Information Disclosure in the Presence of Competition: Evidence from the Pharmaceutical Industry

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Abstract

This paper studies how competition impacts innovative firms' voluntary disclosure of product quality information. Our empirical context is the pharmaceutical industry, where firms must decide whether to disclose private drug quality information acquired in clinical trials. Leveraging variation in clinical trial sponsorship and a difference-in-differences strategy, we show that firms in more competitive markets are less likely to publicly disclose clinical trial results. In exploring mechanisms, we document several sources of evidence that show that firms in competitive settings prioritize secrecy to minimize the risk of knowledge spillovers, market competition effects, and patent invalidation. These findings suggest the competitive environment in which firms operate plays an important role in shaping firms' disclosure strategies.

Keywords: Competition; Information Disclosure; Innovation; Health Care Markets

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1 Introduction

Firms in a wide range of innovation-driven industries, such as automobiles, software, and healthcare, generate private information about the quality of their products. For instance, automobile manufacturers conduct crash tests to generate vehicle safety information; developers conduct software tests to assess the performance of their products; and pharmaceutical firms invest in R&D projects, such as clinical trials, to generate information about the safety and efficacy of their drugs. In leading theoretical models, firms have incentives to voluntarily disclose all private product quality information (Grossman, 1981; Milgrom, 1981; Jovanovic, 1982).

However, the complete "unraveling" of private information is rarely observed in practice.[1] For example, information generated from clinical trials is of substantive interest as it is used to shape the decisions of regulators, consumers, and competitors. Yet, a large policy-oriented literature has conjectured that firms may strategically withhold their clinical trial results.[2] Motivated by concerns about transparency, Congress passed regulation in 2007 requiring clinical trial results reporting within one year of trial completion (Shrank, Rogstad and Parekh, 2019).[3,4] Despite these policies, a 2011 analysis found that two years after 5,600 clinical trials were completed, just 22 percent of their results were reported (Prayle, Hurley and Smyth, 2012).

Industry and media evidence suggest that firms' disclosure decisions are strongly shaped by competitive dynamics. In one of the largest drug recalls in history, the pharmaceutical firm Merck removed Vioxx from the market due to heart-related side effects. At the time, the drug was used by 80 million patients and had annual sales of $2.5 billion (Topol, 2004). However, years before Vioxx's removal, Merck had discovered clinical trial findings showing that Vioxx increased heart attack risks. It was later revealed that Merck withheld disclosing the clinical trial findings due to concerns that Vioxx would be compared negatively to a competing drug, Pfizer's Celebrex (Berenson, 2005*b*). Despite a growing number of policies aimed at motivating firms to disclose their trial results since

[1] For surveys documenting incomplete disclosure across industries, see Milgrom (2008) and Dranove and Jin (2010).

[2] See, e.g., Lexchin et al. (2008), Turner et al. (2008), Mathieu et al. (2009), and Anderson et al. (2015).

[3] The Food and Drug Administration Amendments Act of 2007 (FDAAA) required that clinical trial sponsors report their clinical findings to the public trial registry, ClinicalTrials.gov, within one year of clinical trial completion (FDAAA, 2007). We provide further discussion of this policy in Section 2.

[4] Most recently, concerns over clinical trial transparency have been salient in the race to develop safe and effective treatments for Covid-19: e.g., *STAT* ("Increase Transparency at the FDA: We Need Sunlight to Fight the Pandemic"), the *New York Times* ("Vaccine Makers Keep Safety Details Quiet, Alarming Scientists"), *Nature* ("COVID Vaccine Confidence Requires Radical Transparency"), and the *New England Journal of Medicine* ("Evaluating and Deploying Covid-19 Vaccines—the Importance of Transparency, Scientific Integrity, and Public Trust").

the Vioxx case, widespread underreporting persists with "competitive pressures" often cited as key drivers (Berenson, 2005*a*; Zarin et al., 2011).

To bridge the gap between theory and practice, we examine how competition alters firms' strategic disclosure decisions. Empirically, we leverage the unique features of the pharmaceutical research and development (R&D) setting, including the comprehensive documentation of R&D activity and the staggered arrival of competitor drug approvals, to identify the causal relationship between product market competition and pharmaceutical firms' decisions to disclose their clinical trial results. We focus on how competition shapes two dimensions of disclosure: (i) the probability and (ii) the timing of clinical results reporting. We find that, on average, firms in more competitive markets are less likely to disclose the results of their clinical trials. Conditional on disclosing, firms in more competitive markets are more likely to delay disclosure.

The existing theoretical literature is mixed on how competitive pressures shape firms' disclosure incentives (Board, 2009; Guo and Zhao, 2009; Levin, Peck and Ye, 2009; Gentzkow and Kamenica, 2017; Jansen, 2010, 2017; Markopoulos and Hosanagar, 2018). Further, the empirical literature on market structure and product quality disclosure is sparse and primarily relies on cross-sectional evidence. For example, Jin (2005) documents that competition among health maintenance organizations is negatively correlated with product quality disclosure. However, concerns about real world and unobservable factors (for example, market demand and technological opportunities) may limit the external validity and causal interpretation of existing competition-disclosure estimates. One reason for the sparse empirical literature is that causal relationships are difficult to test since researchers must observe the entire market structure and exogenous changes in competition are rare.

