The economic interpretation for the effect is that the passage of the FDAAA increases the likelihood of suspension by 9.5%. The results for dynamic effects of the FDAAA on the suspension likelihood in Column 6 are stronger than the effects on project duration. The coefficients for Year $_{t+1 \text{ to } 2}$ and Year $_{t+3 \text{ to } 5}$ indicate that the post-FDAAA period are statistically significant and positive at the 1% level, while the coefficients for the year dummy variables indicating the pre-FDAAA period are all insignificant. As a result, the results in Column 6 support the interpretation that the passage of the FDAAA substantially and

significantly influence the suspension decisions of drug-developing firms in our sample because the results are not driven by the pre-trend or a mechanical effect that may exist right after the passage of the regulation.

Overall, we find from our baseline regression results in Table 3 that the passage of the FDAAA expedites the progress of drug development by either shortening the project duration or increasing the chance to suspend projects.

4.2. The effect of disclosure pressure conditional on information diffusion

We now use a difference-in-differences regression specification to examine the effect of enhanced disclosure pressure on drug development cycles from the perspective of existent information diffusion intensity. If the relation between the heightened disclosure pressure through the FDAAA and expedited development cycles is simply picking up some mechanical effects of the increased number of total updates and suspension disclosures, we will not expect to find that information diffusion plays a significant role to explain our findings. On the contrary, if the impact of the heightened disclosure pressure on the development cycle is indeed driven by information diffusion, we expect to find that existent information diffusion intensity enhances the impact of the FDAAA. For example, drug developers may speed up the projects than they used to do because they can learn from peers' experiment designs, success/failure experiences, and the prospects of their projects better from increased information disclosure due to the FDAAA. We examine whether such information diffusion exists by considering different measures.

In Table 4, we report the results from the regressions that are similar to our baseline regressions in Table 3 with the exception that we additionally consider *High Number of Peers* and its interaction term with the post-FDAAA dummy, *Post*. The indicator variable, *High Number of Peers*, equals one if the total number of firms that have projects in the same indication as the project in a given year is greater than the sample median. As in Table 3, the first and last two columns are to examine project durations and suspension likelihood, respectively.

[Insert Table 4 Here]

Column 1 of Table 4 reports the regression results of project durations on the measure of information diffusion and its interaction term with *Post* without other controls but with firm, indication, and phase fixed effects. As the test is a difference-in-differences test considering the interaction term, we additionally include the year fixed effects in the specification that will subsume the variable, *Post*, itself. Column 1 shows that the interaction term between the information diffusion measure and the post-FDAAA dummy is significantly negative at the 5% significance level. Even with the additional year fixed effects, the effect

of the post-FDAAA dummy for the high group exhibits a coefficient estimate with a one and half times larger magnitude than the coefficient estimate of *Post* in Column 1 of Table 3 (-1.54 vs. -1.04). In Column 2, we additionally control firm and industry characteristic variables and find that the effect remains significantly negative. The economic interpretation of the coefficient estimate for the interaction term is that the passage of the FDAAA decreases the duration of phase advance in clinical trials by 14.7% more for the high group, which is equivalent to 67 fewer days in addition for the group. The insignificant coefficient estimate for *High Number of Peers* suggests that the learning effect concentrates on the post-FDAAA period.

We now consider analogous tests for the suspension likelihood in Columns 3 and 4. We find that coefficients for the interaction term in both columns are significantly positive at the 1% level. The economic interpretation for the coefficient of Column 4 is that the passage of the FDAAA increases the suspension likelihood of clinical trials by 4.1% more for the high group. Although the coefficient estimate for *High Number of Peers* is significantly negative, its magnitude is only -0.9%.

The overall results in Table 4 are consistent with our proposition that the passage of the FDAAA substantially and significantly accelerates the drug development cycles and suspension decisions of firms in environments with greater information diffusion.

4.3. Robustness tests

In this section, we present robustness tests for our baseline results. First, we consider three alternative measures of information diffusion. Second, we consider a different sample that includes some types of trials that we previously exclude, covers a longer sample period, or additionally excludes non-active projects without updates for a long time. Third, we consider a more stringent sample that can mitigate a concern related to the 2008-2010 financial crisis.

Table 5 presents results from the analogous tests to Columns 2 and 4 of Table 4 using the following three alternative information diffusion measures as discussed earlier. The first alternative measure, *High Number of Drugs*, is an indicator variable that equals one if the total number of drug projects, not firms, in the same indication as a given firm in a given year is greater than the sample median and zero otherwise. The second is *High Fluidity* that takes the value of one if the product market fluidity from Hoberg, Phillips and Prabhala (2014) at a given year is greater than the sample median. The third is an indicator variable, *Non-Expedited Drug*, that is one if the indication of the project is not designated as the FDA expedited programs.

[Insert Table 5 Here]

Columns 1 to 3 of Table 5 are for project duration. In both Columns 1 and 2, we confirm that our results are robust to using an alternative information diffusion measures based on either the number of drugs in the same indication or product market fluidity: the coefficient estimates for the interaction term between an information diffusion measure and the post-FDAAA dummy are significant and negative at the 5% level, indicating that the passage of the FDAAA shortens the duration of projects more significantly for the high information diffusion group. Moreover, the magnitude of these interaction terms is slightly larger than that in Column 2 of Table 4. Although the coefficient estimate for the interaction term between *Non-Expedited Drug* and *Post* is negative in Column 3, it is insignificant.

Columns 4 to 6 of Table 5 are for the suspension likelihood. In all three regressions, we find that the coefficient estimates for all three interaction terms are positive and significant at the 1% or 5% level. This confirms that the positive effect of the FDAAA on suspension likelihood is strongly manifested in information diffusion environments, and such a finding is robust to various alternative measures.

We conduct additional three sets of robustness checks in which we consider a sample that include clinical trials initiated in the post-FDAAA period or terminated in the pre-FDAAA period, that has a longer time period covering 7 years before and after the enactment of the FDAAA in 2007, and that excludes zombie projects with no progress update for more than 7 years, respectively. Using our main information diffusion measure, *High Number of Peers*, Table 6 presents the results from similar tests to Columns 2 and 4 of Table 4.

[Insert Table 6 Here]

Columns 1 to 3 of Table 6 show the regression results for project duration with the above three different samples. The coefficient estimates for the interaction term between information diffusion and the post-FDAAA dummy in all three columns confirm that our results are robust across different samples. Columns 4 to 6 present the regressing results for suspension likelihood with the same three alternative samples and confirm that the results for suspension likelihood are also robust across different samples.

As the last set of robustness checks, we consider the effects of the recent financial crisis. Because the 2008-2010 financial crisis is close to the enactment of the FDAAA in 2007, our results on the increased suspensions especially can be driven by the reduced funding from the financial distress. Although the inclusion of year fixed effects in the previous regressions could mitigate this concern, for the robustness check, we employee a more stringent specification that additionally includes firm-year joint fixed effects and a refined sample that excludes drug project phase-year observations in the five-year event window, [-

2, +2] (i.e., five-year observations in 2005, 2006, 2007, 2008, and 2009). Table 7 presents the results from similar tests to Columns 2 and 4 of Table 4 with the stringent specification.

[Insert Table 7 Here]

In Table 7, Columns 1 and 2 for project duration and Columns 3 and 4 for suspension likelihood show that our results are robust to including firm-year fixed effects additionally and also to excluding the observations in the financial crisis period. Therefore, the tests reinforce our earlier results and confirm that our results are not driven by financial crisis.

Taken together, the evidence presented thus far suggests robust effects of the increased disclosure pressure through the FDAAA. The increased disclosure pressure is more likely to shorten the project durations of clinical trials and increase suspension rates. The effects are intensified under information diffusion and do not appear to be driven by a simple mechanical effect from the increased number of disclosures or by the financial crisis.

5. Information Diffusion from Peers

In the previous subsection, we provide the evidence of differential effects of the FDAAA in high vs. low information diffusion groups, which mitigates the potential concern that our results may come from the mechanical effect of the increased number of disclosures on progress updates and suspension. In this subsection, we further address this concern by directly examining the effects of peer disclosures on suspensions (bad news) and phase advances (good news). If our results are from the information diffusion, that go beyond the mechanical effect of the increase in the number of own firms' disclosures after the passages of the FDAAA, we expect to find that the suspension likelihood are significantly associated with peer firms' project advances or suspension disclosures. Furthermore, we predict to find that differential peer effects between firms with overall high and low quality (based on the numbers of advance and suspension events), also between projects with and without outside partners. Table 8 reports the regression analyses that examine these predictions.

