Learning from Failure: Evidence from Clinical Trials[☆]

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Abstract

This paper examines how the disclosure of failure shapes innovation activities. Theoretically, mandatory failure disclosure can be socially beneficial through knowledge spillover, but privately costly due to the risk of information leakage. I use the setting of clinical research, as it is one of the few areas where failure information is available. I exploit an expansion of mandatory disclosure requirements for clinical trial results as a positive shock to the availability of failure information. I find a significant increase in the number of new trials initiated following the policy change. The increase is driven by incremental innovations on existing drugs rather than developments of new drugs. Consistent with the knowledge spillover channel, trial sponsors benefit more in medical fields where they had less internal expertise prior to the policy change. Despite the proprietary costs for disclosing entities, my results support more mandatory failure disclosure, as the social benefits outweigh the costs.

Keywords: disclosure, innovation, knowledge spillover, proprietary cost, clinical trials
JEL: D22, D83, L65, O31, O32

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1. Introduction

In academic research and intellectual property in general, the phenomenon of publication bias, or the file drawer problem, presents a significant challenge. Empirical results that reject null hypotheses are disproportionately more likely to get published, and marginally insignificant statistics are underrepresented compared to significant ones (Sterling, 1959; Brodeur et al., 2016; Harvey, 2017; Andrews and Kasy, 2019). Similar bias extends to the patent system, where only those successful inventions get filed and those failed ones remain invisible.

From an individual perspective, this selective disclosure of success is not surprising due to high proprietary costs associated with disclosure (Bhattacharya and Ritter, 1983; Verrecchia, 1983; Anton and Yao, 1994; Glaeser, 2018; Griffin, Hong and Ryou, 2022). Once firms publicly disclose their research findings, competitors can learn from the information disclosed and potentially benefit from it without incurring any associated research costs. Even findings that indicate failures may allow competitors to succeed by modifying the original approach. This free-riding problem reduces appropriability and could discourage R&D investments. Moreover, the market may perceive the disclosure of failures as a negative signal regarding the firms' or inventors' R&D capabilities, which could harm their reputation and access to finance. Hence, there is little incentive for individuals to voluntarily disclose their failures.

However, from a social perspective, the importance of cumulative innovation in scientific and technical advancements has been widely recognized, as suggested by the famous quote from Isaac Newton about standing on the shoulders of giants. Those underreported null results and failed experiments could hold substantial value (Abadie, 2020). When each inventor hides their failures, it may lead to socially suboptimal outcomes. This information asymmetry could result in duplicated research and development investments (Loury, 1979; Reinganum, 1985; Scotchmer, 1991). The loss can be even greater when ideas are harder to find, and more investments in R&D are needed to keep research productivity at the previous level (Bloom et al., 2020). A more complete understanding of what has been done and found could save duplicated and redundant efforts, and

potentially provide insights for future research and innovation.

The main question this paper seeks to answer is whether knowledge of past failures can stimulate future innovation. Two opposing forces are at play. The positive force comes from the spillover effect of knowledge sharing, which save efforts on duplicative research, stimulate new idea generation, and reduce uncertainty inherent in R&D investments (Scotchmer, 1991; Furman and Stern, 2011; Badertscher, Shroff and White, 2013; Furman, Nagler and Watzinger, 2021; Kim and Valentine, 2021; Hegde, Herkenhoff and Zhu, 2023; Dyer et al., 2023). The negative force comes from the deterrence effect due to fear of failure or losing R&D races after observing others' progress (Glaeser and Landsman, 2021; Krieger, 2021; Zhang, 2024). Moreover, the proprietary costs associated with the disclosure, such as the risk of competitors appropriating or expropriating their findings, may deter firms from starting new trials to avoid mandatory disclosure (Aoki and Spiegel, 2009; Kim and Valentine, 2021).

Despite the importance of understanding how failure disclosure affects innovation, existing empirical evidence is scarce for two main reasons. First, failure information is always hidden, as individuals are reluctant to disclose their failures due to fear of copycats and reputation loss. Second, even when failures are observable, the decisions of voluntary disclosure are not exogenous. They may be influenced by factors, such as the availability of investment opportunities and industry competition, which can also affect innovation investments.

I use the setting of clinical research to study the impact of failure disclosure on innovation, as it is one of the few areas where failure information is available and even mandatory under some circumstances. To address the endogeneity concern, I use an expansion of mandatory disclosure requirements for clinical trial results as a positive shock to the availability of failure information. Prior to the policy change, Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA 801) mandated applicable clinical trials of drug, biological, or device products that have been *approved, licensed, or cleared* by the FDA to submit their summary results. Effective as of January 18, 2017, the Final Rule of FDAAA 801 expanded the results submission

requirements to *all* applicable trials, including those of unapproved products. The results disclosure encompasses detailed narratives and statistics on participant flow, demographic and baseline characteristics, primary and secondary outcomes, and adverse events, beyond mere status of success or failure. This change in the mandatory disclosure requirements for trials on unapproved products presents a quasi-natural experiment to study the impact of failure disclosure.

I conduct a Difference-in-Differences (DiD) analysis by comparing medical conditions with lower versus higher disclosure rates of unapproved applicable trials. Following the implementation of the Final Rule, the number of trials initiated in the treatment group, those medical conditions with lower pre-event disclosure rates, increases by 11.5% relative to the control group. The positive effect becomes statistically significant one year after the rule change and persists over time. Despite the increase in new trials, I do not find any significant changes in other trial characteristics, such as the average scale of the new trials and the time needed to complete them.

Next, I zoom into the nature of the new trials by distinguishing between radical and incremental innovation. Within a subsample of interventional drug trials, I classify trials that involve at least one new drug not previously tested or approved by the FDA as radical, and those that involve only existing drugs as incremental. I find a 12.0% increase in new trials on existing drugs. In contrast, the number of trials on new drugs shows no significant change and the coefficient estimate is even negative. These findings suggest that learning from others' failures primarily stimulates incremental improvements on existing drugs rather than the development of novel drug candidates.

To provide further evidence that the new trials initiated after the rule change draw upon previous trials, I quantify the level of learning by the similarity in trial summaries between the new trials and related past trials conducted by other sponsors. A higher similarity indicates a higher level of learning from others. I further differentiate past trials into those with disclosed results and those without. Following the policy change, I observe a significant increase in the similarities to related past trials with disclosed results, while the similarities to past trials without results remain largely unchanged. This evidence supports that the availability of trial outcomes enhances the

learning effect. When the results of past trials are available, subsequent trials are more likely to assimilate and incorporate this external knowledge into their research design.

Finally, I test two mechanisms underlying the effect of failure disclosure on innovation activities. The first one is the knowledge spillover effect that researchers can learn from others' failures, thereby stimulating their own idea generation and innovation. If this channel is in place, I expect a more pronounced increase of innovation in medical fields where sponsors possess limited in-house knowledge. While for areas where sponsors already have substantial internal expertise, the benefits of learning from others diminishes. To alleviate the concern of confounding effects from other unobservable sponsor characteristics, I leverage the variations across medical conditions within the same sponsor. Consistent with the prediction, I find that the increase in new trials concentrates in medical conditions where sponsors initiated fewer trials prior to the event. This finding also helps rule out the deterrence effect, which posits that the perceived risk of failure increases after observing others' failures, thereby discouraging innovation especially in areas where they have limited in-house knowledge.

The second mechanism considers the proprietary costs of disclosure. Once the trial results are made available to the public, competitors can expropriate the disclosed results, thus placing the original sponsor at a competitive disadvantage. Such concern may deter the initiation of new trials in the first place, particularly those under the mandatory disclosure requirements. To test this hypothesis, I split the sponsors into high and low group based on their level of proprietary costs. The proprietary costs are proxied by the number of trials subjected to the disclosure requirements and initiated prior to the issuance of the Final Rule. It measures the sponsors' burden of disclosure under the new rule, and ensures that the decisions to initiate new trials were made ex-ante, thus not influenced by the rule change. Consistent with the prediction, sponsors with higher proprietary costs initiate fewer trials subjected to the mandatory disclosure requirements compared to those with lower proprietary costs. As a placebo test, there is no difference in other trial initiations between sponsors with high and low proprietary costs following the rule change, since those trials

that are not bounded by the mandatory disclosure requirements do not incur proprietary costs.

This paper contributes to the literature in several ways. First, it complements the literature on the effects of disclosure regulations on innovation. Many empirical studies support the positive role of disclosure requirements through knowledge spillover and technology diffusion. Using the American Inventor's Protection Act of 1999 (AIPA) as a positive shock that accelerated patent disclosure, prior studies document improvements in follow-on inventions, patent citations, and efficiency of ideas commercialization post-AIPA (Hegde and Luo, 2018; Lück et al., 2020; Baruffaldi and Simeth, 2020; Kim and Valentine, 2021; Hegde, Herkenhoff and Zhu, 2023). Additionally, Furman, Nagler and Watzinger (2021) find that local patenting activity increases after the opening of patent libraries. Dyer et al. (2023) show that high quality patent disclosures spur follow-on innovation, exploiting the exogenous variation of disclosure quality from the random assignment to patent examiners. In contrast, mandated secrecy, such as the Invention Secrecy Act, the Uniform Trade Secrets Act (UTSA) and the Inevitable Disclosure Doctrine (IDD), can reduce and delay follow-on inventions (Contigiani, Hsu and Barankay, 2018; Rassenfosse, Pellegrino and Raiteri, 2024; Gross, 2019; Ganglmair and Reimers, 2022). However, some studies also point out the adverse effect of mandated disclosure (Bessen, 2005; Aoki and Spiegel, 2009; Kim and Valentine, 2021). Aghion, Bergeaud and Van Reenen (2023) show theoretically and empirically that regulation burden, including but not limited to disclosure requirements, discourages firms from innovation. While most of the prior studies focus on the disclosure of successful inventions, such as patent publications, this paper examines the disclosure of failure information and highlights its importance on future innovations.[1]

Second, this paper broadly relates to the literature on the interaction between disclosure decisions and innovation strategies in the context of R&D competition. On the one hand, when deciding whether to disclose their innovation outcomes, firms trade off the benefits of sending

[1] Krieger (2021) documents that failure news of competitors lead to a 23% jump in the exit rate of focal firm's projects in the same technology area. While his study examines the continuation decisions of ongoing parallel projects, my analysis focused on subsequent trial initiations.

out positive signals on their innovation prospects to attract investors or deter competitors, against the potential risk of losing competitive advantages to their rivals (Bhattacharya and Ritter, 1983; Anton and Yao, 1994; Jones, 2007; Hughes and Pae, 2015; Glaeser and Landsman, 2021; Capkun et al., 2023; Chu et al., 2024). On the other hand, when setting innovation strategies in light of their peers' disclosure, firms trade off the encouragement effect from the resolved uncertainty and knowledge spillover due to greater information available, against the deterrence effect from the fear of losing the race, especially when the competitors are strong rivals or already claim in-term success (Harris and Vickers, 1987; Lippman and McCardle, 1987; Choi, 1991; Doraszelski, 2003; Kim and Valentine, 2021; Hegde, Herkenhoff and Zhu, 2023; Zhang, 2024; Hsu et al., 2019). When studying the impact of disclosure on innovation, such interactions impose endogeneity concern that voluntary disclosure decisions can be influenced by innovation opportunities. To alleviate this concern, this paper examines a policy change in mandatory disclosure requirements for clinical trial results as a quasi-natural experiment, in an effort to provide more causal evidence.