Three features of the pharmaceutical industry allow us to overcome these constraints. First, diseases (e.g., ovarian cancer) provide a natural and distinct categorization of markets. Second, pharmaceutical R&D is subject to substantial regulatory oversight and competitive monitoring which provides researchers with the data to observe each drug as it moves through the development cycle.[5] This careful documentation allows researchers to observe a near "universe" of competing drugs in a disease market and to determine the exact date that clinical trials results are disclosed. Third, uncertainties in the regulatory approval process allow us to take advantage of variation in

[5]For example, the Food and Drug Administration Modernization Act of 1997 (FDAMA) requires trial sponsors to register clinical trials in the federal clinical trial registry, ClinicalTrials.gov. Registration information includes the disease being treated, the drug under investigation, and the clinical trial sponsor. We discuss this further in Section 2.

the plausibly exogenous timing of competitor drug entry to identify the causal effect of competition on firms' disclosure incentives.

We assemble a rich dataset of clinical trials initiated between 2007–2019, which we match to data on clinical trial results reporting on public clinical trial registries, publications, and conferences. Using this data, we assess the causal effect of competition on disclosure using two empirical tests. First, we compare trends among public-sector and private-sector funded clinical trials. We posit that the effect of competition is driven by profit-maximizing institutions that are more likely to respond to the effects of competition (see David, Hall and Toole (2000) for a survey and Budish, Roin and Williams (2015) and Liu and Schmidt (2022) for more recent contributions).[6] Consistent with this view, we document that competition are statistically more negative for private-sector trials relative to public-sector trials.

Second, we test for the causal effect of competition using a difference-in-differences (DiD) strategy that leverages the timing at which the drug regulator approves promising competitor drugs. The motivation behind this empirical analysis is that given that the exact timing of approval is subject to uncertainty, the approval of a rival drug with priority review status in a disease constitutes a large (and plausibly exogenous) increase to competition in that disease (Gilchrist, 2016). Consistent with evidence from the first empirical test, we find that a competitor priority review drug approval lowers the likelihood of clinical trial results reporting by 13 percent.

As a complement to our main findings competition-driven changes in the probability and timeliness of disclosure, we also provide evidence documenting that competition changes the signaling quality of the disclosed clinical information. Using detailed data on the design of clinical trials, we find that competition lowers the likelihood that firms design clinical trials to produce information that rivals are more likely to find useful. Taken together, the totality of evidence suggests that competition lowers firms' incentives to disclose of product quality information.

Finally, we seek to uncover the mechanisms that drive the relationship between competition and disclosure. Some potential mechanisms are non-strategic: for example, a competition-driven decline in product quality may be driving the relationship between competition and disclosure. Under this mechanism, disclosure is simply a proxy for product quality. On the other hand, competition

[6]Indeed, researchers have found results reported by private-sector clinical trials are more favorable relative to those reported by public-sector clinical trials (Davidson, 1986; Friedberg et al., 1999; Oostrom, 2021; Rao, 2022).

may have a more strategic effect and disclosure may increase the potential for positive knowledge spillovers, product market competition, and intellectual property (IP) infringement. Due to these concerns, firms may respond to competition by strategically withholding proprietary product quality information. Accordingly, we look for evidence on whether the competition-disclosure relationship is driven by changes in product quality, by direct changes in disclosure (holding product quality fixed), and by firms' patenting strategies.

We find limited evidence that non-strategic considerations shift firms' disclosure incentives: competition has little effect on firms' investment on the composition of subsequent R&D projects, suggesting that competition-driven changes in product quality are unlikely to be the primary channel through which competition shapes results reporting. Instead, we document consistent decision pattern with respect to disclosure: among both low and high quality projects, we observe that competition leads to a decline in clinical trial results reporting. Looking next to the relationship between firms' strategic disclosure and patenting decisions, we find that in competitive settings, firms are more likely to delay their results reporting to minimize the likelihood that rivals would be able to successfully invalidate any future patents. These findings are consistent with the literature on the importance of factors, such as product quality information, research spillovers, and patenting strategies in competitive markets.[7] This paper shows how such factors have important effects for the design of firms' disclosure strategies.

Our empirical focus on the pharmaceutical industry, a $4 trillion industry characterized by high levels of competition, is of substantiative interest as timely access to information about the quality of novel products has significant consequences for drug manufacturers, competitors, consumers, and regulators (Arrow, 1963; Zarin and Tse, 2008; Harris, 2010).[8] A back-of-the-envelope calculation shows removing the effect of competition on disclosure would have resulted in the results disclosure from an additional 1,374 clinical trials, which represents more than $20 billion in product development. For physicians and patients, lessons from clinical trials may reveal more effective treatments. For policy makers aiming to spur innovation and reduce excessive spending, published clinical trial results facilitate the efficient exchange of ideas (Teece, 1986; Arora, Fosfuri and Gambardella, 2002;

[7] See, e.g., Gans, Hsu and Stern (2008); Mihm, Sting and Wang (2015); Hegde and Luo (2018); Markopoulos and Hosanagar (2018); and Krieger (2021).