[Insert Table 8 Here]

To capture the information diffusion from peers, we measure peer disclosures on suspensions (*Peer Suspension Rate*) with the fraction of projects with suspension events in the same indication as a given project's indication in a given year. Analogously, we measure peer disclosures on advances (*Peer Advance Rate*) with the fraction of projects with phase advance events in the same indication as a given project's indication in a given year. We take out the own firm's suspension and advance events, respectively, when

we calculate those fractions. These variables are also lagged for one year to ensure that the information about peers is known by the focal firm. In addition, we argue that low-quality firms will rely more on information diffusion from their peers than high-quality firms, and define high-quality firms as firms with the total number of advance events greater than the total number of suspension events up to the prior year. Approximately 22% of the observations in our sample are regarded as high-quality firms.

In Column 1 of Table 8, we find that the coefficient of the interaction term between *Peer Suspension Rate* and the post-FDAAA dummy is positive and significant at the 1% level. This indicates that firms respond to the news on peer firms' failures. The economic interpretation is that a one standard deviation increase in peer firm suspension rate in the prior year is associated with a 1.5 percentage point increase in suspension likelihood in the current year. Peer firms' phase advance rate, however, appears to have no effect on the suspension likelihood. This result is consistent with our argument that mandatory disclosure of the FDAAA creates information diffusion and enable firms to learn from their peers about drug development experience and market prospects in the following ways: on the one hand, firms can learn from peers' successful experience; on the other hand, peers' failure in clinical trials in drugs for the same indication suggests some fundamental difficulty and complication.

We now examine triple interaction effects with another variable for the cross-sectional heterogeneity including firm quality and partner involvement. In Column 2, the coefficient estimate for the interaction term between peer firm suspension rate and the post-FDAAA dummy is still comparable to that in Column 1, and the coefficient for the triple interaction term with High Quality is significantly negative at the 1% level. This result is consistent with the interpretation that suspensions increase after peers disclose their failures but the effect is not present for the high-quality firms. In Column 3, in which we consider the existence of partners for a given project instead, we also find that the positive effect of peers' failures on a project's suspension decreases relatively when the project has external partners.

Results in Table 8 consistently show that suspension decisions especially are affected by peers' failures strongly. Therefore, our results thus far are not just driven by any mechanical effects of the increase in own firm disclosures but rather by information diffusion from peer firms within the same indication group.

6. Social Welfare Effects

Our evidence from the previous section strongly supports for the conclusion that increased mandatory disclosure requirement and on-going disclosure pressure accelerate firms' innovation and shorten their drug development cycles, which are reflected by the shorter duration of phase changes and the increased

suspension likelihood of clinical trials. In this section, we examine social welfare implications of the accelerated drug development cycles with the FDAAA. We examine both quality and quantity aspects of drug development before and after the FDAAA. The price effects are, however, not analyzed due to the lack of drug price data. Although a final conclusion for social welfare implications is hard to draw without knowing price effects, our analysis on quality and quantity of drug development is informative as it offers new evidence and insight on the consequences of mandatory disclosures of innovation activities.

6.1. Drug quality

In this section, we first examine whether the overall quality of drug projects has changed after the increased disclosure pressure through the passage of the FDAAA. We use adverse event reports (AER) from the FDA to analyze the quality change of each FDA-approved and thus marketed drug. We expect that the quality of drugs may increase because firms know that their drug development is disclosed to the public and peers, and thus have stronger incentives to pursue safer projects due to reputation concerns and weaker incentives to continue projects without promising clinical outcomes that could be bad signals to the market. Table 9 reports the results from the tests that examine this prediction based on drug project-year observations.

[Insert Table 9 Here]

For the analysis in Table 9, we merge our primary sample with the FDA 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 2012. If a drug in our primary sample has no match with the AERS data, we assume the number of AER that the drug has received in a given year is zero. In Column 1, we use the total number of AER that a given drug has received in a given year as a measure of the drug's quality. We also consider five alternative measures by focusing on whether the given drug is reported as a suspect of the report (Column 2), whether the drug is reported as a primary suspect (Column 3), whether a given report is about serious patient outcomes (Column 4), whether the drug is a suspect of the serious outcome report (Column 5), and whether the drug is a primary suspect of the serious outcome report (Column 6). The main variable of interest is an indicator variable, *Project Initiation After FDAAA*, that is one if the drug project is *initiated* after the passage of the FDAAA and zero otherwise.

Column 1 of Table 9 shows that the coefficient estimate of *Project Initiation After FDAAA* is significantly negative at the 5% level, consistent with our prediction. The effect translates into approximately 54% decrease in the number of AER if the clinical trial of a drug project that is initiated

after the passage of the FDAAA. Considering the average number of AER per year, 28, from Table 1, the 54% increase is equivalent to receiving 15 less AER per drug per year. The effects are significantly negative in all specifications in Columns 2 to 6 that use alternative measures for the drug quality and the magnitudes are comparable across specifications. It is worth noting that the inclusion of year fixed effects in our regressions alleviates the concern that older drugs are more likely to receive a larger number of AER than newer drugs in a given year, or conversely that older drugs are safer for some omitted reasons and thus to receive a fewer number of AER than newer drugs. Furthermore, in an unreported analysis, we confirm that the results are robust with additionally controlling for a variable that captures years from the initiation to eliminate the concern of older drugs being safer.

We next examine the likelihood that a given drug will deliver any adverse event after the enactment of the FDAAA in Table 10. The dependent variables of the first three columns and the last three columns in Table 10 are indicator variables that are one if the drug has received AER with serious adverse outcomes in a given year and one if the drug is a primary suspect of AER in a given year, respectively. Columns 1 and 3 only include year fixed effects and all other columns include firm, and indication fixed effects in addition to the year fixed effects. The coefficient estimates of *Project Initiation After FDAAA* throughout all columns in Table 10 are negative and significant at the 1% or 5% level, suggesting that drug projects developed under the increased disclosures from the FDAAA are less likely to deliver any adverse event. The interpretations of the coefficient estimates in Columns 3 and 6 are 16.3% and 12.6% decreases in the likelihood of receiving serious AER and being a primary suspect of AER, respectively.

[Insert Table 10 Here]

The results in Table 9 and 10 collectively suggest that drug projects under the increased disclosure pressure due to the FDAAA show lower frequency of adverse outcomes and likelihood of delivering any adverse outcome. Overall, these results are consistent with our predictions: pharmaceutical firms pursue safer projects due to the increased information disclosure pressure given that the costs of adverse events and bad outcomes are now transparent to the public.

6.2.Clinical trials and burden of diseases

We now examine the quantity effect, specifically whether the negative effect of the increased disclosure pressure on the number of active projects has any effect on the Burden of Disease.[25] Previous evidence in

[25] The Burden of Disease is the impact of a health problem as measure by financial costs, mortality, morbidity or other indicator and often quantified with Disability-Adjusted Life Years (DALYs) which means the number of years lost due to a given disease.

Section 4 indicates that the FDAAA and increased disclosure pressure lead to greater suspensions of active projects. Also, the mandatory and potential information requirement not only reduces the economic rents and advantages of first-movers and innovative firms but also increases the incentives for firms to be followers and imitators in drug development. The society may lose potential remedies for critical diseases if firms give up their projects earlier or more often. Therefore, we expect that a decrease in active projects can result in an increase in disease burden and thus negatively influence social welfare.

We first focus on indications that intend to take care of the top 20 leading causes (diseases) of the globally measured Disability-Adjusted Life Years (DALYs) for the two snapshots of 2000 and 2016 by the WHO. A disease's DALYs combine the years lived with disability and the years of life lost due to that disease. We first calculate the average annual growth in the number of active projects (i.e., the number of total project minus the number of suspended projects) for pre- and post-FDAAA periods for each indication and then take the difference between the pre- and the post-FDAAA growth rates. Figure 3 visualizes this difference, in which we plot the average number and growth rate of active projects for the DALY-relevant indications over time. We find that the average number of active projects continuously increases in the pre-FDAAA period, but sharply drops after the FDAAA. The time trend for active project growth also confirms that the FDAAA in 2007 appears to slow down the growth rate of active clinical trials significantly. The pre-FDAAA average growth rate is approximately 25%, but the growth collapses nearly to zero and even negative numbers after the FDAAA. Together with prior results, Figure 3 points to a significant drop in new drug development after the FDAAA.