Lastly, this paper connects to the literature on drug development in the context of finance and accounting.[2] The drug development process is characterized by substantial investments, protracted timelines, and high uncertainty with a low probability of success (Lo and Thakor, 2022). Despite a significant demand for financing, Thakor and Lo (2017) argue theoretically that the low success rate and the specialized expertise required to evaluate project potential lead to insufficient investments in R&D. Empirical evidence support that firms underinvest in novel drugs, and short-term stock market downturns lead to discontinuation of drug developments (Krieger, Li and Papanikolaou, 2022; Mace, 2023). Firms also exhibit opportunistic behaviors, such as strategic disclosure or killer acquisitions, which can pre-empt competition (Cunningham, Ederer and Ma, 2021; Zhang, 2024). This paper reveals the potential positive impact that disclosure requirements could have on promoting clinical research.

The rest of the paper proceeds as follows. In Section 2, I explain the institutional background

[2] A comprehensive literature review on financing biomedical innovation is provided by Lo and Thakor (2022)

and research design. Section 3 describes the data. Section 4 examines the impact of failure disclosure on future trial initiation, and Section 5 provides supporting evidence for the learning effect through textual analysis. Section 6 investigates two underlying mechanisms, the knowledge spillover effect and the proprietary costs of disclosure. Section 7 presents additional tests on robustness and other trial characteristics.

2. Institutional Background and Empirical Design

2.1. Clinical Trials Reporting Requirements

The setting of clinical research is one of the few areas that one can find failure disclosure. As the disclosure of trial failures is of great importance, beyond the benefits of knowledge spillover and the reduction of repeated efforts. First, safety is always the top priority in clinical trials that involve human subjects. Any results or indication of adverse events should be made public to enable more informed decision-making by doctors and patients, and to prevent similar incidents in the future. Second, participants of clinical trials have the right to know their condition. Transparency in trial designs and results helps to build trust between participants and researchers.

As one of the early attempts to promote transparency in clinical research, the Food and Drug Administration Modernization Act (FDAMA) of 1997 required the National Institutes of Health (NIH) to establish a publicly accessible website for clinical trials. This act led to the launch of ClinicalTrials.gov, which first became available to the public in February 2000. It allows trial sponsors and investigators to submit and update information about clinical studies and their results, aiming to facilitate information sharing among researchers, healthcare professionals, patients, and the general public. Today, it is the world's largest database of clinical trials, containing studies from around the world and a wide variety of interventions.

The mandatory disclosure requirements for clinical trial results have evolved over time. The regulatory changes present an opportunity to study the effects of failure disclosure on innovation. In September 2007, Congress passed the Food and Drug Administration Amendments Act

(FDAAA) of 2007, which expanded the regulatory requirements for trial registration and results submission to ClinicalTrials.gov. Section 801 of the FDAAA (FDAAA 801) required the submission of summary results information for applicable clinical trials (ACTs) of drugs, biological products, or devices that have been *approved, licensed, or cleared* by the FDA. The submission should be made no later than 12 months after the primary completion date or within 30 days of approval, licensure, or clearance of the drug or device.[3]

To clarify and expand the disclosure requirements for clinical trials, the U.S. Department of Health and Human Services issued a Notice of Proposed Rulemaking (NPRM) for public comment in November 2014. One major change in the proposal is to expand the scope of results submission requirements to include applicable trials on unapproved products. The Final Rule of FDAAA 801 was issued in September 2016, and came into effective on January 18, 2017. This rule mandates that *all* ACTs should submit their summary results within 12 months after their primary completion date, regardless of their approval status.[4] The results disclosure requirements cover a comprehensive set of data points, including participant flow, demographic and baseline characteristics, primary and secondary outcomes, and adverse events. Both narrative and numerical information are required. Delayed submissions are permitted under certain circumstances for up to two additional years.[5]

Information submitted to ClinicalTrials.gov undergoes a quality control review to ensure there is no apparent errors, deficiencies, or inconsistencies.[6] The Final Rule also outlines the potential

[3]Primary completion date is the date of final data collection for the primary outcome measure.

[4]For each trial initiated before January 18, 2017, it is considered as an ACT if it satisfies the following conditions as defined in section 402(j) of the Public Health Service (PHS) Act: (1) it is a non-phase 1 interventional trial of drugs, medical devices, or biologics; (2) it has at least one U.S. research site, or it is conducted under an investigational new drug (IND) application or an investigational device exemption (IDE). For each trial initiated on or after January 18, 2017, it is considered as an ACT if it satisfies the following conditions as defined in 42 CFR Part 11: (1) the study is interventional; (2) it has at least one study facility located in the U.S. or a U.S. territory, or it is conducted under an IND or IDE, or it involves a drug, biological, or device product that is manufactured in and exported from the U.S. or a U.S. territory for study in another country; (3) it evaluates at least one drug, biological, or device product regulated by FDA; (4) it is not a phase 1 trial of a drug and/or biological product, and it is not a device feasibility study.

[5]Responsible parties may request extensions to the results submission deadlines for "good cause", as well as a permanent waiver of results submissions under extraordinary circumstances.

[6]Sponsors and investigators themselves are responsible for ensuring the accuracy, safety and scientific validity.

civil or criminal actions, including civil monetary penalty actions, and grant funding actions that may be taken if responsible parties fail to comply with the requirements.[7] However, the actual enforcement of the rule is limited. According to the estimation of the Bennett Institute at the University of Oxford, the US government could have imposed fines of over 60 trillion USD on non-compliance, yet no fines have been claimed to date.[8]

2.2. *Empirical Design*

My empirical strategy exploits the expansion of the disclosure requirements for trial results, which now includes applicable trials on unapproved products in addition to approved products. This policy change serves as an exogenous shock that increases the availability of failure information. The main regression specification is presented below.

$$Num\ of\ trials\ initiated_{mt} = \beta_0 + \beta_1 Treat_m \times Post_t + \vec{\gamma} \cdot \vec{V}_{mt} + \phi_m + \tau_t + \epsilon_{mt} \tag{1}$$

where m represents medical condition, t represents year.

The dependent variable, $Num\ of\ trials\ initiated_{mt}$, is a count-like variable that measures the number of new trials related to a medical condition, initiated in a given year. I use it as a proxy for innovation activities. Since the Final Rule applies to all medical conditions, I do not have any natural treatment and control groups for the DiD analysis. However, the variations in disclosure levels prior to the rule change suggest that the event does not affect all medical conditions in the same manner. I use this heterogeneity to construct the treatment and control groups. The treatment group are those medical conditions with lower cumulative disclosure rate of unapproved ACTs prior to the event, as they are more exposed to the positive disclosure shock. The cumulative disclosure rate is computed as the number of unapproved ACTs completed and with results

[7] More details on the Final Rule of FDAAA 801 can be found at https://clinicaltrials.gov/policy/fdaaa-801-final-rule, and clinical trial reporting requirements at https://clinicaltrials.gov/policy/reporting-requirements.

[8] More information can be found on their website "FDAAA TrialsTracker" at https://fdaaa.trialstracker.net/trials/.

disclosed on or before 2016, scaled by the number of unapproved ACTs completed on or before 2016. $Post_t$ dummy equals 1 for years on and greater than 2017, when the Final Rule of FDAAA 801 became effective.

To alleviate the concern of the non-random assignment of medical conditions to the treatment and control groups, I control for factors associated with voluntary disclosure decisions. As shown in Appendix C, I find that the likelihood of voluntarily disclosing trial results is related to the types of lead sponsors, the phases of trials, and the competitiveness of medical fields. Among all trials that are completed on or before 2022 and not subjected to mandatory disclosure requirements, the likelihood of disclosure is higher for trials led by industry or government sponsors, trials in later phases, and in less competitive medical fields. In the subsample of ACTs that are not subjected to mandatory disclosure, the likelihood of disclosure is higher for trials led by government sponsors, trials in later phases, and in more competitive fields. Thus, I control for the time-varying characteristics of medical conditions, including the percentage of Phase 1, 2, 3, 4 trials started, the percentage of government-sponsored, industry-sponsored trials started, the percentage of ACTs started, and the Herfindahl-Hirschman index by lead sponsor. I also include medical condition fixed effect and year fixed effect to control for unobservable characteristics across medical conditions and time trends. Standard errors are clustered at medical condition level. The Poisson model is used as the distribution of the outcome variable is right-skewed (Cohn, Liu and Wardlaw, 2022; Chen and Roth, 2024).

3. Data and Sample

3.1. Clinical Trial Data

The trial level data is obtained from ClinicalTrials.gov.[9] For each clinical trial, it provides detailed information on the targeted diseases, study timeline and status, sponsors and collaborators,

[9]The data is downloaded on March 2, 2024 from https://classic.clinicaltrials.gov/AllPublicXML.zip.

experiment design and interventions. I restrict the sample to trials that started between 2000 and 2022 to allow sufficient time for information updates. I also require the primary completion year of the trials to be on or after 2008, when the results database was first released. The final sample consists of 328,177 clinical trials. Details of the sample selection process is reported in Table 1 Panel A, and the definitions of trial characteristics are presented in Appendix B.[10]

Among these trials, 52,457 (16.0%) posted their results on ClinicalTrials.gov. One concern is that trials with no results submitted to ClinicalTrials.gov may disclose their results through other avenues, including journal publications.[11] To ensure the accuracy and completeness of the trial results availability, I supplement the results data from ClinicalTrials.gov with journal publication data from PubMed. Two methods are used to find publications related to clinical trials from PubMed. First, I check for any self-reported results references available on ClinicalTrials.gov. Second, I search for publications in PubMed using the unique identifying number (NCT ID) of each trial.[12] To ensure that the publications are related to trial results, I exclude journal articles published before the trial's primary completion date, or those that mention "study protocol" in their titles. If at least one publication satisfies the above criteria, I mark the trial as having results available. I find 17,484 trials with qualified publications on PubMed. Around 59.6% of these trials did not submit their results to ClinicalTrials.gov. Overall, 62,877 trials have disclosed their results according to these two sources, representing 19.2% of the trial sample.

To identify clinical trials of drugs, biological products, or devices that have been approved, licensed, or cleared by the FDA, I refer to the FDA's Orange Book for drugs and the Purple Book

[10]The definitions of all data elements on ClinicalTrials.gov can be found at https://clinicaltrials.gov/policy/protocol-definitions.

[11]There are alternative sources that sponsors or investigators could disclose there results, such as medical conferences, press releases, company websites, earning conference calls, etc. I do not take them into considerations as the level of detail and reach of the disclosed information are unclear. For example, some may only report the success or failure status of the trials without providing statistics on primary and secondary outcomes. Information shared at medical conferences or during earnings calls may have limited dissemination.

[12]For a trial to be published in journals affiliated with the International Committee of Medical Journal Editors (ICMJE), it has to be registered in a public database, and a unique identifying number of the trial should be provided. This policy was announced by the International Committee of Medical Journal Editors (ICMJE) in September 2004, and applies to any clinical trial that starts enrollment after July 1, 2005 (De Angelis et al., 2004).

for biological products.[13] A trial is considered of approved drug or product if its interventions include a product listed in the Orange or Purple Book, its lead sponsor is the same as the applicant of that product, and its primary completion date precedes the approval date of the product.[14] I supplement this information with commercial databases, including Pharmaprojects and BioMedTracker, which provide approval status along with the NCT IDs of associated trials. Among all ACTs with a primary completion date on or before 2022, the disclosure rate is 94.8% for trials of approved products, and 75.3% for unapproved ones.