[8] National health spending reached $4 trillion in 2020 and accounted for roughly 20% of the Gross Domestic Product (Hartman et al., 2022).

Gans and Stern, 2003) and minimize wasteful spending on ineffective products, which can cost up to $28.6 billion annually (Eichler et al., 2013; Shrank, Rogstad and Parekh, 2019).

This analysis reveals provides important insights for managers and policy makers (Guo and Zhao, 2009). Although firm disclosure of product quality information may minimize the threat of regulatory penalties and in some cases, enhance consumer demand (e.g., by convincing skeptical consumers to adopt a novel product), firms in competitive settings may prioritize secrecy to minimize the risk of knowledge spillovers, competition effects, and patent invalidation. In these settings, firms' disclosure strategies may be critical to maintaining their competitive advantage. Finally, for policy makers seeking to design effective transparency policies, our paper highlights the importance of taking into account firms' strategic decisions and competitive environment.[9]

The remainder of the paper proceeds as follows. Section 2 describes the setting and the conceptual framework. Section 3 introduces the data. Section 4 presents the paper's empirical approach and main results regarding competition and disclosure, and Section 5 examines the mechanisms that drive this relationship. Section 6 concludes.

2 Background and Related Literature

2.1 Clinical Trials

The US pharmaceutical industry, one of the largest sectors in terms of domestic R&D spending, provides a useful setting to monitor firm disclosure of product quality information.[10] In the United States, drug development—which is characterized by a high uncertainty and large capital investments—consists of a series of stages: the process typically begins with extensive preclinical laboratory research that involves testing a new drug candidate on animals and human cells. When these preclinical tests demonstrate efficacy, drug manufacturers begin the most expensive aspect of drug development: human testing of drugs in a series of clinical trials, in which costs increase with each subsequent phase. Drugs that successfully demonstrate safety in phase I clinical trials proceed to phase II clinical trials in which their efficacy is tested in a few hundred patients. Phase III is the final stage of clinical development and involves assessing efficacy in thousands of patients

[9] For a survey of existing transparency policies, see Fung, Graham and Weil (2007).

[10] The pharmaceutical sector makes up nearly 17 percent of industrial R&D and accounts for 62 percent of industrial R&D spending with health applications (National Science Foundation and Census Bureau, 2018).

and examining them over a longer period of time. Importantly, safety continues to be monitored throughout each phase.

Drug manufacturers have substantial leeway in determining how and whether to publicly disclose their clinical results. Regulators, such as the US Food and Drug Administration (FDA), must balance their need to ensure transparency against their obligations to protect firms' proprietary information (Kesselheim and Mello, 2007). For example, drug manufacturers seeking regulatory approval of a novel drug to treat a specific disease (indication) must submit a drug application containing clinical trial data to the FDA (Appendix Figure A1, Panel A).[11] If the drug is approved, the FDA will release summary reports of the drug's clinical findings after its approval. However, if the drug is not approved, drug manufacturers are not required to publicly disclose their clinical trial results (Appendix Figure A1, Panel B).[12]

Once a drug is approved, the drug manufacturer may seek to test the drug in additional Phase II and Phase III clinical trials.[13] In most cases, drug manufacturers conducting clinical trials for non-regulatory purposes are not required to submit these "post-market" findings to the FDA (Appendix Figure A1, Panel C). To illustrate, consider a case where a firm manufactures a drug that is approved to treat colorectal cancer. To increase demand among existing users, the firm may generate additional clinical evidence that further confirms the effectiveness of the drug in treating colorectal cancer. Suppose the firm is also interested in expanding the use of the drug to treat non-approved, or "off-label" indications (for example, ovarian cancer).[14] While firms are not permitted to directly advertise off-label indications, firms may use evidence generated from clinical trials (in so-called "seeding trials") to indirectly promote additional indications to physicians (Kessler et al., 1994). In both cases, the firm may not need to report any clinical trial results

[11] The FDA requires that drugs meet a minimum quality standard when deciding whether to approve a novel drugs (Malani and Philipson, 2012). Proponents for testing approved drugs in additional clinical trials and increasing access to the results of such trials note that the high level of specificity (e.g., the drug development and approval process is indication-specific) and uncertainty (e.g., safety issues that were previously unknown may be uncovered later) in the approval process suggest that this requirement fails to ensure that approved drugs are safe and effective for *all* patient populations (see, e.g., Bertolini, Sukhatme and Bouche (2015)). This claim is supported evidence documenting higher levels of adverse events associated with the use of drugs for purposes other than the approved indication (so-called "off-label" drug use) (Eguale et al., 2016).