[Insert Figure 3 Here]

To further quantify the social welfare loss in DALYs due to the slowdown in drug development for those critical conditions, we compare the reduction of DALY in a high-growth indication group to that in a low-growth indication group and use the difference as social loss due to the slowdown. Based on the difference between the pre- and the post-FDAAA growth rates of active projects for each indication, we then split indications into two groups: (a) the Low Growth Indications group if the difference is less than the sample median and in (b) the High Growth Indications group otherwise. For the two indication groups, (a) and (b), we examine the following statistics in Table 11. The first two statistics are about the number of projects for the two groups. We examine the differences between pre- and post-FDAAA active projects growth rates and suspension rates, and show these differences between the two indication groups in Rows 1 and 2 of Panel A. Because the division of the two indication groups is based on the first statistics presented in Row 1, we see the clear difference between the two groups. In the Low Growth Indications

group, the active project growth rates decrease by 54% after the FDAAA, while those rates essentially haven't changed in the High Growth Indications group. Based on our previous evidence on the substantial increase in suspensions following the FDAAA, we attribute the decrease in active projects growth to the increased suspensions associated with the FDAAA. We confirm this conjecture with the statistics presented in Row 2. We find that in the Low Growth Indications group the average suspension rate is indeed higher than that in the high group by 4% and this difference is significant at the 5% level.

[Insert Table 11 Here]

We then quantify the social costs associated with new drugs based on DALY in Panel B. In Rows 1 and 2, we show DALY statistics for the two indication groups for a pre-FDAAA year. As we discuss previously, the detailed DALY data are only available from the WHO for the 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 the diseases related to the low- and high-growth groups in 2000 are 88,385 days and 96,132 days, respectively, but the difference between the two statistics is not statistically significant. Results are similar for the other measure of DALY that uses % in Row 2. In Rows 3 and 4, we consider the difference between 2000 and 2016 for the same statistics. We find that the decrease in DALY from 2000 to 2016 is only present in the high group. In the low group, DALY increase instead. To sum up, in Row 5 the % DALY changes from 2000 to 2016 are -19.24% decrease for the high-growth indication group and +1.82% for the low-growth indication group. These statistics suggest that if the low group receives the same efforts as the high group does, DALY of the low-growth group may also drop by the same magnitude (19.24%). This finding, together with Table 3 and Figure 3, suggests that the increased disclosure requirement and on-going pressure result in greater suspensions of active projects and in turn possibly the increase in the Burden of Disease for our society. These results reflect potential unintended consequences of the FDAAA and thus have important policy implications.

7. Conclusion

The role of information disclosure in innovation competition has been an important research topic in the literature. We use a unique policy change, the enactment of the Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA 801), to examine how mandatory disclosure of pharmaceutical firms' clinical trials influences their innovation strategies captured by trial durations and suspension decisions. Specifically, we find shorter trial durations and higher suspension probabilities after the FDAAA, suggesting that increased information transparency accelerates pharmaceutical firms'

innovative activities. Moreover, such an effect is enhanced by information diffusion intensity, which is consistent with the benefits associated with information disclosure because firms can learn more from their peers' drug development and market fundamentals. We also justify the information diffusion channel by showing that a firm's suspension decision is explained by peers' suspensions after the FDAAA. As a result, the mandatory disclosure of the FDAAA indeed creates information diffusion to peer firms and enables pharmaceutical firms to learn from their peers' experience.

Our empirical investigation has policy and social welfare implications as it highlights both the intended and unintended consequences of the FDAAA. On the one hand, the original goals of disclosing information to the public and accelerating the drug development cycles have been achieved. We indeed find fewer Adverse Event Reports (AER) per drug after the FDAAA, suggesting an improvement of drug quality. On the other hand, due to reputation concern and disclosure costs, pharmaceutical firms become less motivated to initiate risky projects and more likely cut projects that do not deliver good outcomes in earlier stages. Such risk-averse approach will result in fewer new projects and drugs for critical conditions, which lower the life quality of the public in the long run.

Appendix A. 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 filed, *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 as the suspect product but not deemed as being associated with the event. The *Suspect* filed can be further classified as *Secondary Suspect* when needed. In the following four adverse event reports, for *Androgel,* Number of AER is four, both Number of AER Suspect and Number of AER Primary Suspect are four, Number of Serious AER is three, both Number of Serious AER Suspect and Number of Serious AER Primary Suspect are three. For *Zocor* which is reported as a concomitant drug, Number of AER is two, both Number of AER Suspect and Number of AER Primary Suspect are zero, Number of Serious AER is two, both Number of Serious AER Suspect and Number of Serious AER Primary Suspect 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 B. Variable Definitions

- Log(1+Duration of Phase Change): The log of one plus the duration in days between the current and previous phases.
- Suspension (Indicator): An indicator that takes the value of one if the project is suspended in a given year.
- Post (Indicator): An indicator that takes the value of one after the passage of FDAAA in 2007 and zero otherwise.
- Information Diffusion: The total number of firms that have drug projects in the same indication as a given project in a given year.
- High Information Diffusion (Indicator): An indicator that takes the value of one if the total number of firms that have drug projects in the same indication as a given project in a given year is greater than the sample median and zero otherwise.
- Number of Drugs: The total number of drug projects in the same indication as a given project in a given year.
- High Number of Drugs (Indicator): An indicator that takes the value of one if the total number of drug projects in the same indication as a given project in a given year is greater than the sample median and zero otherwise.
- Fluidity: The product market fluidity measure from Hoberg, Phillips and Prabhala (2014).
- High Fluidity (Indicator): An indicator that takes the value of one if the product market fluidity from Hoberg, Phillips and Prabhala (2014) is greater than the sample median and zero otherwise.
- Non-Expedited Drugs (Indicator): An indicator that takes the value of one if the drug project is not designated as the FDA expedited programs including fast track, breakthrough therapy, and orphan drug and zero otherwise.
- Peer Phase Advance Rate (Lagged): The average phase advance rate (number of phase advances divided by total number of projects) of projects in the same indication as a given project in the prior year excluding the firm's own projects.
- Peer Suspension Rate (Lagged): The average phase suspension rate (number of suspensions divided by total number of projects) of projects in the same indication as a given project in the prior year excluding the firm's own projects.
- Project with Partner (Indicator): An indicator that takes the value of one if the project has partners in a given year and zero otherwise.
- Log(1+Number of Preclinical Projects): The log of one plus the firm's preclinical projects in a given year.
- Percent of Matured Projects: The percentage of matured projects (post- clinical phases) 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 the total number of both private and public firms with new drug development in each industry (indication-level) in a given year.
- Industry Failure Rate: The industry average of suspension rates in a given year.
- Percent of Industry Matured Projects: The industry percentage of matured projects (post-clinical phases) in a given year.
- Log(1+Number of AER): The log of one plus the total number of reports in the adverse event reports (AER) for the drug.

- Log(1+Number of AER Suspect): The log of one plus the total number of AER where the drug is reported as a primary or secondary suspect.
- Log(1+Number of AER Primary Suspect): The log of one plus the total number of AER where the drug is reported as a primary suspect.
- Log(1+Number of Serious AER): The log of one plus the total number of AER where the patient outcome is one of the following serious conditions: death, life-threatening, hospitalization, disability, congenital anomaly, required intervention to prevent permanent impairment and damage.
- Log(1+Number of Serious AER Suspect): The log of one plus the total number of AER with serious patient outcomes where the drug is reported as a primary or secondary suspect.
- Log(1+Number of Serious AER Primary Suspect): The log of one plus the total number of AER with serious patient outcomes where the drug is reported as a primary suspect.
- Project Initiation After FDAAA (Indicator): An indicator that takes one if the drug project is initiated after the passage of the FDAAA in 2007 and zero otherwise.
- Component in Serious AER (Indicator): An indicator that takes the value of one if the approved drug is one of the components in AER with serious patient outcome and zero otherwise.
- Primary Suspect in AER (Indicator): An indicator that takes the value of one if the approved drug is one of the primary suspects in AER and zero otherwise.