In the full sample of clinical trials, 15.8% of them are ACTs under FDA regulation. When categorized by study type, interventional studies constitute the majority, representing 76.3% of the trials, while observational studies account for the remaining 23.7%. Among the various classes of lead sponsors, a small fraction of the trials are sponsored by government agencies, with 0.9% by the FDA and 1.4% by the NIH. 22.5% of the trials are sponsored by industry entities, such as pharmaceutical firms and biotechnology companies. The remaining 75.2% are sponsored by other organizations, including hospitals, research institutes, and individuals. Regarding the distribution by trial phases, 8.3% are phase 1 trials, 16.0% in phase 2, 9.5% in phase 3, and 6.8% in phase 4.[15]

3.2. Medical Condition-Year Sample

To construct the medical condition-year sample for analysis, I first define medical condition based on the tree structure of Medical Subject Headings (MeSH). The MeSH vocabulary serves as a thesaurus that facilitates searching and indexing literature in the life sciences. It is used by ClinicalTrials.gov, as well as PubMed and NLM's catalog of book holdings. Each MeSH term is located in one or more trees. The tree structure goes from broader categories to more specific

[13] Orange Book can be downloaded from https://www.fda.gov/drugs/drug-approvals-and-databases/orange-book-data-files. Purple Book can be downloaded from https://purplebooksearch.fda.gov/downloads.

[14] If there are multiple approval date, due to different route of administration, product presentation, or submission type, I use the latest one to minimize the likelihood of missing trials on approved products.

[15] The remaining trials are either without phases (for example, studies of devices or behavioral interventions), or with missing value of "Study Phase".

ones as the levels increases.[16] I define medical conditions based on MeSH tree structure at Level 3 (Zhang, 2024). Then I compute the number of trials initiated, the cumulative disclosure rate of trial results, the average trial enrollment, the average time to completion, and other control variables for each medical condition per year. If a trial is associated with N different MeSH, I count it as $\frac{1}{N}$ for each MeSH to ensure that the total number of new trials is not inflated by a higher number of associated MeSH. The definitions of these variables are provided in Appendix A.

In the sample selection process, I exclude medical conditions with less than 10 trials completed over the period from 2008 to 2022. Since few trials have been conducted in those areas, leaving little prior knowledge for future researchers to learn. Moreover, these niche areas may not be comparable to those large ones. Less than 0.1% of the clinical trials fall exclusively into those medical conditions.[17] I further exclude years before 2013 for the DiD analysis, as the disclosure rates are relatively low in those early years. It also provides a five-year history of past trials for the content analysis in Section 5. The final MeSH-year sample comprises 9,210 observations, spanning years 2013 to 2022. The sample composition is reported in Table 1 Panel B.

Table 2 Panel A presents the summary statistics for the MeSH-year sample. Around 23.0 trials are initiated per MeSH per year on average, with a standard deviation of 42.7. The average cumulative disclosure rate of unapproved ACTs is 51.7% over the ten-year period. For MeSH belonging to the treatment group, the average cumulative disclosure rate of unapproved ACTs prior to the event is 25.7%. While the control group exhibits a higher average disclosure rate of 62.2%. Following the implementation of the Final Rule, the treatment group experiences a greater increase in the average disclosure rate of unapproved ACTs, rising to 58.9% in 2022. The average disclosure rate of the control group also increases, but with a lower growth rate, reaching 75.7% in 2022.[18]

[16] More details of the MeSH tree structure can be found on https://meshb-prev.nlm.nih.gov/treeView.

[17] The main results remain robust under alternative thresholds. For example, the results hold when excluding medical conditions with fewer than 20, 30, 40, or 50 completed trials.

[18] The cumulative disclosure rate of ACTs is not the same as the compliance rate to the Final Rule. Because it does not account for the one-year period for results submission after the primary completion date, or the delayed

3.3. Sponsor-Medical Condition-Year Sample

To test the underlying mechanisms, I construct a sponsor-MeSH-year sample to account for the heterogeneity across sponsors and sponsor-MeSH pairs. Only the lead sponsor of each trial is considered to ensure a one-to-one match between trials and their sponsors.[19] Similar to the MeSH-year sample, I count the number of trials initiated per sponsor per MeSH per year. To exclude inactive sponsors and under-represented MeSH, I restrict the sample to sponsors with at least 10 trials completed, and MeSH with at least 10 trials completed. This results in 30,577,200 observations from 3,320 sponsors across 921 MeSH over the sample period from 2013 to 2022.

Then I exclude sponsor-MeSH pairs with zero trials initiated during the sample period, as it is highly likely that the sponsor do not work on those areas. To make the treatment and control groups more comparable, I limit the analysis to sponsors who have similar number of trials in the treatment and control groups prior to the event. Specifically, I exclude sponsors whose ratio of trials initiated in the treated MeSH to trials in the control MeSH falls outside the range of 0.5 to 1.5. The final sponsor-MeSH-year sample consists of 899,250 observations from 1,175 sponsors and 921 MeSH. On average, a sponsor initiates 0.079 trials per year for a given medical condition. The sample composition is reported in Table 1 Panel C and its descriptive statistics in Table 1 Panel C.

4. Failure Disclosure and New Trial Initiation

4.1. Baseline Analysis

Table 3 reports estimates obtained from the Poisson regression in Equation (1). I find a positive effect of failure disclosure on future trial initiations. Column (1) presents the baseline DiD analysis. On average, the number of trials initiated in the treatment group is 12.3% ($e^{0.116} - 1$)

submissions with "good cause". Moreover, it does not exclude the early trials which are not subjected to the Final Rule. The actual compliance rate should be higher than the cumulative disclosure rate, though there remains room for improvement.

[19] In most of the clinical trials, the lead sponsor is also the responsible party.

more compared to the control group, following the policy change. Column (2) reports the dynamic effects over time. There is no significant difference in trial initiations between the treatment and control groups prior to the policy change, which satisfies the parallel trend assumption. This positive effect becomes evident one year after the implementation of the Final Rule, and the effect persists over time. To ensure the treatment and control MeSH groups are comparable, I present the DiD results after entropy balance using means, variances, and skewness for all control variables in columns (3) and (4). The positive effect remains statistically significant, with a slightly reduced magnitude of 11.5% ($e^{0.109} - 1$). These results are consistent with the learning effect that researchers learn from past failures and generate more new ideas. Figure 1 plots the dynamic trends of the differential effect between treatment and control groups around the rule change for both the DiD analysis and after entropy balance.

4.2. Trials on New vs Existing Drugs

To investigate whether the increased innovation activities are radical or incremental in nature, I differentiate trials on new drugs from those on existing drugs within a subsample of interventional clinical trials that only involve drug interventions and have disclosed their intervention names. I classify a clinical trial as a radical innovation if at least one of its interventions is not found in past trials that started before the current trial, nor in the FDA Orange Book with an approval date prior to the start date of the current trial. If all of its interventions can be found in either past trials or the Orange Book, I classify it as an incremental innovation. To alleviate the matching error due to non-standardized intervention name, I remove dosage, frequency, routes of administration, brand name, and only keep the name of the drugs using GPT-3.5 model. Among 93,080 interventional drug trials, 33.3% of them involve new drugs, while the remainder only involve existing drugs.

Table 4 reports the results. I find that the increase in trial initiations dominates in trials on existing drugs. As presented in columns (3) and (4), the number of new trials on existing drugs increases by 12.0% in the treatment group compared to the control group after the rule change. While The number of trials on new drugs shows little change, even a slight decrease as shown in

columns (1) and (2). This evidence suggests that the innovation activities spurred by past failures are primarily incremental or exploitative innovations, focusing on modifications or improvements within existing drug compounds (intensive margin), such as exploring optimal dosages, testing combinations of multiple drugs, and applying existing drugs to other diseases. However, it did not inspire more radical or exploratory innovations that venture into new territories in search of new drug candidates (extensive margin). This finding aligns with the learning effect, as the improvements in the availability of past trial results enable better evaluations of follow-on trials that built upon prior studies and existing drugs. While the developments of new drugs are much more time-consuming and expertise-intensive, which usually start from pre-clinical research on the toxicity and mechanism of action of drug compounds. This process, taking up to several years of laboratory and animal studies, remains difficult to accelerate, even with access to past failure information.

4.3. Trials by Phases

The drug development process follows several phases. It starts from pre-clinical research in lab, then promising drug compounds can enter clinical trials that involve human participants. The Phase 1 trial of a drug aims to test its safety and determine the appropriate dosage, usually involving a small number of participants and lasting for several months. If successful, the Phase 2 trial investigates the efficacy and potential side effects of the drug. It involves more participants and takes up longer time. Next, to assess whether the drug provides net treatment benefits, the Phase 3 trial conducts more extensive and rigorous testing of the drug's efficacy. This phase is based on a much larger sample and can last for several years. Upon successful completion of the Phase 3 trial, the developer can submit an application to the FDA for approval. Finally, the Phase 4 trial, also known as post-marketing surveillance study, is usually conducted after the drug has been approved to provide further evidence on the drug's long-term efficacy and potential side effects in a boarder patient pool.

As shown in Table 5, there exists variations in the timing of the effects across different phases of clinical trials. Positive effects tend to show up quicker in early phase trials compared to later

phases. The number of Phase 1 trials initiated significantly increased one year after the policy change, while it takes around two years for Phase 2 and later trials. The delayed response in late-phase trials is not surprising, as the initiations of these trials are contingent on the completion and success of early-phase trials. This evidence further supports that the increase in the number of new trials is likely driven by the change in disclosure policy.

5. Learning Effect: Text-Based Evidence

To provide more evidence that researchers learn from past trial results, I quantify the level of learning using textual analysis. For each trial initiated on or after 2013, I compute the textual similarity between its summary and those of related past trials. To qualify as a related past trial, a trial need to meet all of the following criteria: (1) medical relevance: it shares at least one common medical condition with the current trial; (2) information availability: it is posted before the start year of the current trial; (3) information recency: its primary completion year is no more than 5 years before the start year of the current trial; (4) external knowledge: it does not have the same primary sponsor as the current trial. The textual similarity between a pair of related trials is calculated as the cosine similarity of their Term Frequency-Inverse Document Frequency (TF-IDF) vectors, rescaled to the range of 0 to 100.[20] When computing the TF-IDF vectors, I remove stopwords from trial summaries, and exclude infrequent words from the corpus if they appear in less than 100 trial summaries.[21] If a trial has multiple related past trials that satisfy the above criteria, I take the average similarity. If a trial does not have related past trial, its similarity is defined as zero.

Further, I distinguish between related past trials that disclosed results and those that did not disclose results before the year in which the current trial started. I estimate the change in the level

[20]Term frequency (TF) measures the relative frequency of each term in a trial summary. Inverse document frequency (IDF) measures the commonality of each term across trial summaries. A higher value suggests the term is less common and provides more information.

[21]I obtain the generic stopwords list ("StopWords_Generic.txt") from the Notre Dame Software Repository for Accounting and Finance (SRAF) at https://sraf.nd.edu/textual-analysis/stopwords/.

of learning before and after the rule change, between trials in the treatment and control groups. The regression model is presented below.

$$Similarity_i = \beta_0 + \beta_1 Treat_i \times Post_t + \vec{\gamma} \cdot \vec{V}_{it} + \sigma_s + \tau_t + \epsilon_i \tag{2}$$

where i represents clinical trial, s represents the lead sponsor of the trial, t represents the year when the trial started.