[12] This policy runs counter to the rising public preference for more transparency in the drug development process: in a nationally representative survey of 1,035 US adults, nearly 90 percent of participants supported the disclosure of information about drugs that were not approved (Azad et al., 2022).

[13] The FDA may also require that manufacturers conduct Phase IV (safety-focused) clinical trials.

[14] Approximately 90 percent of FDA-approved drugs have additional therapeutic uses and "off-label" drug use is common, with estimates ranging from 22 percent to 75 percent (Gelijns, Rosenberg and Moskowitz, 1998; Pfister, 2012; Conti et al., 2013; Bach, 2015; Molitor and Agha, 2018).

generated from testing the drug in the approved (colorectal cancer) or an off-label (ovarian cancer) indication.

2.1.1 ClinicalTrials.gov

Clinical trial sponsors are required to register most clinical trials in a public web-based clinical trial registry, ClinicalTrials.gov.[15] Established under the Food and Drug Administration Modernization Act of 1997 (FDAMA), ClinicalTrials.gov is considered the world's largest clinical trial registry and is seen as providing a near census of non-Phase I clinical trials (Steinbrook, 2004; Zarin et al., 2011).[16] Under existing clinical trial registration requirements, clinical trial sponsors must prospectively report basic clinical trial information (for example, the clinical trial's purpose, design, patient eligibility criteria, location) when the clinical trial is first initiated (see Appendix Figure A2).[17]

Since 2007, ClinicalTrials.gov has contained a clinical results database contains critical clinical trial efficacy and safety outcomes for non-Phase I trials (Zarin et al., 2016). ClinicalTrials.gov's clinical results database is the world's largest clinical trial results repository and has been shown to have meaningful effects in shaping subsequent firm decisions (Aghamolla and Thakor, 2022; Hsu et al., 2022). Under the FDAAA, clinical trial sponsors must submit clinical trial outcomes in a series of simple forms (see Appendix Figure A3). Once submitted, the results are then publicly posted in a standardized and structured format (see Appendix Figure A4). With some exceptions, clinical trial sponsors must submit their clinical trial findings no later than one year after the date of final data collection for the primary outcome measure (the "primary completion date").[18]

While ClinicalTrials.gov is considered the dominant platform for clinical results reporting, firms may reveal clinical trial results through other platforms, such as in conferences, publications, and their own publicly available registries. While the clinical trial registration of clinical trials has

[15] While ClinicalTrials.gov requires the registration of Phase II and III clinical trials, Phase I clinical trials are not required to be registered.

[16] Under the FDAMA and subsequent regulations, such as The Food and Drug Amendments Act of 2007 (FDAAA), all clinical trial sponsors must register all non-phase I interventional studies of drugs, biologics, and devices that have at least one U.S. site, are manufactured in and exported from the United States, or are conducted under an FDA drug application. (Clinical Trials Registration and Results Information Submission Final Rule, 2016). For a comprehensive timeline, see `https://ClinicalTrials.gov/ct2/about-site/background`.

[17] Other policies reinforce ClinicalTrials.gov registration requirements: since 2005, the International Committee of Medical Journal Editors (ICMJE) has required prospective clinical trial registration in ClinicalTrials.gov, or another major clinical trial registry, as a condition of publication. For a detailed timeline, see `https://ClinicalTrials.gov/ct2/about-site/history`.

[18] Delays of up to two additional years are permitted in some cases, such as if the clinical trial sponsors is aiming to seek regulatory approval for a new indication.

become standard practice, concerns about the selective reporting of clinical trial results persist (Bourgeois, Murthy and Mandl, 2010; Hudson, Lauer and Collins, 2016; Miller et al., 2017).

2.1.2 Regulatory Concerns

Concerned that firms may strategically withhold information, regulators have implemented several policies aimed at inducing clinical trial results reporting. For example, failure to submit clinical trial results on ClinicalTrials.gov can lead to FDA-issued fines of $10,000 a day or withholding of NIH grants funds (FDAAA, 2007). In addition to facing fines from the FDA, firms that withhold clinical findings may trigger costly litigation (Marinovic and Varas, 2016). For example, in February 2021, Bristol Myers Squibb and Sanofi were ordered to pay $834 million to the State of Hawaii for violating consumer protection laws by failing to disclose that their drug, Plavix, was less effective for people of Asian or Pacific Island descent in clinical trials. In particular, "the court finds that defendants knew at the time of launch that there was a significant issue regarding diminished patient response to Plavix...for many years defendants deliberately turned a blind eye toward the problem out of concern that addressing it might adversely affect Plavix sales and defendants' profits" (Anderson, 2021).[19]

Despite the threat of a financial penalty, results reporting remains low. For example, Anderson et al. (2015) examine 13,000 clinical trials and find that 38 percent of clinical trials reported results at any time prior to September 2013. In addition to strategic considerations, such as competition, reasons for the relatively low levels of clinical trial results reporting may include the perceived low risk of penalties for non-reporting: until April 2021, the FDA has never publicly threatened to enforce the $10,000 a day civil penalty.[20] Further, while the ICMJE mandates clinical trial registration, results reporting is not a universal prerequisite for publication.