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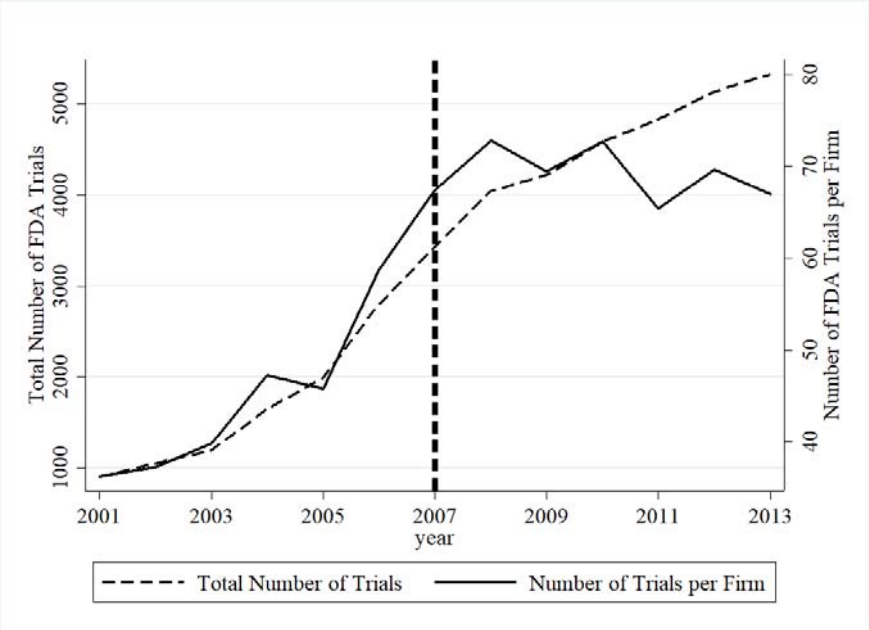
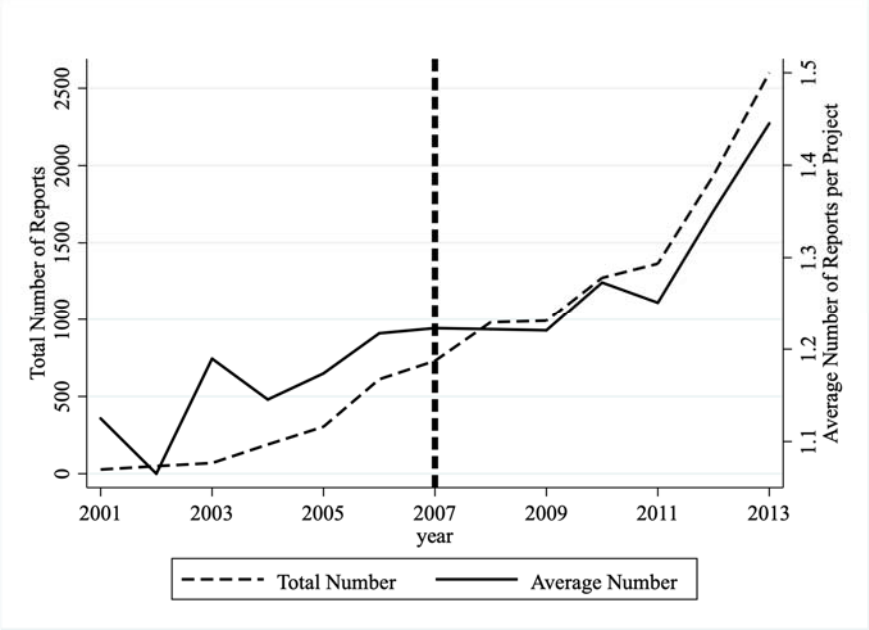
Figure 1. Pre- and Post-FDAAA Trends of Clinical Trials and Disclosures

The figures present the aggregate time trends of clinical trials from 2001 to 2013. Figure (a) shows the total number of clinical trials and the average number of clinical trials per firm. The number of clinical trials includes all on-going projects that are not publicly disclosed as terminated one. Figure (b) shows the total number of progress updates (e.g., trial initiation, progress update, trial progressing, updated results) and the average number of progress updates per project. The frequency of progress updates can vary across trials.



(a) The number of clinical trials



(b) Disclosure intensity

Figure 2. Pre- and Post-FDAAA Trends of Project Duration and Phase Advance and Suspension Rates

The figure presents the aggregate time trends of clinical trials from 2001-2013. Figure shows the average project duration of phase changes in the left y-axis and the average suspension rate (the total number of suspension events divided by the total number of projects in a given year) in the right y-axis. Log (1+Duration of Phase Change) is the log of one plus the duration in days between the current and previous phases, conditioning on the events of phase advances.

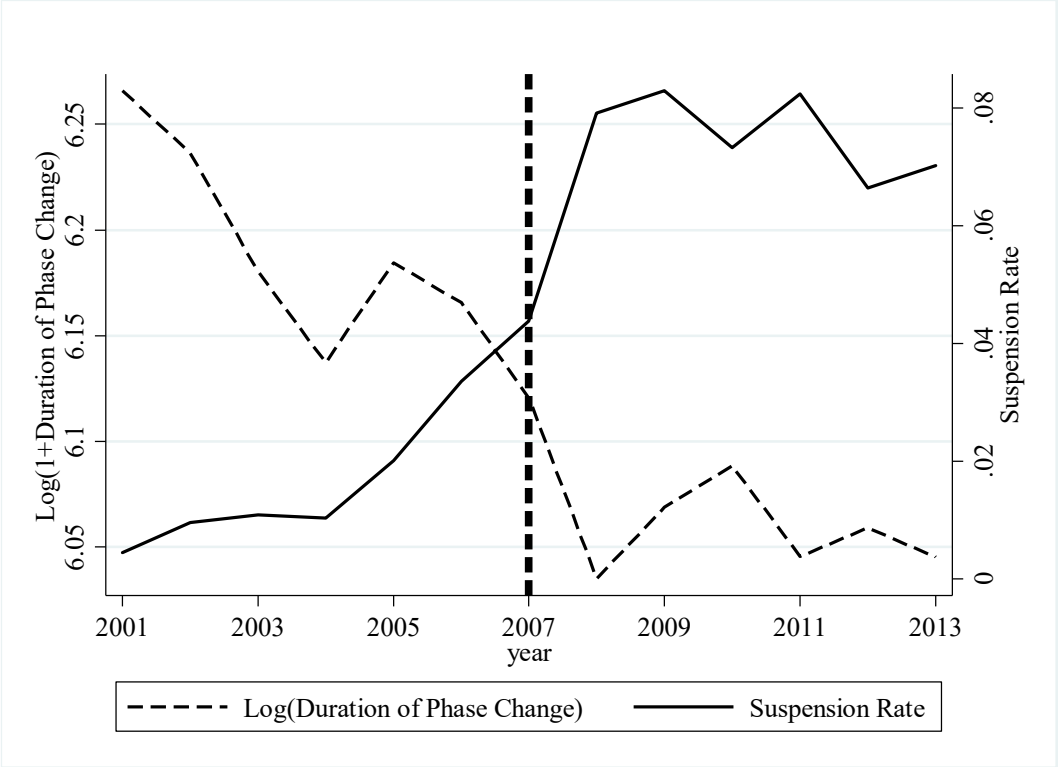


Figure 3. Pre- and Post-FDAAA Number and Growth of Active Projects

The figure presents the time trends of the average number and growth rate of active projects within indication from 2001 to 2013. The number of active projects is the total number of projects minus the number of suspended project in a given year for a given indication. The active project growth is the percentage growth in the number of active projects for a given indication, which is the number of active projects in the prior year divided by the number of active projects in a given year minus one.