The sample for this analysis consists of trials started on or after 2013 to allow for a five-year history of past trials. I also require that trials have at least one condition MeSH from the 921 MeSH used in the baseline analysis. The dependent variable is the similarity of trial summaries between current and related past trials. A clinical trial is assigned to the treatment group if its MeSH is in the treatment MeSH group as defined in Equation (1). If a trial has multiple MeSH, it is assigned to the treated group if more than half of its MeSH are in the treated group. Control variables include hase 1, 2, 3, 4 trials started, the percentage of government-sponsored, industry-sponsored trials started, the percentage of ACTs started, and the Herfindahl-Hirschman index by lead sponsor based on a trial's MeSH and its initiation year. For trials with multiple MeSH, the average values are taken. I add sponsor and year fixed effects. Standard errors are clustered by sponsor. The descriptive statistics are reported in Table 2 Panel B.

Table 6 presents the results. After the event, trials associated with MeSH from the treated group became more similar in study summary to prior trials with results available. In terms of magnitude, the increase in similarity is around 2.7% compared to the sample mean, when sponsor fixed effect and year fixed effect are added in column (1), and 3.1% when sponsor-year fixed effect is included in column (3). In contrast, the similarity between treated trials and past related trials without results available remains unchanged before and after the policy change, as shown in columns (2) and (4). The differences in the effects between the two measures, similarity to past related trials with results available versus similarity to those without results, are statistically significant. These

results support that the learning mainly comes from past trials that have disclosed their results. As the increase in results disclosure after the rule change comes from failed trials, the increased similarity suggests more learning from past failures. Results remain consistent if $Treat_i$ is defined as a continuous variable, measured by the proportion of MeSH belonging to the treatment group for a given trial.

6. Mechanism Tests

This section presents the mechanism tests. Two main mechanisms tested are: (1) the knowledge spillover effect that the disclosure of failures stimulates idea generation, thus, leads to an increase in future trial initiations; (2) the proprietary costs of disclosure that competitors could take advantage of the disclosed results at minimal expense. To test the two hypotheses, I construct the sponsor-MeSH-year sample to capture the heterogeneity across sponsor-MeSH pairs. If the knowledge spillover effect is in place, sponsors would benefit more in those research areas (MeSH) where they have less in-house knowledge. If the proprietary costs of disclosure plays a role, sponsors facing a higher risk of information leakage to their competitors would be discouraged to initiate new trials after the policy change, especially for those trials that are subjected to mandatory disclosure requirements. The regression model is shown below.

$$Num\ of\ trials\ initiated_{smt} = \beta_0 + \beta_1 Treat_m \times Post_t + \vec{\gamma} \cdot \vec{V}_{mt} + \phi_m + \lambda_{st} + \epsilon_{smt} \tag{3}$$

where s represents sponsor, m represents medical condition, t represents year.

The dependent variable is the number of new trials initiated by a sponsor related to a medical condition in a given year. The treatment and control groups follow the same definition as in Equation (1). I control for sponsor-year fixed effect and MeSH fixed effect to capture unobservable characteristics. I also include time-varying MeSH characteristics as control variables.

In untabulated results, there is no significant increase in the number of trials initiated using the

full sample of sponsor-MeSH-year data. The null results are consistent across various specifications, including controlling for sponsor-year fixed effect or sponsor and year fixed effect separately, and applying entropy balance.

6.1. Knowledge Spillover Effect

Knowledge spillover refers to the diffusion of insights and findings from one entity to others. When more trial results are made publicly available, they can contribute to a collective pool of knowledge and enhance the innovation potential of the entire industry. To test this knowledge spillover effect, I use the cumulative number of trials initiated prior to the policy change as a proxy for in-house knowledge. The high group comprises sponsor-MeSH pairs with more trials compared to other MeSH within the same sponsor. The more trials that a sponsor has conducted in a medical field, the more experienced and knowledgeable he might be, thus, the potential benefits from knowledge spillover are likely limited. Comparisons within a sponsor mitigate the concern of other unobservable or confounding sponsors characteristics. For example, sponsors with fewer trials initiated may also be more financially constrained, thus, less capable of investing in new trials. By comparing across MeSH within a single sponsor, the results are not affected by those common sponsor characteristics.

Table 7 presents the results. In columns (1) and (2), the low and high groups are partitioned based on the median number of trials initiated per MeSH within the same sponsor. For areas where sponsors have lower levels of in-house knowledge accumulation, there is a significant increase of 19.5% ($e^{0.178} - 1$) in the number of trials initiated after the policy change. While no effect is observed in areas where sponsors possess higher levels of internal expertise. In columns (3) and (4), I compare the bottom quartile with the lowest in-house knowledge to the top quartile. Consistent with prior findings, the positive effect concentrates in areas where sponsors possess less internal expertise. The difference between the coefficients of the high and low groups is greater in magnitude and more statistically significant compared to partition by median. These findings support the knowledge spillover channel that sponsors who possess limited internal knowledge rely

more on external information sources, and benefit more from learning from others. Moreover, the results reject the prediction of deterrence effect that the fear of failure, amplified by the knowledge of others' failures, would deter innovation. If the fear of failure plays a dominant role, sponsors are expected to shy away from medical fields where they possess less in-house knowledge, as the perceived risk of failure is likely higher.

6.2. Proprietary Costs of Disclosure

Proprietary costs reflect the value of trial results as exclusive assets to its sponsors. Once these results are mandated to disclose publicly, they can no longer enjoy the benefits of exclusivity. Their competitors could free ride without incurring the original research cost, undermining the sponsors' competitiveness or first-mover advantages. If proprietary costs are one of the decisive factors of trial initiations, sponsors with higher proprietary costs are expected to initiate fewer trials after the policy change to avoid disclosing results. To examine this mechanism, I use the number of ACTs started before September 21, 2016, when the Final Rule was issued and completed after January 18, 2017, when the rule came into effective, as a proxy for proprietary costs. The high proprietary costs group consists of sponsors whose number of trials meeting the above criteria exceeds the median of all sponsors.[22] Those trials are subjected to the mandatory disclosure requirements, but their sponsors did not know this ex-ante when they made the decision to start the trials. This ensures that the grouping is not endogenously affected by the policy change.

Since the proprietary costs are primarily relevant for trials that are subjected to mandatory disclosure requirements, I expect the negative effect mainly comes from trials that are mandated to disclose their summary results after the rule change. In September 2016, together with the issuance of Final Rule of FDAAA 801, the final NIH policy also mandated disclosure of trial results. The NIH policy applies to all clinical trials funded in whole or in part by the NIH and initiated after January 18, 2017. So the number of trials subjected to mandatory results disclosure includes both

[22]Majority of the sponsors have zero trials satisfying the above criteria, namely, the median value is zero.

the number of ACTs under FDA regulation and NIH-funded trials. As shown in Table 8 columns (1) and (2), sponsors with lower proprietary costs initiate significantly more trials subjected to mandatory disclosure following the policy change, while there is no change among sponsors with high proprietary costs. The coefficient difference between the high and low groups is statistically significant at 5% level.

As a placebo test, I also examine the differential effects on other trials that are not subjected to mandatory disclosure, where the proprietary costs should not have any effect. Consistently, I do not find significant difference between sponsors with higher and lower proprietary costs in columns (3) and (4). Both groups of sponsors do not experience significant change in trials initiation after the shock. These findings collectively suggest that when sponsors are already facing high proprietary costs and the risk of potential information leakage, they are less willing to start new trials that are subjected to the mandatory disclosure requirements compared to those sponsors with lower proprietary costs. However, this does not affect the initiation of non-applicable trials, which are not bounded by the disclosure requirements and do not incur proprietary information cost.

7. Additional Tests

In this section, I conduct additional tests to assess the validity and robustness of the results, and to evaluate the effect of failure disclosure on other trial characteristics.

7.1. Validation Tests

Since the Final Rule applies exclusively to ACTs, one concern is that the policy change may not have a meaningful impact on the overall availability of failure information. To address this, I compare the changes in cumulative disclosure rates between the treatment and control groups before and after the Final Rule. Appendix D presents the results. Columns (1) and (2) show a positive impact on the disclosure rate of unapproved ACTs following the policy change. Specifically, the disclosure rate of MeSH in the treatment group increased by 10.6% more than that of

the control group after the policy change. More importantly, when considering the disclosure rate of all trials on unapproved products, not limited to ACTs, columns (3) and (4) support that the disclosure rate also experienced a significant increase, though the magnitude drops to 1.8%.

7.2. Robustness Tests

To address concerns on the design of my DiD strategy, I conduct multiple tests to check the robustness of my results.

7.3. Confounding Effects of Innovation Opportunities

One major endogeneity concern with my DiD strategy is the non-random assignment of treatment and control groups. It is possible that the voluntary disclosure decisions are correlated with other alternative, concurrent shocks, such as shocks to innovation opportunities or technology advancements. Medical fields with lower disclosure rates before the rule change may also be more exposed to innovation opportunities, leading to more trial initiations even in absence of the Final rule. To alleviate this concern, I conduct a robustness test using the disclosure rate of early years as the grouping variable. As the time gap between the grouping variable and the event becomes larger, the disclosure rate is less likely to correlate with the innovation opportunities in years after the policy change.

Appendix E reports the results. Columns (1) to (8) present the estimates where the treatment and control groups are classified based on the cumulative disclosure rate of unapproved ACTs in each year from 2008 to 2015, respectively. All of them support an increase in the number of new trials after the policy change, and the effect is statistically significant except for the year 2011. Moreover, the coefficient estimates are around 10%, which are similar to the baseline results and do not exhibit an upward trend in the coefficients over time.[23] Overall, these findings mitigate the endogeneity concern arising from sectoral variations in innovation opportunities.

[23] I do not use early-year disclosure rate as the grouping variable for the baseline analysis because the number of applicable trials is limited, especially in initial years after the launch of ClinicalTrials.gov.

7.3.1. Dosage Effects

Throughout the main analysis, I define the treatment group as medical conditions with below median cumulative disclosure rate of unapproved ACTs prior to the policy change, and the control group as those with above median disclosure rate. In this section, I examine the "dosage effects" of the policy change by comparing outcomes across different quartiles of the disclosure rate distribution following (Campello and Larrain, 2016). If my empirical strategy is sound, the effect should increase (decrease) as the distance between treatment and control groups in the disclosure rate distribution grows (narrows).

Appendix F reports the results. In columns (1) and (2), I classify those MeSH in the bottom (first) quartile as the treatment group and those in the top (fourth) quartile of the disclosure rate as the control group. In columns (3) and (4), the treatment group consists of MeSH in the second quartile, while the control group remains the top quartile. In columns (5) and (6), the treatment group remains the second quartile, and the control group is the third quartile. As expected, the effect diminishes in magnitude and the estimation becomes less precise as the disclosure rate in the treatment and control groups move closer to each other. In untabulated results, I replace the binary treatment dummy with the continuous variable of unapproved ACTs' disclosure rate. The interaction term between the disclosure rate and the *Post* dummy loads significant negatively.

7.3.2. Effects of COVID-19

Another potential concern arises from the overlap between COVID-19 pandemic and the latter part of my sample period. The positive effect could be driven by the abnormal increase in clinical trials related to COVID-19. To alleviate this concern, I exclude COVID-related trials, COVID-related medical conditions, or COVID period from 2020 to 2022.[24] As reported in Appendix G, the positive effect remains statistically significant, though its magnitude drops to around 5-7%.

[24] A trial is classified as COVID-related if it mentions "COVID-19" in its condition MeSH terms. COVID-related MeSH are "C01.748.610", "C01.925.705", "C01.925.782", "C08.381.677", and "C08.730.610".