[19] Other well-known examples include: GlaxoSmithKline, which was fined $3 billion by the Department of Justice for concealing safety information associated with its drug, Advandia (Wilson, 2011); and Roche, which is a defendant in a $1.5 billion False Claims Act suit alleging that the firm concealed safety and efficacy information relating to its drug, Tamiflu (Dyer, 2020).

[20] In April 2021, the FDA issued its first non-compliance notice to Acceleron Pharma Inc. for failure to submit clinical trial results to ClinicalTrials.gov (Tanne, 2021).

2.2 Conceptual Framework

We build on a broad literature that examines seller incentives related to disclosure of product quality information.[21] In this section, we discuss three potential mechanisms through which competition may shape firms' disclosure decisions.

Under the first mechanism, competition may shape firms' disclosure decisions through changing their R&D decisions—namely, their incentives to invest in high quality R&D projects. For example, firms may only choose to invest in R&D projects that exceed a given investment threshold of expected product quality. We posit that an increase in competition could lead firms to increase their investment threshold (and thus, only invest in high quality products), as firms attempt to soften the direct (e.g., price) impacts of competition (Shaked and Sutton, 1982). In markets with higher levels of competition, we should thus observe a decline in the overall level of projects and an increase in the quality of the average project.

In the drug development setting, a clinical trial is considered a high quality project if its drug is safe and effective in treating a particular indication.[22] If firms only disclose results for clinical trials that exceed a given disclosure threshold (Viscusi, 1978; Grossman and Hart, 1980; Jovanovic, 1982), competition-driven changes project quality (i.e., an overall decline in the level and an increase in the average project quality) could result in lower levels of disclosure.[23] Under this mechanism, product quality disclosure is simply a proxy for project quality; the effect of competition on disclosure hinges on the effect of competition on project quality.

The existing empirical literature here is mixed: Matsa (2011) and Bennett and Yin (2019) find that higher levels of competition are associated with product quality improvements in the supermarket and the retail pharmacy market, respectively.[24] Focusing on the field of structural biology, Hill and Stein (2021), on the other hand, find that higher levels of competition can lead to racing effects and incentives to obtain first-mover advantages dampen incentives to invest in high quality research projects. Contrasting these studies, Aghion et al. (2005) and Garfinkel and

[21] For an overview, see Milgrom (2008) and Dranove and Jin (2010).

[22] This could also be described as "drug-indication quality." For simplicity, we refer to "drug-indication quality" as "project quality" and "product quality" in the remainder of the paper.

[23] This disclosure threshold can be a function of a variety of factors, including the products' current sales and the risk associated with disclosure (e.g., the likelihood that disclosing negative product quality information will trigger a product recall).

[24] Additional empirical evidence suggesting that competition leads to improvements in product quality include Milgrom (2008); Gaynor (2011); and Bloom et al. (2015).

Hammoudeh (2022) find that product market competition and innovation have an inverted-U relationship.

Under the second mechanism, competition has a more direct role in shaping firms' strategic disclosure decisions. Here, competition increases the strategic relevance of product quality information. In particular, firms seeking to protect their competitive position may seek to withhold product quality information from rivals due to concerns about learning spillovers and market competition. In regards to learning spillovers, the disclosure of product quality information may help rivals navigate their own R&D processes (Krieger, 2021). Firm's product quality information can provide rivals with useful information about potential risks (e.g., drug adverse events), fruitful avenues for future research (e.g., novel indications that might also be treated by the rival's existing drug), and likely payoffs (e.g., probability that a project will ultimately lead to FDA approval). More broadly, the disclosure of product quality information may help rivals minimize R&D investments that are unlikely to be successful, and to redirect resources towards investments that are more likely to be worthwhile. For example, following the safety-related withdrawal of Merck's Vioxx, Pfizer—the producer of Vioxx's competitor, Celebrex—halted existing trials on Celebrex and redirected efforts towards assessing the drug's safety—activities that Pfizer could have avoided or initiated sooner had Merck disclosed Vioxx's safety risks earlier (Solomon et al., 2005; Vonkeman, Brouwers and van de Laar, 2006). Under this strategic disclosure mechanism, firms may strategically withhold product quality information due to concerns that rivals will free-ride off their R&D efforts (Markopoulos and Hosanagar, 2018).