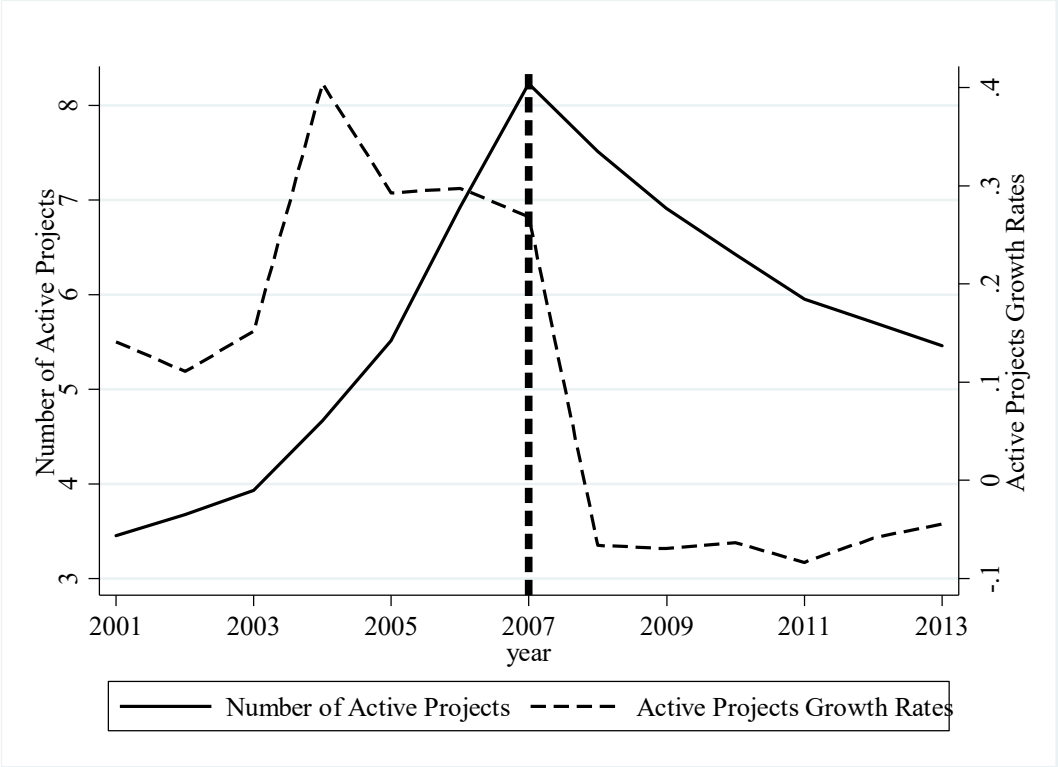


Table 1. Summary Statistics

This table presents summary statistics for clinical trials that have been covered by the BioMedTracker database for our sample period from 2002 to 2012. The sample consists of 25,212 new drug project phase-year observations. 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 1trials, which are not subject to the FDAAA; and (iv) trials initiated in the post-FDAAA period or terminated in the pre-FDAAA period. Log (1+Duration of Phase Change) is the log of one plus the duration in days between the current and previous phases, conditioning on the events of phase advances. Suspension (Indicator) is an indicator variable that takes the value of one if the project is suspended in a given year and zero otherwise. Post (Indicator) is an indicator variable that takes the value of one after the passage of FDAAA in 2007 and zero otherwise. The detailed descriptions of other variables are available in Appendix B.

	Mean	SD	Min	Median	Max	Obs
Log(1+Duration of Phase Change)	6.12	0.55	3.18	6.03	8.36	1,588
Duration of Phase Change	533.56	369.06	23.00	415.00	4287.00	1,588
Suspension (Indicator)	0.05	0.21	0.00	0.00	1.00	25,212
Post (Indicator)	0.56	0.50	0.00	1.00	1.00	25,212
Number of Peers	13.84	11.75	1.00	10.00	58.00	25,212
High Number of Peers (Indicator)	0.46	0.50	0.00	0.00	1.00	25,212
Number of Drugs	20.27	19.32	1.00	14.00	92.00	25,212
High Number of Drugs (Indicator)	0.49	0.50	0.00	0.00	1.00	25,212
Fluidity	11.57	3.70	3.38	11.53	27.73	7,063
High Fluidity (Indicator)	0.52	0.50	0.00	1.00	1.00	7,063
Non-Expedited Drugs (Indicator)	0.87	0.34	0.00	1.00	1.00	25,212
Peer Phase Advance Rate (Lagged)	0.14	0.18	0.00	0.10	3.00	21,594
Peer Suspension Rate (Lagged)	0.10	0.15	0.00	0.00	3.00	21,594
Project with Partner (Indicator)	0.51	0.50	0.00	1.00	1.00	25,212
Log(1+Number of Preclinical Projects)	0.25	0.46	0.00	0.00	1.95	25,212
Percent of Matured Projects	0.40	0.31	0.00	0.38	1.00	25,212
Percent of Projects with Partner	0.49	0.27	0.00	0.47	1.00	25,212
Log(1+Number of Competitors)	5.02	0.87	0.69	5.26	6.15	25,212
Industry Failure Rate	0.11	0.09	0.00	0.09	0.36	25,212
Industry Total Number of Matured Projects	0.32	0.26	0.06	0.24	1.00	25,212
Log(1+Number of AER)	3.37	2.91	0.00	3.22	10.60	4,897
Log(1+Number of AER Suspect)	3.01	2.79	0.00	2.71	10.58	4,897
Log(1+Number of AER Primary Suspect)	2.79	2.68	0.00	2.40	10.30	4,897
Log(1+Number of Serious AER)	3.03	2.76	0.00	2.71	10.16	4,897
Log(1+Number of Serious AER Suspect)	2.65	2.62	0.00	2.20	10.14	4,897
Log(1+Number of Serious AER Primary Suspect)	2.44	2.48	0.00	1.95	9.70	4,897
Project Initiation After FDAAA (Indicator)	0.10	0.30	0.00	0.00	1.00	4,897
Component in Serious AER (Indicator)	0.69	0.46	0.00	1.00	1.00	4,897
Primary Suspect in AER (Indicator)	0.66	0.47	0.00	1.00	1.00	4,897

Table 2. Univariate Analysis

This table presents summary statistics for clinical trials that have been covered by the BioMedTracker database for our sample period from 2002 to 2012. The sample consists of 25,212 new drug project phase-year observations. In Panel A, we divide the sample into pre- and post-FDAAA period observations. In Panel B, we divide the pre-FDAAA sample into the two groups with high and low information diffusion. High Number of Peers (Indicator) is an indicator variable that takes the value of one if the total number of firms that have drug projects in the same indication as a given drug in a given year is greater than the sample median. The last column, Difference, reports t-statistics in the t-tests for equality of means in the two groups. Appendix B provides detailed descriptions of the variables. ***, **, and * denote statistical significance at the 1%, 5%, and 10% levels, respectively.

Panel A. Variable Comparison for Pre- and Post-FDAAA Periods

	(1) Pre-FDAAA			(2) Post-FDAAA			Difference
	Mean	Median	Obs	Mean	Median	Obs	
Log(1+Duration of Phase Change)	6.14	6.04	834	6.09	6.02	754	0.05*
Duration of Phase Change	557.81	419.50	834	506.74	409.00	754	51.07***
Suspension (Indicator)	0.00	0.00	11,066	0.08	0.00	14,146	-0.08***
Number of Peers	12.42	9.00	11,066	14.95	12.00	14,146	-2.53***
High Number of Peers (Indicator)	0.40	0.00	11,066	0.50	1.00	14,146	-0.10***
Number of Drugs	18.24	12.00	11,066	21.86	16.00	14,146	-3.62***
High Number of Drugs (Indicator)	0.43	0.00	11,066	0.54	1.00	14,146	-0.11***
Fluidity	11.09	10.45	3,021	11.93	12.04	4,042	-0.84***
High Fluidity (Indicator)	0.40	0.00	3,021	0.62	1.00	4,042	-0.22***
Non-Expedited Drugs (Indicator)	0.89	1.00	11,066	0.86	1.00	14,146	0.03***
Peer Phase Advance Rate (Lagged)	0.09	0.00	8,095	0.18	0.14	13,499	-0.09***
Peer Suspension Rate (Lagged)	0.03	0.00	8,095	0.14	0.10	13,499	-0.11***
Project with Partner (Indicator)	0.50	1.00	11,066	0.52	1.00	14,146	-0.01**
Log(1+Number of Preclinical Projects)	0.10	0.00	11,066	0.36	0.00	14,146	-0.26***
Percent of Matured Projects	0.54	0.57	11,066	0.29	0.29	14,146	0.25***
Percent of Projects with Partner	0.50	0.49	11,066	0.49	0.47	14,146	0.01***
Log(1+Number of Competitors)	4.47	4.63	11,066	5.45	5.66	14,146	-0.97***
Industry Failure Rate	0.03	0.03	11,066	0.18	0.17	14,146	-0.14***
Percent of Industry Matured Projects	0.49	0.49	11,066	0.18	0.09	14,146	0.31***

Panel B. Pre-Treatment Variable Comparison by Information Diffusion

	(1) High Number of Peers=1			(2) High Number of Peers=0			Difference
	Mean	Median	Obs	Mean	Median	Obs	
Log(1+Duration of Phase Change)	6.17	6.06	378	6.12	6.03	456	0.05
Duration of Phase Change	559.92	427.50	378	556.06	414.00	456	3.86
Suspension (Indicator)	0.00	0.00	4,426	0.00	0.00	6,640	-0.00
Number of Drugs	23.02	20.00	4,426	5.35	5.00	6,640	17.67***
High Number of Drugs (Indicator)	0.96	1.00	4,426	0.08	0.00	6,640	0.88***
Fluidity	11.91	11.02	1,224	10.53	10.00	1,797	1.38***
High Fluidity (Indicator)	0.49	0.00	1,224	0.34	0.00	1,797	0.16***
Non-Expedited Drugs (Indicator)	0.90	1.00	4,426	0.88	1.00	6,640	0.02***
Peer Phase Advance Rate (Lagged)	0.11	0.10	3,400	0.07	0.00	4,695	0.04***
Peer Suspension Rate (Lagged)	0.04	0.00	3,400	0.02	0.00	4,695	0.02***
Project with Partner (indicator)	0.52	1.00	4,426	0.49	0.00	6,640	0.03***
Log(1+Number of Preclinical Projects)	0.12	0.00	4,426	0.09	0.00	6,640	0.03***
Percent of Matured Projects	0.44	0.47	4,426	0.61	0.67	6,640	-0.17***
Percent of Projects with Partner	0.50	0.50	4,426	0.50	0.47	6,640	-0.00
Log(1+Number of Competitors)	4.78	4.88	4,426	4.27	4.22	6,640	0.51***
Industry Failure Rate	0.04	0.04	4,426	0.03	0.03	6,640	0.01***
Percent of Industry Matured Projects	0.39	0.35	4,426	0.56	0.56	6,640	-0.16***