7.4. Effects on Other Trial Characteristics

Previous analysis focus on the number of new trials initiated as a proxy for innovation activities. It implicitly assumes that more trials suggests greater innovation and social benefits. However, other characteristics of the trials may be importance as well. For example, does the scale of newly initiated trials differ from the past? If sponsors learn from past failure, does that help accelerate trial completion or increase the probability of success in future trials?

In Table 9, I examine the impact of failure disclosure on the scale and pace of new innovation. The scale of innovation is proxied by the average number of participants enrolled in each clinical trial. The pace of innovation is proxied as the average number of days needed to complete the trial, namely, days between the trial's start date and its primary completion date.[25] I do not find significant effect on either trial enrollment or time to completion. The effect on approval rate is not presented due to the limited time span since the implementation of the Final Rule. It usually takes years for trials to receive approval. Nevertheless, a preliminary check of the available data suggests a positive effect on the approval rate.

8. Conclusion

In this study, I examine the effect of failure disclosure on future innovation activities in the setting of clinical research. Using an expansion of the mandatory disclosure requirements for clinical trial results as a positive shock to the availability of failure information, I document an increase in trial initiations following the policy change. The positive effect on innovation is primarily at the intensive margin, driven by incremental innovations based on existing drugs rather than the developments of new drug compounds. Textual analysis of trial summaries provides further support that the newly initiated trials learn from related past trials, especially those with disclosed results. Consistent with the knowledge spillover channel, sponsors benefit more from the disclosure of

[25] For trials that have not yet completed the data collection for all primary outcomes. The primary completion date reflects the estimated completion date.

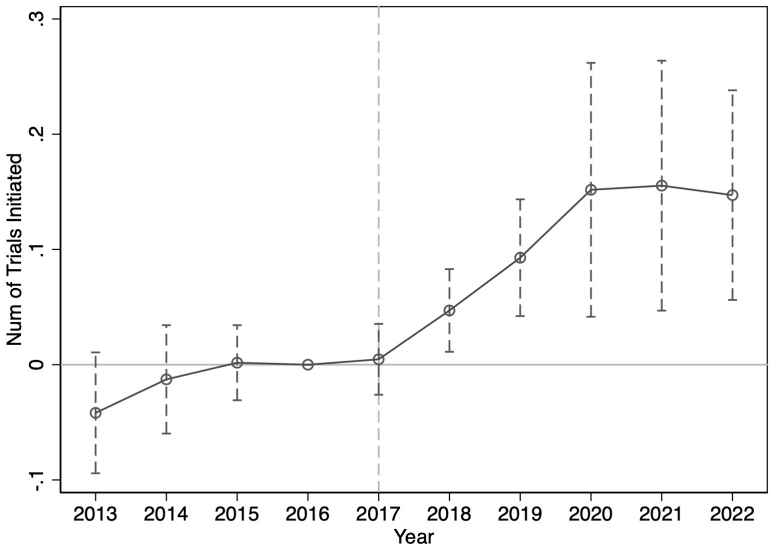
others' failures in medical fields where they possess less in-house knowledge. The proprietary costs associated with disclosure also influences the decision to initiate trials. Sponsors facing higher proprietary costs are less willing to start new trials that are subject to mandatory disclosure requirements.

This paper contributes to the discussion on whether and how failure disclosure can stimulate innovation activities, an area that, despite its importance, lacks empirical evidence. The findings support mandated disclosure policies, when failure disclosure is privately costly but socially beneficial. They also echo the ongoing efforts to promote greater research transparency. However, the optimal level of disclosure requirements remains an open question for future research. The relationship between mandated failure disclosure and innovation may not be linear, and it can vary depending on the current level of failure disclosure. Additionally, the quality of innovation is also worth considering in welfare analyses. When designing disclosure policies and systems, regulators need to balance the social benefits from knowledge spillover against the proprietary costs borne by the innovating entities.

Figure 1: Dynamic Trends

This figures show the dynamic effects of the expansion in disclosure requirements on new trials initiation over the period from 2013 to 2022. Figure (a) presents the dynamic plot of the DiD analysis, and Figure (b) presents the plot after entropy balance. The confidence interval of 5% significance level is presented. Control variables include the percentage of phase 1, 2, 3, 4 trials started, percentage of FDA, NIH, industry-sponsored trials per year per medical condition. MeSH fixed effect and year fixed effect are included. The regression results are reported in Table 3. The sample composition is presented in Table 1 and variable definition in Appendix A.

(a) DID



(b) DID+Entropy balance

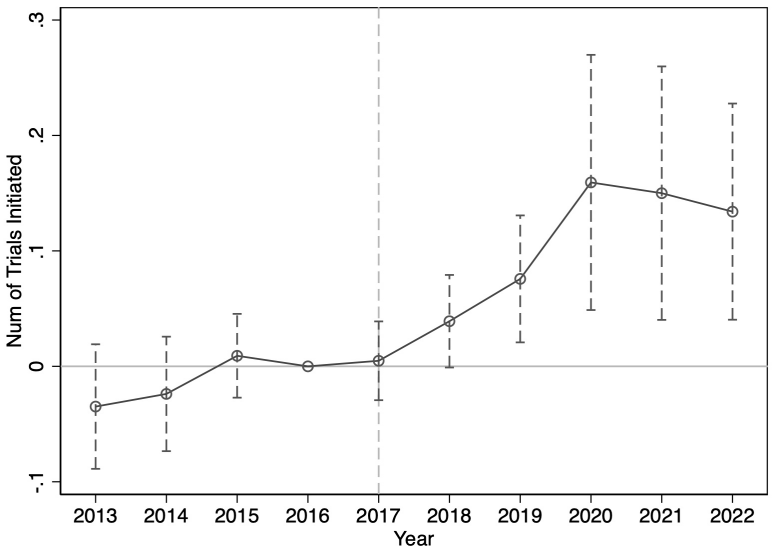


Table 1: Sample composition

Panel A. Clinical trials sample

	Trial obs
Clinical trials data[26]	485,171
minus: initiation year before 2000, or after 2022	(56,915)
minus: primary completion year before 2008	(30,342)
minus: missing condition MeSH	(69,737)
Clinical trials sample	328,177

Panel B. Medical condition-year sample

	MeSH-year obs
MeSH-year sample from 328,177 trials	31,890
minus: MeSH with less than 10 trials completed	(18,075)
minus: years on or before 2012	(4,605)
MeSH-year sample	9,210

Panel C. Sponsor-medical condition-year sample

	Sponsor-MeSH-year obs
Sponsor-MeSH-year sample from sponsors with at least 10 trials completed, and MeSHs with at least 50 trials completed	30,577,200
minus: sponsor-MeSH pairs with zero trial started	(28,604,970)
minus: sponsors with an incomparable number of trials in treated and control MeSH groups	(1,072,980)
Sponsor-MeSH-year sample	899,250

This table shows the sample composition. Panel A presents the sample selection of clinical trials from ClinicalTrials.gov. Panel B presents the medical condition-year sample used in Section 4. Panel C presents the sponsor-medical condition-year sample used in Section 6.

[26]Data downloaded from ClinicalTrials.gov on March 2, 2024.

Table 2: Summary statistics

Panel A. Medical condition-year sample

	Obs	Mean	Std. Dev.	P10	P25	P50	P75	P90
Num of trials initiated	9,210	22.972	42.723	1.283	2.515	6.427	21.961	61.355
Num of trials initiated (new drug)	9,210	1.630	3.458	0.000	0.000	0.333	1.450	4.479
Num of trials initiated (old drug)	9,210	4.140	9.153	0.000	0.200	0.950	3.444	10.233
Enrollment	9,137	1155	3785	53	91	185	484	1943
Time to completion	9,137	888	368	470	633	838	1079	1372
Cum disclosure rate	9,210	0.230	0.108	0.097	0.158	0.223	0.295	0.371
Cum disclosure rate (unapproved)	9,210	0.226	0.106	0.097	0.157	0.221	0.290	0.365
Cum disclosure rate (unapproved ACT)	9,210	0.517	0.266	0.000	0.367	0.550	0.704	0.818
Treat	9,210	0.499	0.500	0.000	0.000	0.000	1.000	1.000
Post	9,210	0.600	0.490	0.000	0.000	1.000	1.000	1.000
% Phase 1	9,210	0.062	0.082	0.000	0.000	0.032	0.095	0.170
% Phase 2	9,210	0.124	0.134	0.000	0.000	0.083	0.188	0.318
% Phase 3	9,210	0.079	0.096	0.000	0.000	0.053	0.112	0.196
% Phase 4	9,210	0.058	0.079	0.000	0.000	0.030	0.085	0.155
% Gov sponsored	9,210	0.015	0.034	0.000	0.000	0.000	0.015	0.048
% Ind sponsored	9,210	0.190	0.183	0.000	0.036	0.151	0.291	0.443
% ACT	9,210	0.146	0.136	0.000	0.041	0.122	0.213	0.323
HHI	9,210	0.120	0.164	0.010	0.023	0.066	0.145	0.274

Panel B. Clinical trials sample

	Obs	Mean	Std. Dev.	P10	P25	P50	P75	P90
Similarity (with results)	232,135	4.688	3.366	1.635	2.419	3.717	5.858	9.034
Similarity (without results)	232,135	4.640	3.088	1.797	2.541	3.748	5.760	8.707
Treat	232,135	0.375	0.484	0.000	0.000	0.000	1.000	1.000
Post	232,135	0.675	0.469	0.000	0.000	1.000	1.000	1.000
% Phase 1	232,135	0.076	0.065	0.017	0.032	0.059	0.100	0.152
% Phase 2	232,135	0.139	0.105	0.035	0.061	0.107	0.189	0.306
% Phase 3	232,135	0.077	0.045	0.025	0.046	0.071	0.100	0.132
% Phase 4	232,135	0.056	0.040	0.014	0.026	0.047	0.077	0.111
% Gov sponsored	232,135	0.015	0.016	0.000	0.005	0.012	0.019	0.032
% Ind sponsored	232,135	0.203	0.115	0.073	0.125	0.187	0.258	0.347
% ACT	232,135	0.144	0.068	0.07	0.101	0.133	0.178	0.236
HHI	232,135	0.023	0.030	0.005	0.007	0.012	0.024	0.054

Panel C. Sponsor-medical condition-year sample

	Obs	Mean	Std. Dev.	P10	P25	P50	P75	P90
Num of trials initiated	899,250	0.079	0.210	0.000	0.000	0.000	0.000	0.250
Num of trials initiated (mandated disc.)	899,250	0.006	0.041	0.000	0.000	0.000	0.000	0.000
Num of trials initiated (no mandated disc.)	899,250	0.070	0.191	0.000	0.000	0.000	0.000	0.250
Treat	899,250	0.450	0.497	0.000	0.000	0.000	1.000	1.000
Post	899,250	0.600	0.490	0.000	0.000	1.000	1.000	1.000
In-house knowledge[27]	899,250	0.534	1.429	0.000	0.000	0.143	0.500	1.317
Proprietary cost[28]	899,250	3.656	9.782	0.000	0.000	0.000	1.000	11.500
% Phase 1	899,250	0.067	0.064	0.000	0.021	0.051	0.097	0.150
% Phase 2	899,250	0.126	0.108	0.011	0.048	0.097	0.173	0.289
% Phase 3	899,250	0.077	0.062	0.000	0.034	0.068	0.106	0.153
% Phase 4	899,250	0.058	0.053	0.000	0.019	0.046	0.083	0.126
% Gov sponsored	899,250	0.016	0.023	0.000	0.000	0.009	0.020	0.039
% Ind sponsored	899,250	0.194	0.137	0.032	0.092	0.174	0.267	0.378
% ACT	899,250	0.141	0.088	0.035	0.082	0.130	0.185	0.258
HHI	899,250	0.040	0.062	0.005	0.008	0.016	0.040	0.101

This table shows the number of observations, the mean, the standard deviation, and 10^{th}, 25^{th}, 50^{th}, 75^{th}, 90^{th} percentiles for the variables and observations used in my empirical tests. Panel A presents the summary statistics for the medical condition-year sample used in Section 4. Panel B comprises the sub-sample of clinical trials used for the textual analysis in Section 5. Panel C comprises the sponsor-medical condition-year sample used in Section 6. Continuous variables are winsorized at 1%.