In addition to concerns about learning spillovers, the potential that disclosure could intensify subsequent market competition effects could lead firms to withhold product quality information. For example, a producer of a low quality product may withhold information due to concerns that disclosure may lead stakeholders to update their expectations about the product's quality and lower demand among consumers (e.g., physicians, patients), dampen investor interest, and intensify competition along other dimensions (e.g., price).[25] In the same vein, if disclosure is costly and reveals useful information to stakeholders about a product's quality, a producer of a high quality

[25] A large literature explores how firms can use product quality information to advertise (Azoulay, 2002; Mizik and Jacobson, 2008; Narayanan and Manchanda, 2009; Shapiro, 2018; Sinkinson and Starc, 2019) and complement other signals of product quality, such as prices (Daughety and Reinganum, 1995).

product may fear that disclosure could lead to increased demand for rivals' products (if they are sufficiently similar) (Jin, 2005).

Finally, under the third mechanism, strategic firms' concerns around IP infringement risk connect competition to product quality disclosure. Within competitive R&D-intensive industries, a firm's decision of whether and when to patent is a strategic choice with significant implications for its profits (Mihm, Sting and Wang, 2015).[26] In the pharmaceutical R&D setting, firms may seek to protect their inventions with multiple patents, including product patents (which cover the drug substance) and method-of-use patents (which are typically filed after the product patent and may cover diseases treated by the drug substance) (Masur and Ouellette, 2020; Marandett and Savage, 2021).

While firms face strong incentives to obtain product patents prior to the start of any clinical trials (Budish, Roin and Williams, 2015), firms' face a key trade-off when deciding when to file method-of-use patents and disclosure of related clinical trial results (IOM, 2015).[27] On the one hand, a patenting firm must clearly disclose its underlying invention in its patent application; this may increase the likelihood that the firm publicly discloses related trial results prior to filing its patent. On the other hand, patented inventions must be novel and non-obvious. As a result, in competitive markets, pre-patent clinical trial results disclosure may compromise future method-of-use patents that are based on the clinical data; rivals seeking to invalidate existing competitor patents may argue that pre-patent clinical trial disclosures serve as invalidating prior art.

3 Data

To understand the relationship between competition and disclosure, we begin with data on clinical trials registered on ClinicalTrials.gov. For each clinical trial, we obtain data on the drug being tested (e.g., bevacizumab), the sponsoring firm (e.g., Genentech), sponsor type (e.g., private-sector), and the clinical trial start date (as determined by the date on which the patient is first enrolled).

[26] See, e.g., Anton and Yao (1994); Gans, Hsu and Stern (2008); and Williams (2017). Firms' patenting strategies also have implications for the timing of its financing outcomes (Saidi and Zaldokas, 2021), licensing opportunities (Hegde and Luo, 2018), and acquisition (Chondrakis, Serrano and Ziedonis, 2021).

[27] While firms must file a patent within one year of disclosure (35 USC. 102), whether this disclosure occurs before or after patenting remains less clear.

Our primary market categorization comes from identifying, for each clinical trial, the disease (e.g., eye cancer) being treated.[28,29] ClinicalTrials.gov categorizes clinical trial diseases using Medical Subject Heading (MeSH) codes, a hierarchical controlled vocabulary maintained by the National Library of Medicine. Using MeSH codes to delineate discrete product markets, we generate a trial-MeSH level dataset where we relate a trial's disclosure decision to the level of competition within that MeSH code.[30,31]

We next incorporate data from Clarivate Analytics' Cortellis Competitive Intelligence and Clarivate Analytics' Cortellis Clinical Trials Intelligence (hereafter, "Cortellis") to measure clinical trial disclosure costs (e.g., clinical trial patient enrollment, use of clinical trial services, such as contract research organizations), disclosure demand (e.g., clinical trial duration, phase, market size of the trial disease, sponsor R&D experience, public equity funding), and additional trial characteristics (e.g., molecular mechanism of action).[32]

As a proxy for the market size of trial disease (denoted as "disease market size"), we obtain estimates of national patient diagnoses using the Medical Expenditure Panel Survey database: in particular, for each clinical trial, we count the total number of patients diagnosed in the trial's associated diseases in the year that the trial begins. As a proxy for sponsor R&D experience (denoted as "Sponsor Experience"), we count the total number of clinical trials initiated by the trial's sponsor in the previous five years.

Finally, we make two sample restrictions. First, we focus on clinical trials in Phases II, II/III, and III for four reasons: nearly all non-Phase I trials are required to be registered on ClinicalTrials.gov, they constitute a substantial investment,[33] they assess both critical safety and efficacy outcomes, and they are the focus of clinical trial results reporting regulations (FDAAA, 2007). A second restriction we make is that we focus on clinical trials that start on or after 2007 (when most clinical

[28] An alternative strategy for categorizing markets would be to focus on the drug's underlying technology (e.g., its molecular mechanism of action).

[29] This measure follows an empirical literature that treats drugs within the same disease as likely substitutes and their manufacturers as likely competitors (See, e.g., Allain, Henry and Kyle (2016), Krieger (2021), and Krieger, Li and Papanikolaou (2022) are some recent examples).

[30] To focus on a standard "level" of disease, we focus on 9-digit MeSH codes. Examples include "Eye Neoplasms" or "Pneumonia, Viral." See Appendix B for details.