Table 3. Effects of the FDAAA on Project Duration and Suspension

This table presents the results from OLS (Columns 1 to 3) and linear probability model (Columns 4 to 6) regressions using clinical trials data that have been covered by the BioMedTracker database for our sample period from 2002 to 2012. In Columns 1 to 3, the sample consists of 1,349 observations of phase advances, and in Columns 4 to 6, the sample consists of 25,206 new drug project phase-year observations. The dependent variable in Columns 1 to 3 is Log (1+Duration of Phase Change) that is the log of one plus the duration in days between the current and previous phases, conditioning on the events of phase advances. The dependent variable in Columns 4 to 6 is Suspension (Indicator) that takes the value of one if the project is suspended in a given year and zero otherwise. Post (Indicator) is an indicator variable that takes the value of one for project-years in the post-FDAAA period (Year $_{t+1 \text{ to } 2}$, and Year $_{t+3 \text{ to } 5}$) and zero for the pre-FDAAA period (Year $_{t-2}$, Year $_{t-1}$, and Year $_{t}$), where Year $_{t}$ is the year in which the FDAAA is enacted. The detailed descriptions of other variables are available in Appendix B. *t*-statistics reported in parentheses are based on robust standard errors clustered by firm. ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Log (1+Duration of Phase Change)			Suspension (Indicator)		
	(1)	(2)	(3)	(4)	(5)	(6)
Post (Indicator)	-0.104***	-0.100*		0.084***	0.091***	
	(-2.71)	(-1.86)		(15.72)	(11.17)	
Year $_{t-2}$			0.123			-0.005
			(1.35)			(-1.29)
Year $_{t-1}$			-0.009			-0.008
			(-0.09)			(-1.29)
Year $_{t}$			-0.094			-0.012
			(-0.92)			(-1.44)
Year $_{t+1 \text{ to } 2}$			-0.191			0.078***
			(-1.64)			(6.03)
Year $_{t+3 \text{ to } 5}$			-0.345*			0.069***
			(-1.86)			(3.69)
Project with Partner (Indicator)		-0.027	-0.022		-0.023***	-0.023***
		(-0.59)	(-0.48)		(-7.58)	(-7.58)
Log(1+Number of Preclinical Projects)		-0.047	-0.052		0.004	0.004
		(-1.21)	(-1.42)		(0.40)	(0.36)
Percent of Matured Projects		-0.053	-0.078		0.067***	0.062***
		(-0.36)	(-0.49)		(4.51)	(3.88)
Percent of Projects with Partner		-0.113	-0.120		-0.018	-0.016
		(-0.54)	(-0.56)		(-0.95)	(-0.85)
Log(1+Number of Competitors)		0.001	0.011		0.008	0.008
		(0.01)	(0.15)		(1.14)	(1.07)
Industry Failure Rate		-0.074	0.856		0.127***	0.181**
		(-0.20)	(1.15)		(2.75)	(2.25)
Percent of Industry Matured Projects		-0.039	-0.096		0.064***	0.052**
		(-0.20)	(-0.45)		(3.10)	(2.28)
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	1,349	1,349	1,349	25,206	25,206	25,206
R-squared	0.362	0.363	0.369	0.142	0.148	0.148
Adjusted R-squared	0.108	0.103	0.108	0.106	0.112	0.112

Table 4. Information Diffusion and Effects of the FDAAA on Project Duration and Suspension Rate: Difference-in-Differences
This table presents the results from difference-in-differences tests using clinical trials data that have been covered by the BioMedTracker database for our sample period from 2002 to 2012. In Columns 1 and 2, the sample consists of 1,349 observations of phase advances, and in Columns 3 and 4, the sample consists of 25,206 new drug project phase-year observations. The dependent variable in Columns 1 and 2 is Log (1+Duration of Phase Change) that is the log of one plus the duration in days between the current and previous phases, conditioning on the events of phase advances. The dependent variable in Columns 3 and 4 is Suspension (Indicator) that takes the value of one if the project is suspended in a given year and zero otherwise. Post (Indicator) is an indicator variable that takes the value of one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. High Number of Peers (Indicator) is one if the total number of firms that have drug projects in the same indication as a given project in a given year is greater than the sample median. The detailed descriptions of other variables are available in Appendix B. *t*-statistics reported in parentheses are based on robust standard errors clustered by firm. ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Log (1+Duration of Phase Change)		Suspension (Indicator)	
	(1)	(2)	(3)	(4)
High Number of Peers (Indicator) X Post (Indicator)	-0.154**	-0.159**	0.040***	0.040***
	(-2.04)	(-2.04)	(6.84)	(6.88)
High Number of Peers (Indicator)	0.058	0.060	-0.009**	-0.009**
	(0.59)	(0.61)	(-1.97)	(-2.07)
Project with Partner (Indicator)		-0.018		-0.023***
		(-0.39)		(-7.56)
Log(1+Number of Preclinical Projects)		-0.034		0.006
		(-0.94)		(0.61)
Percent of Matured Projects		-0.122		0.062***
		(-0.76)		(3.90)
Percent of Projects with Partner		-0.120		-0.014
		(-0.57)		(-0.74)
Industry Failure Rate		1.477		0.185**
		(1.20)		(2.13)
Percent of Industry Matured Projects		-0.136		0.026*
		(-0.79)		(1.89)
Firm Fixed Effects	Yes	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes
Observations	1,349	1,349	25,206	25,206
R-squared	0.372	0.375	0.148	0.151
Adjusted R-squared	0.112	0.110	0.111	0.114

Table 5. Information Diffusion and Effects of the FDAAA on Project Duration and Suspension Rate: Alternative Measures for Information Dfiffusion

This table presents results from difference-in-differences tests using clinical trials data that have been covered by the BioMedTracker database for our sample period from 2002 to 2012. The dependent variable in Columns 1 to 3 is Log (1+Duration of Phase Change) that is the log of one plus the duration in days between the current and previous phases, conditioning on the events of phase advances. The dependent variable in Columns 4 to 6 is Suspension (Indicator) that takes the value of one if the project is suspended in a given year and zero otherwise. Post (Indicator) is an indicator variable that takes the value of one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. High Number of Drugs (Indicator) is one if the total number of drug projects in the same indication as a given project in a given year is greater than the sample median and zero otherwise. High Fluidity (Indicator) is one if the product market fluidity from Hoberg, Phillips and Prabhala (2014) is greater than the sample median and zero otherwise. Non-Expedited Drugs (indicator) is one if the drug project is not designated as the FDA expedited programs including fast track, breakthrough therapy, and orphan drug and zero otherwise. The detailed descriptions of other variables are available in Appendix B. *t*-statistics reported in parentheses are based on robust standard errors clustered by firm. ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Log (1+ Duration of Phase Change)			Suspension (Indicator)		
	(1)	(2)	(3)	(4)	(5)	(6)
High Number of Drugs (Indicator) X Post (Indicator)	-0.174**			0.033***		
	(-2.28)			(5.66)		
High Number of Drugs (Indicator)	0.120			-0.002		
	(1.08)			(-0.41)		
High Fluidity (Indicator) X Post (Indicator)		-0.176**			0.038**	
		(-2.04)			(2.29)	
High Fluidity (Indicator)		0.206**			-0.013	
		(2.10)			(-1.02)	
Non-Expedited Drugs (Indicator) X Post (Indicator)			-0.044			0.021**
			(-0.57)			(2.37)
Non-Expedited Drugs (Indicator)			0.149**			0.024***
			(2.15)			(4.15)
Project with Partner (Indicator)	-0.022	0.037	-0.014	-0.023***	-0.028***	-0.022***
	(-0.47)	(0.54)	(-0.31)	(-7.55)	(-3.76)	(-7.32)
Log(1+Number of Preclinical Projects)	-0.034	-0.119	-0.039	0.005	0.017	0.005
	(-0.91)	(-1.58)	(-0.98)	(0.53)	(1.30)	(0.53)
Percent of Matured Projects	-0.125	-0.113	-0.097	0.062***	0.041	0.062***
	(-0.77)	(-0.35)	(-0.61)	(3.92)	(1.59)	(3.83)
Percent of Projects with Partner	-0.119	-0.246	-0.106	-0.014	0.063*	-0.018
	(-0.56)	(-0.91)	(-0.50)	(-0.76)	(1.78)	(-0.95)
Industry Failure Rate	1.433	2.653*	1.410	0.194**	0.251	0.214**
	(1.18)	(1.95)	(1.15)	(2.20)	(1.63)	(2.36)
Percent of Industry Matured Projects	-0.159	0.040	-0.136	0.029**	0.002	0.035**
	(-0.92)	(0.11)	(-0.79)	(2.07)	(0.06)	(2.43)
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
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Observations	1,349	667	1,349	25,206	9,464	25,206
R-squared	0.375	0.381	0.374	0.151	0.126	0.151
Adjusted R-squared	0.111	0.065	0.109	0.114	0.078	0.114