[27] In-house knowledge is measured by the number of clinical trials initiated on or before 2016 per sponsor-MeSH

[28] Proprietary cost is measured by the number of clinical trials initiated before Sep 21, 2016 and completed after Jan 18, 2017 per sponsor

Table 3: New Trials Initiation

	Num of trials initiated			
	DID		DID+Entropy balance	
	(1)	(2)	(3)	(4)
Treat × Post	0.116***		0.109***	
	(0.037)		(0.037)	
Treat × Pre4		-0.042		-0.035
		(0.027)		(0.028)
Treat × Pre3		-0.013		-0.024
		(0.024)		(0.025)
Treat × Pre2		0.002		0.009
		(0.017)		(0.019)
Treat × Post0		0.005		0.005
		(0.016)		(0.017)
Treat × Post1		0.047**		0.039*
		(0.018)		(0.020)
Treat × Post2		0.093***		0.076***
		(0.026)		(0.028)
Treat × Post3		0.152***		0.159***
		(0.056)		(0.056)
Treat × Post4		0.155***		0.150***
		(0.055)		(0.056)
Treat × Post5		0.147***		0.134***
		(0.046)		(0.048)
Controls	Yes	Yes	Yes	Yes
MeSH FE	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	Yes	Yes
Obs	9,210	9,210	9,210	9,210

This table shows the impact of the expansion in disclosure requirements on new trial initiations using Poisson regression model. The dependent variable is the number of new trials related to a medical condition (MeSH) initiated in a given year. The treated group are those MeSH with lower cumulative disclosure rate of ACTs' results prior to the event. Columns (1) and (2) present the DiD analysis and its dynamic trends. In columns (3) and (4), the matching is based on entropy balancing using means, variances, and skewness for all control variables. Control variables include the percentage of Phase 1, 2, 3, 4 trials among trials started per year per MeSH, the percentage of government-sponsored (FDA or NIH), industry-sponsored trials started, the percentage of ACTs, and the Herfindahl-Hirschman index by lead sponsors. MeSH fixed effect and year fixed effect are added. The sample composition is presented in Table 1 and variable definition in Appendix A. Standard errors are clustered at MeSH level and reported in parentheses. *, **, and *** denote statistical significance at the 10%, 5%, and 1% levels, respectively.

Table 4: New Trials Initiation: New vs Existing Drug

	Num of trials initiated			
	New Drug		Existing Drug	
	(1)	(2)	(3)	(4)
Treat × Post	-0.023		0.113***	
	(0.044)		(0.044)	
Treat × Pre4		-0.050		0.006
		(0.056)		(0.042)
Treat × Pre3		-0.031		-0.014
		(0.055)		(0.034)
Treat × Pre2		0.078		0.004
		(0.054)		(0.032)
Treat × Post0		-0.139***		0.023
		(0.050)		(0.035)
Treat × Post1		-0.021		0.041
		(0.050)		(0.036)
Treat × Post2		-0.152***		0.135***
		(0.055)		(0.039)
Treat × Post3		0.033		0.190**
		(0.076)		(0.084)
Treat × Post4		0.066		0.165**
		(0.078)		(0.068)
Treat × Post5		0.031		0.104**
		(0.065)		(0.048)
Controls	Yes	Yes	Yes	Yes
MeSH FE	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	Yes	Yes
Obs	8,590	8,590	9,030	9,030

This table compares the impact of expansion in disclosure requirements on new trial initiations between trials on new drugs and trials on existing drugs, using Poisson regression model. The dependent variable of columns (1) and (2) is the number of drug trials initiated related to at least one new drug per medical condition (MeSH) per year. A drug is considered new if it has never used in previous trials or included in FDA Orange Book. The dependent variable of columns (3) and (4) is the number of drug trials initiated related to existing drugs per MeSH per year. The treated group are those MeSH with lower cumulative disclosure rate of unapproved ACTs' results prior to the event. The matching is based on entropy balancing using means, variances, and skewness for all control variables. Control variables include the percentage of Phase 1, 2, 3, 4 trials among trials started per year per MeSH, the percentage of government-sponsored (FDA or NIH), industry-sponsored trials started, the percentage of ACTs, and the Herfindahl-Hirschman index by lead sponsors. MeSH fixed effect and year fixed effect are added. The sample composition is presented in Table 1 and variable definition in Appendix A. Standard errors are clustered at MeSH level and reported in parentheses. *, **, and *** denote statistical significance at the 10%, 5%, and 1% levels, respectively.

Table 5: New Trials Initiation: By Phases

	Num of trials initiated (by phases)			
	Phase 1	Phase 2	Phase 3	Phase 4
	(1)	(2)	(3)	(4)
Treat × Pre4	0.036	-0.007	-0.009	0.028
	(0.043)	(0.041)	(0.061)	(0.055)
Treat × Pre3	0.062	0.020	0.037	-0.033
	(0.048)	(0.033)	(0.054)	(0.063)
Treat × Pre2	0.052	0.020	0.034	0.100**
	(0.039)	(0.035)	(0.066)	(0.045)
Treat × Post0	0.063	0.021	0.026	0.059
	(0.040)	(0.030)	(0.048)	(0.048)
Treat × Post1	0.102***	0.031	0.041	0.073
	(0.039)	(0.041)	(0.047)	(0.048)
Treat × Post2	0.147***	0.086**	0.122**	0.092*
	(0.045)	(0.038)	(0.061)	(0.052)
Treat × Post3	0.345***	0.206**	0.224**	0.232**
	(0.094)	(0.084)	(0.092)	(0.093)
Treat × Post4	0.253***	0.229***	0.220**	0.257***
	(0.074)	(0.084)	(0.089)	(0.087)
Treat × Post5	0.262***	0.142**	0.241***	0.184***
	(0.061)	(0.059)	(0.093)	(0.063)
Controls	Yes	Yes	Yes	Yes
MeSH FE	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	Yes	Yes
Obs	8,640	8,880	8,840	8,690

This table compares the impact of expansion in disclosure requirements on new trial initiations by phases using Poisson regression model. The dependent variable is the number of trials related to a medical condition (MeSH) initiated in a given year: column (1) for Phase 1 trials, column (2) for Phase 2 trials, column (3) for Phase 3 trials, and column (4) for Phase 4 trials. The treated group are those MeSH with lower cumulative disclosure rate of unapproved ACTs' results prior to the event. The matching is based on entropy balancing using means, variances, and skewness for all control variables. Control variables include the percentage of Phase 1, 2, 3, 4 trials among trials started per year per MeSH, the percentage of government-sponsored (FDA or NIH), industry-sponsored trials started, the percentage of ACTs, and the Herfindahl-Hirschman index by lead sponsors. MeSH fixed effect and year fixed effect are added. The sample composition is presented in Table 1 and variable definition in Appendix A. Standard errors are clustered at MeSH level and reported in parentheses. *, **, and *** denote statistical significance at the 10%, 5%, and 1% levels, respectively.

Table 6: Learning Effect: Analysis of Trial Summaries

	Similarity of trial summaries			
	w/ results	w/o results	w/ results	w/o results
	(1)	(2)	(3)	(4)
Treat × Post	0.126***	0.025	0.145***	0.043
	(0.037)	(0.035)	(0.043)	(0.040)
Test of coefficient difference between similarity to past trials with results and without results				
Difference (p-value)	0.100*** (0.000)		0.102*** (0.000)	
Controls	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	No	No
Sponsor FE	Yes	Yes	No	No
Year × Sponsor FE	No	No	Yes	Yes
Obs	217,134	217,134	191,771	191,771
Adj. R^2	0.152	0.131	0.149	0.126

This table examines the learning effect based on the textual analysis of trial summaries. In columns (1) and (3), the dependent variables are the similarity of trial summaries between the current trial and its past related trials with disclosed results. In columns (2) and (4), the dependent variables are the similarity of trial summaries between the current trial and its past related trials without disclosed results. The treated group consists trials with medical condition (MeSH) in the treated group as defined in Table 3. If a trial has multiple MeSH, it is assigned to the treated group if more than half of its MeSH are in the treated group. Control variables include the percentage of Phase 1, 2, 3, 4 trials, the percentage of government-sponsored (FDA or NIH), industry-sponsored trials started, the percentage of ACTs, and the Herfindahl-Hirschman index by lead sponsors based on the trial's MeSH and its initiation year. For trials with multiple MeSH, the average values are taken. Sponsor and year fixed effect are added. The sample comprises trials started on or after 2013 and with at least one condition MeSH within the 921 MeSH used in Table 3. Standard errors are clustered at sponsor level and reported in parentheses. *, **, and *** denote statistical significance at the 10%, 5%, and 1% levels, respectively.

Table 7: New Trials Initiation: Knowledge Spillover

In-house knowledge =	Num of trials initiated			
	Low 1/2	High 1/2	Low 1/4	High 1/4
	(1)	(2)	(3)	(4)
Treat × Post	0.178***	0.008	0.311***	0.008
	(0.060)	(0.066)	(0.069)	(0.073)
Test of coefficient difference between high-knowledge areas and low-knowledge areas				
Difference (p-value)	0.170* (0.056)		0.303*** (0.002)	
Controls	Yes	Yes	Yes	Yes
MeSH FE	Yes	Yes	Yes	Yes
Sponsor × Year FE	Yes	Yes	Yes	Yes
Obs	384,077	336,375	238,661	172,318

This table compares the impact of the expansion in disclosure requirements on new trial initiations between areas where sponsors process high and low in-house knowledge, using Poisson regression model. The dependent variable is the number of new trials per sponsor per medical condition (MeSH) per year. The sample includes the MeSH where sponsors have lower in-house knowledge in columns (1) and (3), and the MeSH where sponsors have higher proprietary cost in columns (2) and (4). The in-house knowledge is measured by the cumulative number of trials initiated by the sponsor in the MeSH prior to the policy change. The treated group are those MeSH with lower cumulative disclosure rate of unapproved ACTs' results prior to the event. The matching is based on entropy balancing using means, variances, and skewness for all control variables. Control variables include the percentage of Phase 1, 2, 3, 4 trials among trials started per year per MeSH, the percentage of government-sponsored (FDA or NIH), industry-sponsored trials started, the percentage of ACTs, and the Herfindahl-Hirschman index by lead sponsors. MeSH fixed effect and year fixed effect are added. The sample composition is presented in Table 1 and variable definition in Appendix A. Standard errors are clustered at MeSH level and reported in parentheses. *, **, and *** denote statistical significance at the 10%, 5%, and 1% levels, respectively.