[31] Using MeSH codes to classify disease markets follows the methodology of prior literature (Azoulay, Graff Zivin and Wang, 2010; Myers, 2020; Azoulay, Greenblatt and Heggeness, 2021).

[32] For example, higher levels of patient enrollment may increase disclosure costs due to the additional costs of collecting, validating, and analyzing trial patient data.

[33] Martin et al. (2017) report that median Phase II and Phase II costs are $8.6 million and $21.4 million, respectively.

trial registration became mandatory) and are completed by 2019 (to allow for at least two years of results reporting). This results in a final sample of 147,413 clinical trial-MeSH observations.

Next, we collect data on clinical trial results disclosure and competition.

Clinical Trial Results Disclosure

Our primary measures of disclosure comes from examining clinical trial results reporting on ClinicalTrials.gov. We focus on two key measures: (i) an indicator for whether results have been reported within two years of clinical trial completion and (ii) time from clinical trial completion to results reporting among clinical trials whose results are reported. To supplement these disclosure measures, we collect additional disclosure data on clinical trial results that are published in a scientific journals and presented at conferences (see Appendix B).

In one set of analyses, we examine how competitor priority drug approvals shape the likelihood that firms invest in clinical trials with high quality design. It is widely believed that the design of a clinical trial plays an important role in shaping the usefulness of the information generated, with better designed trials providing "better signals" of the drug's safety and efficacy (Ioannidis, 2005; Prasad and Berger, 2015). For example, patient randomization, in which patients are assigned to treatment and control arms by chance, allow researchers to generate clinical trial outcomes that are less susceptible to bias from patient selection. We there identify trials with high quality design as those with: patient randomization, double-blinding, randomized and double-blinding, and use of an active control.[34]

Competition

We generate two types of product market competition measures using clinical trial and FDA drug approval data from ClinicalTrials.gov, Cortellis, and Drugs@FDA.[35] Our first type of competition measure focuses on trial-based competition: for each trial-MeSH observation, we determine the number of unique competitor clinical trials previously tested in the same MeSH code in the five

[34]There are different types of control arms, with active control drugs (for example, use of standard of care) considered to be a more rigorous threshold compared to placebo control drugs.

[35]Competition can be described based on product market competition and technology competition (Krieger, 2021). This paper focus on the effects of product market competition, though an analyses that incorporates rivalry generated from technology competition would be a valuable extension to consider in future work.

years prior to the start of the focal clinical trial.[36] For any given clinical trial intervention, focusing on competitor clinical trials in the previous five years, rather than all clinical trials, allows us to isolate the set of products that are more likely to use comparable drug development technologies and constitute a competitive threat.

Our second type of measure is based directly on drug-based competition: for each trial-MeSH observation, we identify competitor FDA drug approvals within the same MeSH code. In the following analysis, we utilize both the staggered arrival of competitor drug approvals and the total number of drugs previously approved in the same MeSH code (similar to the trial-based competition measure) to document the relationship between competition and disclosure. To focus on the subset of drug approvals that constitute a major shock to competition, we focus on the subset of primary drug approvals with priority review status, drugs that the FDA determines are likely "significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions."[37]

Summary Statistics

Table 1 presents trial-MeSH level summary statistics for the main trial features. Panel A documents substantial underreporting of clinical trial results: roughly 30 percent of trial-MeSH observations report results in ClinicalTrials.gov within two years of clinical trial completion. Appendix Figure C1 shows that 20 percent of clinical trials in the sample have submitted clinical trial results within 12 months of the study's primary completion date (and meet the results reporting deadline mandated by the FDAAA). Appendix Figure C2 shows that while clinical trial reporting rates have increased between 2000 and 2016, they just exceed 25 percent and have been declining in recent years. Panel A of Table 1 also shows that there are substantial delays in clinical results reporting: conditional on reporting results, clinical trial sponsors typically take more than two years to report results to ClinicalTrials.gov.

Table 1, Panel B describes the competitive environment for each trial-MeSH. The first measure of competition (the trial-based measure) shows the average trial-MeSH faces roughly 180 trial-MeSH

[36] This method follows the logic of prior literature (Krieger, 2021; Cunningham, Ederer and Ma, 2021).

[37] https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review

tested in the same MeSH code in the prior five years.[38] Looking to the second measure of competition (the drug-based measure), we see that roughly 30 percent of trial-MeSH are initiated in a MeSH code where a competitor priority review drug has been approved.