Table 6. Information Diffusion and Effects of FDAAA on Project Duration and Suspension: Robustness Tests

This table presents results from difference-in-differences tests using clinical trials data that have been covered by the BioMedTracker database for our sample period from 2002 to 2012. We consider three sets of robustness checks in which we consider a sample that include clinical trials initiated in the post-FDAAA period or terminated in the pre-FDAAA period (Columns 1 and 4), that has a longer time period covering 7 years before and after the enactment of the FDAAA in 2007 (Columns 2 and 5), and that excludes zombie projects with no progress update for more than 7 years (Columns 3 and 6), respectively. The dependent variable in Columns 1 to 3 is Log (1+Duration of Phase Change) that is the log of one plus the duration in days between the current and previous phases, conditioning on the events of phase advances. The dependent variable in Columns 4 to 6 is Suspension (Indicator) that takes the value of one if the project is suspended in a given year and zero otherwise. Post (Indicator) is an indicator variable that takes the value of one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. High Number of Peers (Indicator) is one if the total number of firms that have drug projects in the same indication as a given project in a given year is greater than the sample median. The detailed descriptions of other variables are available in Appendix B. *t*-statistics reported in parentheses are based on robust standard errors clustered by firm. ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Log (1+ Duration of Phase Change)			Suspension (Indicator)		
	(1) Including all Pre-/Post-FDAAA Trials	(2) Longer Window [-7,+7]	(3) Dropping Zombie Projects	(4) Including all Pre-/Post-FDAAA Trials	(5) Longer Window [-7,+7]	(6) Dropping Zombie Projects
High Number of Peers (Indicator) X Post	-0.114*	-0.147**	-0.157**	0.014***	0.037***	0.041***
	(-1.90)	(-2.16)	(-1.99)	(2.59)	(7.54)	(5.28)
High Number of Peers (Indicator)	0.103	0.205*	0.060	-0.001	-0.007	-0.013**
	(1.33)	(1.77)	(0.62)	(-0.18)	(-1.45)	(-2.04)
Project with Partner (Indicator)	-0.010	-0.025	-0.015	-0.028***	-0.022***	-0.034***
	(-0.28)	(-0.53)	(-0.32)	(-8.19)	(-7.39)	(-7.32)
Log(1+Number of Preclinical Projects)	-0.018	-0.009	-0.032	0.007	0.004	0.008
	(-0.59)	(-0.21)	(-0.88)	(0.84)	(0.56)	(0.57)
Percent of Matured Projects	0.007	0.038	-0.118	0.046***	0.064***	0.036*
	(0.05)	(0.25)	(-0.74)	(3.19)	(4.68)	(1.73)
Percent of Projects with Partner	-0.159	-0.154	-0.131	-0.001	-0.003	0.009
	(-0.90)	(-0.75)	(-0.63)	(-0.05)	(-0.21)	(0.36)
Industry Failure Rate	-0.630	1.435	1.528	0.169*	0.103	0.171
	(-0.86)	(1.40)	(1.24)	(1.87)	(1.53)	(1.21)
Percent of Industry Matured Projects	-0.168	-0.167	-0.131	0.014	0.024**	0.007
	(-1.05)	(-0.99)	(-0.75)	(0.97)	(2.00)	(0.32)
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
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Observations	2,531	1,509	1,345	34,861	31,198	17,948
R-squared	0.284	0.344	0.376	0.114	0.141	0.162
Adjusted R-squared	0.057	0.083	0.111	0.074	0.111	0.112

Table 7. Information Diffusion and Effects of the FDAAA on Project Length and Suspend Rate: Financial Crisis

This table presents results from difference-in-differences tests using clinical trials data that have been covered by the BioMedTracker database for our sample period from 2002 to 2012. We consider the effects of the 2008-2010 financial crisis neighboring the enactment of the FDAAA in 2007. We employ a more stringent specification that additionally include firm and year fixed effects in Columns 1 and 2 and a refined sample that excludes observations in the two-year event window, [-2, +2] (i.e., five year observations in 2005, 2006, 2007, 2008, and 2009) in Columns 3 and 4. The dependent variable in Columns 1 and 2 is Log (1+Duration of Phase Change) that is the log of one plus the duration in days between the current and previous phases, conditioning on the events of phase advances. The dependent variable in Columns 3 and 4 is Suspension (Indicator) that takes the value of one if the project is suspended in a given year and zero otherwise. Post (Indicator) is an indicator variable that takes the value of one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. High Number of Peers (Indicator) is one if the total number of firms that have drug projects in the same indication as a given project in a given year is greater than the sample median. The detailed descriptions of other variables are available in Appendix B. *t*-statistics reported in parentheses are based on robust standard errors clustered by firm. ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Log (1+Length of Phase Change)		Suspension Rate (Indicator)	
	(1) Including Firm X Year FE	(2) Excluding Financial Crisis Window [-2, +2]	(3) Including Firm X Year FE	(4) Excluding Financial Crisis Window [-2, +2]
High Number of Peers (Indicator) X Post	-0.218**	-0.544***	0.028***	0.042***
	(-2.06)	(-3.55)	(4.70)	(5.09)
High Number of Peers (Indicator)	-0.057	0.232	-0.004	-0.002
	(-0.51)	(1.43)	(-0.93)	(-0.26)
Project with Partner (Indicator)	-0.046	-0.181	-0.023***	-0.024***
	(-0.83)	(-1.60)	(-6.99)	(-4.27)
Log(1+Number of Preclinical Projects)		-0.016		0.012
		(-0.16)		(1.30)
Percent of Matured Projects		-0.100		0.042***
		(-0.56)		(2.64)
Percent of Projects with Partner		-0.564		-0.000
		(-1.05)		(-0.00)
Industry Failure Rate		3.079		0.133
		(1.52)		(1.55)
Percent of Industry Matured Projects		-0.068		0.029
		(-0.20)		(1.09)
Firm X Year Fixed Effects	Yes	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes
Observations	910	432	23,304	12,995
R-squared	0.520	0.570	0.309	0.218
Adjusted R-squared	0.120	0.180	0.214	0.154