Table 8: New Trials Initiation: Proprietary Cost of Disclosure

	Num of trials initiated (mandated disc.)		Num of trials initiated (no mandated disc.)	
Proprietary cost =	Low	High	Low	High
	(1)	(2)	(3)	(4)
Treat × Post	0.274**	0.000	-0.000	0.062
	(0.125)	(0.046)	(0.038)	(0.040)
Test of coefficient difference between sponsors with high and low proprietary costs				
Difference (p-value)	0.273** (0.041)		-0.062 (0.260)	
Controls	Yes	Yes	Yes	Yes
MeSH FE	Yes	Yes	Yes	Yes
Sponsor × Year FE	Yes	Yes	Yes	Yes
Obs	60,483	209,290	240,265	571,257

This table shows the impact of the expansion in disclosure requirements on new trial initiations between sponsors with high and low proprietary cost, using Poisson regression model. The dependent variable is the number of new trials subjected to result disclosure requirements per sponsor per medical condition (MeSH) per year in columns (1) and (2), and the number of new trials not subjected to result disclosure requirements per sponsor per MeSH per year in columns (3) and (4). The sample includes sponsors with lower proprietary cost in columns (1) and (3), and sponsors with higher proprietary cost in columns (2) and (4). The proprietary cost is measured by the number of ACTs started before September 21, 2016, when the Final Rule was issued and completed after January 18, 2017, when the rule came into effective. The treated group are those MeSH with lower cumulative disclosure rate of unapproved ACTs' results prior to the event. The matching is based on entropy balancing using means, variances, and skewness for all control variables. Control variables include the percentage of Phase 1, 2, 3, 4 trials among trials started per year per MeSH, the percentage of government-sponsored (FDA or NIH), industry-sponsored trials started, the percentage of ACTs, and the Herfindahl-Hirschman index by lead sponsors. MeSH fixed effect and year fixed effect are added. The sample composition is presented in Table 1 and variable definition in Appendix A. Standard errors are clustered at MeSH level and reported in parentheses. *, **, and *** denote statistical significance at the 10%, 5%, and 1% levels, respectively.

Table 9: Trial Enrollment and Time to Completion

	Trial enrollment		Time to completion	
	DID	DID+EB	DID	DID+EB
	(1)	(2)	(3)	(4)
Treat × Post	-205.713	-245.404	7.731	15.839
	(167.667)	(168.018)	(13.891)	(16.340)
Controls	Yes	Yes	Yes	Yes
MeSH FE	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	Yes	Yes
Obs	9,137	9,137	9,137	9,137
Adj R2	0.218	0.226	0.544	0.508

This table presents the impact of expansion in disclosure requirements on the enrollment and time to completion of new trials. The dependent variable of Columns (1) and (2) is the average number of enrollment per trial for each medical condition (MeSH) and year. The dependent variable of Columns (3) and (4) is the average number of days to completion per trial for each medical condition (MeSH) and year. The days to completion is calculated as the days between the trial initiation and primary completion. The treated group are those MeSHs with lower cumulative disclosure rate of unapproved ACTs' results prior to the event. Columns (1) and (3) present the DiD analysis. Columns (2) and (4) present the matching results based on entropy balancing using means, variances, and skewness for all control variables. Control variables include the percentage of Phase 1, 2, 3, 4 trials among trials started per year per MeSH, the percentage of government-sponsored (FDA or NIH), industry-sponsored trials started, the percentage of ACTs, and the Herfindahl-Hirschman index by lead sponsors. MeSH fixed effect and year fixed effect are added. The sample composition is presented in Table 1 and variable definition in Appendix A. Standard errors are clustered at MeSH level and reported in parentheses. *, **, and *** denote statistical significance at the 10%, 5%, and 1% levels, respectively.

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Appendix A. Variable Definition

This table shows the definitions of all variables and their sources. MeSH-year level and Sponsor-MeSH-year level variables are constructed from trial level data. CT stands for ClinicalTrials.gov. PM stands for PubMed. FDA stands for the Orange Book and Purple Book from the Food and Drug Administration (FDA). PP stands for PhamaProject. BMT stands for BioMedTracker.

Variable	Definition	Source
Num of trials initiated	The number of clinical trials associated with a given medical condition (MeSH) and initiated in a given year. If a trial is associated with N different MeSH, it is counted as $\frac{1}{N}$ for each MeSH.	CT
Num of trials initiated (new drug)	The number of interventional drug trials that involves new drugs and initiated in a given year associated with a given MeSH. A trial is considered as involving new drugs if it has at least one intervention that cannot be found neither in the past trials with start date earlier than the current trial, nor in the Orange Book with approval date earlier than the start date of the current trial.	CT, OB
Num of trials initiated (existing drug)	The number of interventional drug trials that only involves existing drugs and initiated in a given year associated with a given MeSH. A trial is considered as only involving existing drugs if all of its interventions can be found either in the past trials with start date earlier than the current trial, or in the Orange Book with approval date earlier than the start date of the current trial.	CT, OB
Enrollment	The average number of participants enrolled among trials associated with a given MeSH and initiated in a given year.	CT
Time to completion	The average number of days between the trial start date and its primary completion date among trials associated with a given MeSH and initiated in a given year.	CT
Cumulative disclosure rate	The number of trials completed and with results disclosed on or before a given year, scaled by the total number of trials completed on or before that year. A trial is considered as completed in a given year if its "Primary Completion Date" falls within that year, and its "Overall Recruitment Status" is marked as "Completed" or "Terminated" according to ClinicalTrials.gov. Results disclosure through both ClinicalTrials.gov and journal publications are considered.	CT, PM

Cumulative disclosure rate (unapproved)	The number of unapproved trials completed and with results disclosed on or before a given year, scaled by the total number of unapproved trials completed on or before that year. A trial is considered of approved drug or product if its intervention includes a product listed in the Orange Book or Purple Book, its lead sponsor is the same as the applicant of that product, and the primary completion date of the trial precedes the approval date of the product. I supplement this information with commercial databases, including Pharmaprojects and BioMedTracker, which provide approval status along with the NCT IDs of associated trials.	CT, PM, FDA, PP, BMT
Cumulative disclosure rate (unapproved)	The number of unapproved applicable clinical trials (ACTs) completed and with results disclosed on or before a given year, scaled by the total number of unapproved ACTs completed on or before that year. For each trial initiated before January 18, 2017, it is considered as an ACT if it satisfies the following conditions as defined in section 402(j) of the Public Health Service (PHS) Act: (1) it is a non-phase 1 interventional trial of drugs, medical devices, or biologics; (2) it has at least one U.S. research site, or are conducted under an investigational new drug (IND) application or an investigational device exemption (IDE). For each trial initiated on or after January 18, 2017, it is considered as an ACT if it satisfies the following conditions as definedd in 42 CFR Part 11: (1) the study is interventional; (2) it has at least one study facility located in the U.S. or a U.S. territory, or it is conducted under an IND or IDE, or it involves a drug, biological, or device product that is manufactured in and exported from the U.S. or a U.S. territory for study in another country; (3) it evaluates at least one drug, biological, or device product regulated by FDA; (4) it is not a Phase 1 trial of a drug and/or biological product, and it is not a device feasibility study.	CT, PM, FDA, PP, BMT
Treat	Dummy variable that equals 1 for MeSH with lower cumulative disclosure rate of unapproved ACTs compared to the sample mean.	CT
Post	Dummy variable that equals 1 for years on or after 2017.	
% Phase 1	Proportion of phase 1 trials associated with a given MeSH initiated in a given year relative to the total number of trials initiated in that MeSH during the same year.	CT
% Phase 2	Proportion of phase 2 trials associated with a given MeSH initiated in a given year relative to the total number of trials initiated in that MeSH during the same year.	CT
% Phase 3	Proportion of phase 3 trials associated with a given MeSH initiated in a given year relative to the total number of trials initiated in that MeSH during the same year.	CT

% Phase 4	Proportion of phase 4 trials associated with a given MeSH initiated in a given year relative to the total number of trials initiated in that MeSH during the same year.	CT
% Gov sponsored	Proportion of trials led by government sponsors, including NIH and FDA, associated with a given MeSH initiated in a given year relative to the total number of trials initiated in that MeSH during the same year.	CT
% Ind sponsored	Proportion of trials led by industry sponsors associated with a given MeSH initiated in a given year relative to the total number of trials initiated in that MeSH during the same year.	CT
HHI	The Herfindahl-Hirschman index (HHI) by lead sponsor in a given MeSH in a given year. It is calculated by summing the squares of the market share of each sponsor in that MesSH in that year. The market share is the number of trials initiated by that sponsor in that MeSH, scaled by the total number of trials initiated in the same MeSH in the same year. Only the lead sponsor of each trial is considered.	CT
Similarity	The textual similarity between the "Brief Summary" of a trial and its related past trials. The similarity is calculated as the cosine similarity of their TF-IDF vectors, rescaled to the range of 0 to 100. If the trial has multiple related past trials that satisfy the above criteria, the average similarity is used. If the trial has no related past trial, the similarity is defined as zero. I differentiate related past trials with disclosed results versus those without. The selection criteria of related past trials are explained in Section 5.	CT
In-house knowledge	The number of clinical trials led by a given sponsor, initiated on or before 2016, and associated with a given MeSH.	CT
Proprietary cost	The number of clinical trials led by a given sponsor, initiated before Sep 21, 2016 when the Final Rule was issued and completed after Jan 18, 2017 when the Final Rule came into effective.	CT

Appendix B. Trial Characteristics from ClinicalTrials.gov

This table presents the definitions of trial characteristics obtained from ClinicalTrials.gov.

Variable	Definition
Study type	The nature of the investigation or investigational use for which clinical study information is being submitted. The type falls into one of the following options: Interventional; Observational; Expanded Access.
Overall recruitment status	The recruitment status for the clinical study as a whole, based upon the status of the individual sites. The status falls into one of the following options: Not yet recruiting; Recruiting; Enrolling by invitation; Active, not recruiting; Completed; Suspended; Terminated; Withdrawn.
Study start date	The estimated date on which the clinical study will be open for recruitment of participants, or the actual date on which the first participant was enrolled.
Primary completion date	The date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concluded according to the pre-specified protocol or was terminated.
Results first posted date	The date when the results of the study was first available on ClinicalTrials.gov.
Brief summary	A short description of the clinical study, including a brief statement of the clinical study's hypothesis, written in language intended for the lay public. The length limit is 5,000 characters.
Primary disease (Condition MeSH)	The name(s) of the disease(s) or condition(s) studied in the clinical study, or the focus of the clinical study. Use, if available, appropriate descriptors from NLM's Medical Subject Headings (MeSH)-controlled vocabulary thesaurus.
Study phase	The numerical phase of a clinical trial for a drug or biological product, consistent with terminology in 21 CFR 312.21 and in 21 CFR 312.85 for Phase 4 studies. The phase falls into one of the following options: Early Phase 1, Phase 1, Phase 1/Phase 2, Phase 2, Phase 2/Phase 3, Phase 3, Phase 4, N/A. In Section 4.3, I classify trials belonging to "Early Phase 1" and "Phase 1" as phase 1 trials, "Phase 1/Phase 2" and "Phase 2" as phase 2 trials, "Phase 2/Phase 3" and "Phase 3" as phase 3 trials, "Phase 4" as phase 4 trials.
Sponsor name	The name of the entity or the individual who is the sponsor of the clinical study. When a clinical study is conducted under an investigational new drug application (IND) or investigational device exemption (IDE), the IND or IDE holder is considered the sponsor. When a clinical study is not conducted under an IND or IDE, the single person or entity who initiates the study, by preparing and/or planning the study, and who has authority and control over the study, is considered the sponsor.