Table 8. Information Diffusion from Peers for Suspension

This table presents results from peer effect tests using clinical trials data that have been covered by the BioMedTracker database for our sample period from 2002 to 2012. The dependent variable in Columns 1 to 3 is Suspension (Indicator) that takes the value of one if the project is suspended in a given year and zero otherwise. Post (Indicator) is an indicator variable that takes the value of one for project-years in the post-FDAAA period and zero for the pre-FDAAA period. High Quality (Indicator) is an indicator variable that takes the value of one for a firm whose overall success rate is positive and zero otherwise. Success rate is as the total number of advance events minus the total number of suspension events up to the prior year. Partner (Indicator) is an indicator variable that is one if the project has a partner company and zero otherwise. Peer Advance Rate (Lagged*)* is the average phase advance rate, the number of phase advances divided by the total number of projects, of projects in the same indication as a given project in the prior year excluding the firm's own projects. Peer Suspension Rate (Lagged*)* is the average phase suspension rate, the number of suspensions divided by the total number of projects, of projects in the same indication as a given project in the prior year excluding the firm's own projects. The detailed descriptions of other variables are available in Appendix B. *t*-statistics reported in parentheses are based on robust standard errors clustered by firm. ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Suspension (Indicator)		
	(1)	(2)	(3)
Peer Suspension Rate (Lagged) X Post	0.071***	0.096***	0.113***
	(3.35)	(3.44)	(3.41)
Peer Advance Rate (Lagged) X Post	-0.006	-0.013	-0.003
	(-0.63)	(-1.07)	(-0.20)
Peer Suspension Rate (Lagged) X Post X High Quality		-0.127***	
		(-3.24)	
Peer Advance Rate (Lagged) X Post X High Quality		0.047*	
		(1.68)	
Peer Suspension Rate (Lagged) X Post X Partner			-0.083**
			(-2.20)
Peer Advance Rate (Lagged) X Post X Partner			-0.000
			(-0.00)
Peer Suspension Rate (Lagged) X High Quality		0.068**	
		(2.11)	
Peer Advance Rate (Lagged) X High Quality		-0.012	
		(-0.90)	
Post X High Quality		-0.059***	
		(-5.21)	
High Quality		0.007*	
		(1.79)	
Peer Suspension Rate (Lagged) X Partner			0.043
			(1.49)
Peer Advance Rate (Lagged) X Partner			0.008
			(0.52)
Post X Partner			-0.015*
			(-1.76)
Peer Suspension Rate (Lagged)	-0.066***	-0.089***	-0.090***
	(-3.59)	(-3.46)	(-3.41)
Peer Advance Rate (Lagged)	0.002	0.008	-0.004
	(0.23)	(0.65)	(-0.28)
Project with Partner (Indicator)	-0.026***	-0.026***	-0.014***
	(-7.11)	(-7.13)	(-3.04)
Firm Fixed Effects	Yes	Yes	Yes
Phase Fixed Effects	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes
Other Controls	Yes	Yes	Yes
Observations	21,455	21,455	21,455
R-squared	0.163	0.165	0.164
Adjusted R-squared	0.125	0.128	0.126

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

This table presents results from OLS regressions 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 2012. The AERS data starts in 2004. We restrict our sample to the FDA approved drugs that are initiated and approved in and after 2000. 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. Log(1+Number of Serious AER) is the log of one plus the total number of AER where the patient outcome is one of the following serious conditions: death, life-threatening, hospitalization, disability, congenital anomaly, required intervention to prevent permanent impairment and damage. In Columns 2 and 5, we count the number of AER where the drug is reported as primary or secondary suspect. In Columns 3 and 6, we count the number of AER where the drug is reported as primary suspect. Project Initiation After FDAAA (Indicator) is an indicator variable that takes the value of one if the drug project is initiated after the passage of FDAAA in 2007 and zero otherwise. The detailed descriptions of other variables are available in Appendix B. *t*-statistics reported in parentheses are based on robust standard errors clustered by firm. ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Log(1+Number of AER)	Log(1+Number of AER Suspect)	Log(1+Number of AER Primary Suspect)	Log(1+Number of Serious AER)	Log(1+Number of Serious AER Suspect)	Log(1+Number of Serious AER Primary Suspect)
	(1)	(2)	(3)	(4)	(5)	(6)
Project Initiation After FDAAA (Indicator)	-0.768**	-0.720**	-0.692**	-0.733**	-0.717**	-0.670***
	(-2.23)	(-2.31)	(-2.47)	(-2.25)	(-2.52)	(-2.62)
Project with Partner (Indicator)	0.393	0.419*	0.494**	0.383	0.405*	0.477**
	(1.57)	(1.74)	(2.18)	(1.57)	(1.74)	(2.22)
Log(1+Number of Preclinical Project)	-0.046	-0.006	0.004	-0.049	-0.021	-0.002
	(-0.47)	(-0.06)	(0.04)	(-0.59)	(-0.26)	(-0.02)
Percent of Matured Projects	0.341	0.317	0.326	0.238	0.269	0.318
	(1.03)	(0.93)	(1.00)	(0.75)	(0.88)	(1.08)
Percent of Projects with Partner	-0.047	0.181	0.231	-0.078	0.106	0.165
	(-0.09)	(0.38)	(0.50)	(-0.17)	(0.24)	(0.38)
Log(1+Number of Competitors)	-0.077	0.037	0.036	-0.080	0.031	0.048
	(-0.51)	(0.23)	(0.24)	(-0.54)	(0.20)	(0.35)
Industry Failure Rate	0.064	0.703	0.795	0.416	0.917	0.906
	(0.05)	(0.54)	(0.62)	(0.33)	(0.78)	(0.79)
Percent of Industry Matured Projects	0.503	0.702	0.719	0.479	0.676	0.740
	(0.91)	(1.30)	(1.45)	(0.89)	(1.31)	(1.61)
Firm Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Indication Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Observations	4,876	4,876	4,876	4,876	4,876	4,876
R-squared	0.578	0.587	0.588	0.585	0.597	0.598
Adjusted R-squared	0.536	0.547	0.547	0.545	0.558	0.558

Table 10: Likelihood of Delivering AER

This table presents results from linear probability model regressions 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 2012. The AERS data starts in 2004. We restrict our sample to the FDA approved drugs that are initiated and approved in and after 2000. In Columns 1 to 3, the dependent variable is Component in AER Serious Reports (Indicator) that is one if the drug is one of the components in AER with serious patient outcome and zero otherwise. In Columns 4 to 6, the dependent variable is Primary Suspect in AER (Indicator) that is one if the drug is one of the primary suspects in AER and zero otherwise. Project Initiation After FDAAA (Indicator) is an indicator variable that takes the value of one if the drug project is initiated after the passage of FDAAA in 2007 and zero otherwise. The detailed descriptions of other variables are available in Appendix B. *t*-statistics reported in parentheses are based on robust standard errors clustered by firm. ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

	Component in AER Serious Reports (Indicator)			Primary Suspect in AER (Indicator)		
	(1)	(2)	(3)	(4)	(5)	(6)
Project Initiation After FDAAA (Indicator)	-0.181***	-0.161***	-0.163***	-0.165***	-0.126**	-0.126**
	(-3.60)	(-3.40)	(-3.33)	(-3.15)	(-2.32)	(-2.25)
Project with Partner (indicator)			-0.037			-0.010
			(-0.95)			(-0.23)
Log(1+Number of Preclinical Project)			-0.024			-0.025
			(-1.38)			(-1.26)
Percent of Matured Projects			0.105			0.114
			(1.60)			(1.41)
Percent of Projects with Partner			-0.087			0.068
			(-0.80)			(0.54)
Log(1+Number of Competitors)			-0.051*			-0.023
			(-1.71)			(-0.74)
Industry Failure Rate			-0.074			-0.140
			(-0.25)			(-0.45)
Percent of Industry Matured Projects			-0.064			-0.028
			(-0.78)			(-0.34)
Firm Fixed Effects	No	Yes	Yes	No	Yes	Yes
Indication Fixed Effects	No	Yes	Yes	No	Yes	Yes
Year Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Observations	4,897	4,876	4,876	4,897	4,876	4,876
R-squared	0.015	0.461	0.463	0.012	0.481	0.482
Adjusted R-squared	0.013	0.409	0.410	0.010	0.431	0.431

Table 11: Disability-Adjusted-Life-Years (DALY) by Active Project Growth

This table examines how the changes in active project growth rates and in suspension rates between the pre- and post-FDAAA periods are associated with changes in DALY at the indication level. We use the two points DALY data from the WHO for 2000 and 2016. We divide our indications into the two groups of low and high active project growth in (a) and (b), respectively. The significance in the column, Difference (a)-(b) is based on *t*-statistics for the t-tests for equality of means in the two groups. ***, **, and * indicate statistical significance at the 1%, 5% and 10% levels, respectively.

Panel A	(a) Low Growth Indications	(b) High Growth Indications	Difference (a)–(b)	*t*-stat
Difference, Post – Pre:				
(1) Active projects growth rates	-0.536	-0.097	-0.438***	-7.66
(2) Suspension rates	0.072	0.034	0.039**	2.45
Observations	22	20	42	

Panel B	(a) Low Growth Indications	(b) High Growth Indications	Difference (a)–(b)	*t*-stat
Pre-FDAAA period, 2000:				
(1) DALY (000s)	100593.048	124100.815	-23507.767	-1.23
(2) DALY (%)	3.58%	4.41%	-0.84%	-1.23
Difference, 2016 – 2000:				
(3) DALY (000s)	771.260	-37381.927	38153.188**	2.75
(4) DALY (%)	0.23%	-1.13%	1.36%**	2.67
Percentage Change:				
(5) (2016 DALY – 2000 DALY) / 2000 DALY	1.82%	-19.24%	21.06%*	1.88
Observations	22	20	42	