Intervention name(s)	A brief descriptive name used to refer to the intervention(s) studied in each arm of the clinical study. A non-proprietary name of the intervention must be used, if available. If a non-proprietary name is not available, a brief descriptive name or identifier must be used. The length limit is 200 characters.
Results reference	Citations to publications related to results from this clinical study, provided in PubMed Unique Identifier (PMID) and/or bibliographic citation.

Appendix C. Voluntary Disclosure Decision

This table presents the relationship between trial characteristics and the decision to voluntarily disclose trial results. In Columns (1) and (2), the dependent variables are the indicator variables that equal one if the trial results are disclosed. In Columns (3) and (4), the dependent variables are the indicator variables that equal one if the trial results are disclosed within 12 months after the primary completion. In Columns (5) and (6), the dependent variables are the indicator variables that equal one if the trial results are disclosed within 36 months after the primary completion. The trial characteristics include the lead sponsor, the trial phase, and the competitiveness of the medical fields. The competitiveness is measured using the Herfindahl-Hirschman index (HHI), computed as the sum of squares of the shares of lead sponsors for each medical condition and each year. A higher HHI indicates lower competition. If the trial relates to multiple medical conditions, the average value is taken. In Panel A, the sample consists of all trials that are completed on or before 2022 and are not subjected to mandatory disclosure requirements. The variable definition is presented in Appendix A. Standard errors are clustered at lead sponsor level and reported in parentheses. *, **, and *** denote statistical significance at the 10%, 5%, and 1% levels respectively.

Panel A. Trials exempt from mandatory disclosure requirements

	Results disclosed		Results disclosed in 12 months		Results disclosed in 36 months	
	(1)	(2)	(3)	(4)	(5)	(6)
Industry sponsor	0.161***		0.063***		0.162***	
	(0.019)		(0.013)		(0.018)	
Government sponsor	0.279***		0.073***		0.232***	
	(0.069)		(0.021)		(0.059)	
Phase 1	-0.072***	-0.126***	-0.007	-0.026***	-0.059***	-0.101***
	(0.014)	(0.014)	(0.005)	(0.008)	(0.010)	(0.011)
Phase 2	0.203***	0.222***	0.030***	0.036***	0.117***	0.131***
	(0.016)	(0.017)	(0.006)	(0.007)	(0.013)	(0.014)
Phase 3	0.202***	0.224***	0.050***	0.056***	0.165***	0.191***
	(0.016)	(0.018)	(0.010)	(0.010)	(0.016)	(0.017)
Phase 4	0.144***	0.181***	0.050***	0.056***	0.135***	0.162***
	(0.013)	(0.014)	(0.008)	(0.009)	(0.012)	(0.013)
HHI	0.008	0.078***	-0.007	0.021*	0.038	0.074***
	(0.039)	(0.023)	(0.015)	(0.011)	(0.035)	(0.017)
Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Sponsor FE	No	Yes	No	Yes	No	Yes
Obs	178,356	167,364	178,356	167,364	178,356	167,364
Adj. R^2	0.164	0.343	0.034	0.115	0.122	0.296

Panel B. ACTs exempt from mandatory disclosure requirements

	Results disclosed		Results disclosed in 12 months		Results disclosed in 36 months	
	(1)	(2)	(3)	(4)	(5)	(6)
Industry sponsor	-0.185***		-0.003		-0.076***	
	(0.019)		(0.015)		(0.023)	
Government sponsor	0.034		0.068***		0.117***	
	(0.046)		(0.021)		(0.033)	
Phase 2	-0.055***	-0.025**	0.011	0.001	-0.062***	-0.058***
	(0.016)	(0.011)	(0.009)	(0.011)	(0.018)	(0.017)
Phase 3	0.066***	0.063***	0.047***	0.029**	0.126***	0.120***
	(0.016)	(0.013)	(0.013)	(0.012)	(0.022)	(0.018)
Phase 4	0.024	0.050***	0.089***	0.082***	0.140***	0.145***
	(0.018)	(0.014)	(0.018)	(0.018)	(0.025)	(0.024)
HHI	-0.093	-0.008	-0.076	-0.010	0.038	0.124
	(0.093)	(0.063)	(0.049)	(0.054)	(0.097)	(0.089)
Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Sponsor FE	No	Yes	No	Yes	No	Yes
Obs	18,925	17,232	18,925	17,232	18,925	17,232
Adj. R^2	0.067	0.456	0.051	0.138	0.089	0.285

Appendix D. Validation: Effect on Disclosure Rate

This table presents the impact of expansion in disclosure requirements on cumulative disclosure rate. The dependent variable of Columns (1) and (2) is the cumulative disclosure rate of unapproved ACTs per medical condition (MeSH) per year. The dependent variable of Columns (3) and (4) is the cumulative disclosure rate of unapproved trials per medical condition (MeSH) per year. The treated group are those MeSHs with lower cumulative disclosure rate of unapproved ACTs' results prior to the event. The matching is based on entropy balancing using means, variances, and skewness for all control variables. Control variables include the percentage of phase 1, 2, 3, 4 trials among trials started per year per MeSH, percentage of government-sponsored (FDA or NIH), industry-sponsored trials started, percentage of ACTs, and the Herfindahl-Hirschman index by lead sponsors. MeSH fixed effect and year fixed effect are added. The sample composition is presented in Table 1 and variable definition in Appendix A. Standard errors are clustered at MeSH level and reported in parentheses. *, **, and *** denote statistical significance at the 10%, 5%, and 1% levels respectively.

	Cum disclosure rate (unapproved ACTs)		Cumdisclosure rate (unapproved)	
	DID	DID+EB	DID	DID+EB
	(1)	(2)	(3)	(4)
Treat × Post	0.085***	0.106***	0.009**	0.018***
	(0.012)	(0.014)	(0.004)	(0.005)
Controls	Yes	Yes	Yes	Yes
MeSH FE	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	Yes	Yes
Obs	9,210	9,210	9,210	9,210
Adj. R^2	0.682	0.663	0.822	0.815

Appendix E. Robustness: Confounding Effects

This table shows the robustness test using early-year disclosure rates as the grouping variable. The dependent variable is the number of new trials related to a medical condition (MeSH), initiated in a given year. In Column (1), the treated group includes those MeSHs with below-median cumulative disclosure rate of unapproved ACTs by 2008. Similarly, Column (2) presents the grouping based on disclosure rate by 2009, Column (3) by 2010, Column (4) by 2011, Column (5) by 2012, Column (6) by 2013, Column (7) by 2014, and Column (8) by 2015. Control variables include the percentage of phase 1, 2, 3, 4 trials among trials started per year per MeSH, percentage of government-sponsored (FDA or NIH), industry-sponsored trials started, percentage of ACTs, and the Herfindahl-Hirschman index by lead sponsors. MeSH fixed effect and year fixed effect are added. The sample composition is presented in Table 1 and variable definition in Appendix A. Standard errors are clustered at MeSH level and reported in parentheses. *, **, and *** denote statistical significance at the 10%, 5%, and 1% levels, respectively.

	Num of trials initiated							
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
$Treat_{2008} \times Post$	0.137***							
	(0.036)							
$Treat_{2009} \times Post$		0.138***						
		(0.040)						
$Treat_{2010} \times Post$			0.103**					
			(0.046)					
$Treat_{2011} \times Post$				0.051				
				(0.035)				
$Treat_{2012} \times Post$					0.068**			
					(0.034)			
$Treat_{2013} \times Post$						0.081***		
						(0.031)		
$Treat_{2014} \times Post$							0.139***	
							(0.037)	
$Treat_{2015} \times Post$								0.095**
								(0.037)
Controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
MeSH FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Obs	9,210	9,210	9,210	9,210	9,210	9,210	9,210	9,210

Appendix F. Robustness: Dosage Effects

This table shows the impact of expansion in disclosure requirements on new trial initiations considering dosage effect, using Poisson regression model. The dependent variable is the number of new trials related to a medical condition (MeSH), initiated in a given year. In Columns (1) and (2), the treated group includes those MeSHs with cumulative disclosure rate of unapproved ACTs at the lowest quartile prior to the event, and the control group includes those MeSHs with cumulative disclosure rate of unapproved ACTs' at the highest quartile. In Columns (3) and (4), the treated group includes those MeSHs with cumulative disclosure rate of unapproved ACTs at the second lowest quartile, and the control group includes those MeSHs at the highest quartile. In Columns (5) and (6), the treated group includes those MeSHs with cumulative disclosure rate of unapproved ACTs at the second lowest quartile prior to the event, and the control group includes those MeSHs at the second highest quartile. Control variables include the percentage of phase 1, 2, 3, 4 trials among trials started per year per MeSH, percentage of government-sponsored (FDA or NIH), industry-sponsored trials started, percentage of ACTs, and the Herfindahl-Hirschman index by lead sponsors. MeSH fixed effect and year fixed effect are added. The sample composition is presented in Table 1 and variable definition in Appendix A. Standard errors are clustered at MeSH level and reported in parentheses. *, **, and *** denote statistical significance at the 10%, 5%, and 1% levels, respectively.

	Num of trials initiated					
	DID	DID+EB	DID	DID+EB	DID	DID+EB
	(1)	(2)	(3)	(4)	(5)	(6)
$\text{Treat}_{Q1-Q4} \times \text{Post}$	0.234***	0.220***				
	(0.072)	(0.070)				
$\text{Treat}_{Q2-Q4} \times \text{Post}$			0.109**	0.121***		
			(0.045)	(0.046)		
$\text{Treat}_{Q2-Q3} \times \text{Post}$					0.089**	0.084**
					(0.040)	(0.041)
Controls	Yes	Yes	Yes	Yes	Yes	Yes
MeSH FE	Yes	Yes	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Obs	4,560	4,560	4,660	4,660	4,650	4,650

Appendix G. Robustness: Exclude COVID-19

This table shows the impact of expansion in disclosure requirements on new trial initiations after excluding the effect of COVID-19, using Poisson regression model. The dependent variable is the number of new trials related to a medical condition (MeSH), initiated in a given year. The treated group are those MeSHs with lower cumulative disclosure rate of unapproved ACTs prior to the event. Columns (1) and (2) present the DiD analysis and DiD after entropy balance (DID+EB) for the sample excluding COVID-related trials. Columns (3) and (4) present the results using the sample excluding COVID-related MeSHs. Columns (5) and (6) present the results for sample period from 2013 to 2019 before COVID-19. Control variables include the percentage of phase 1, 2, 3, 4 trials among trials started per year per MeSH, percentage of government-sponsored (FDA or NIH), industry-sponsored trials started, percentage of ACTs, and the Herfindahl-Hirschman index by lead sponsors. MeSH fixed effect and year fixed effect are added. The sample composition is presented in Table 1 and variable definition in Appendix A. Standard errors are clustered at MeSH level and reported in parentheses. *, **, and *** denote statistical significance at the 10%, 5%, and 1% levels, respectively.

	Number of trials initiated					
	Exclude COVID trials		Exclude COVID MeSH		Exclude COVID period	
	DID	DID+EB	DID	DID+EB	DID	DID+EB
	(1)	(2)	(3)	(4)	(5)	(6)
Treat × Post	0.071***	0.064**	0.067***	0.061**	0.056***	0.047**
	(0.025)	(0.026)	(0.026)	(0.027)	(0.022)	(0.023)
Controls	Yes	Yes	Yes	Yes	Yes	Yes
MeSH FE	Yes	Yes	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	Yes	Yes	Yes	Yes
Obs	9,200	9,200	9,160	9,160	6,447	6,447