4 Impact of Competition on Disclosure

We begin by comparing results disclosure across trial-MeSH that vary in their level of competition. Our primary empirical strategy is aimed at examining how clinical trial results disclosure varies across competition levels. This empirical strategy rests on the assumption that trial-MeSH facing relatively higher levels of competition are comparable to trial-MeSH facing relatively lower levels of competition. [39] For trial-MeSH observation id, we estimate the following:

$$Disclosure_{id} = \beta_1 Competition_{id} + \boldsymbol{\gamma'} \boldsymbol{X_{id}} + \delta_d + \epsilon_{id} \tag{1}$$

where $Disclosure_{id}$ is a measure of clinical trial results reporting (for example, an indicator for whether trial results are reported within two years following clinical trial completion). Focusing first on the effects of trial-based competition, $Competition_{id}$ is the log of one plus the number of competitor clinical trials initiated in MeSH code d within five years prior to the start of clinical trial i, and the coefficient β_1 is the main estimate of interest.[40]

To control for differences in scientific opportunities, market demand, and disclosure costs, our main regressions include disease (MeSH code) fixed effects (δ_d) and detailed clinical trial controls ($\boldsymbol{X}_i$) for disease market size, sponsor experience, patient enrollment, duration, and phase. While common scientific and market opportunity shocks are unlikely (Krieger, 2021), we include year fixed effects in $\boldsymbol{X}_i$.

Table 2 shows the relationship between competition and disclosure. We show estimates from OLS linear probability models and reported heteroskedasticity-robust standard errors clustered at the MeSH code.[41] Column 1 documents a negative correlation between competition and the

[38] Appendix Figure C3 demonstrates the substantial variation in competition across trial-MeSH observations.

[39] Appendix Figure C4 show that clinical trials in high and low competition markets appear ex ante different on several observable factors: clinical trials in more competitive markets are associated with trial sponsors with less R&D experience, more patients, and more likely to be Phases II-III or III. We control for these differences in Equation (1).

[40] In Appendix B, we show our results are robust to alternative measures of competition.

[41] Logit models yield very similar results, but linear probability models allow us to include more controls.

probability of clinical trial results reporting in ClinicalTrials.gov within two years following clinical trial completion. The estimated coefficient in Column 1 implies that a 10 percent increase in competition is associated with a 3.5 percent ($\approx 10 \cdot \frac{-0.119}{100} \cdot \frac{1}{0.336} \cdot 100$) decrease in the probability of clinical trial results reporting.[42] Controlling for market size (Column 2) and additional trial characteristics (Column 3) does little to change the competition-reporting estimates.

Columns 4-6 report the impact of competition on time to clinical trial results reporting on ClinicalTrials.gov. The estimated coefficient in Column 6 suggests that a 10 percent increase in competition delays is associated with a roughly 0.7 percent increase in time to results reporting. These findings suggest competition is associated with a negative and statistically significant decrease in the speed with which firms disclose clinical findings to the public. Figure 1 illustrates the relationship between competition and our two dislosure measures.

4.1 Robustness Checks and Extensions

Appendix B provides a detailed discussion of robustness checks and extensions on these correlations. In the interest of space, we present a summary of our six main findings. First, we confirm that the competition-disclosure correlations are robust to other dimensions of disclosure: competition leads to delays in trial registration on ClinicalTrials.gov (Appendix Table B1) and reporting in publications and conferences (Appendix Figure B1 and Table B2). Second, we show that the competition-disclosure correlations are found across all clinical trial phases, though the effects are more pronounced among Phase II and II-III clinical trials (Appendix Figure B3). Third, Appendix Tables B3 and B4 demonstrate the robustness of our findings to alternative measures of competition such as firm-based and drug-based competition counts. In Section 4.4, we further explore the causal effects of drug-based competition using the arrival of competitor drug approvals. Our fourth set of robustness checks is motivated by the fact that a single trial can be linked to multiple MeSH codes (e.g., a trial may test a drug in multiple conditions).[43] Appendix Table B5 verifies that our results are results are robust to using an alternative trial sample and alternative strategies for linking trials to diseases. Fifth, Appendix Table B6 shows our results are robust

[42] While we include disease fixed effects, our main results are robust to the exclusion of disease fixed effects, suggesting that the negative competition-disclosure relationship exists both within and across diseases.

[43] For example, a trial assessing the treatment of a therapy that targets BRCA 1/2 gene mutations may enroll ovarian cancer and breast cancer patients with BRCA 1/2 gene mutations.

when controlling for contract research organizations, which may change drug manufacturers' clinical trial reporting costs (Mirowski and Van Horn, 2005). Finally, to demonstrate that the estimated correlations between competition and disclosure are unlikely to be statistical noise, we run 2,000 placebo experiments where we randomly reassign trial-based competition levels across different trial-MeSH. Appendix Figure B4 confirms that the estimated t-statistic from original data (as shown in Column 3 of Table 2) is substantially more negative than all 2,000 placebo test estimates.

4.2 Interpreting the Correlations between Competition and Disclosure

The previous analyses document a striking negative correlation between competition and disclosure. However, concerns around unobservable factors (e.g. heterogeneity in demand or scientific opportunities) may limit the causal interpretation of the results. While regression controls, such as disease fixed effects, mitigate some of these concerns, unobservable factors may continue to drive these correlations. In the following analyses, we address these concerns directly by conducting two empirical tests to document causal evidence that competition lowers firms' incentives to disclose product quality information.

4.3 Clinical Trial Funding Design

Before turning to the quasi-experimental evidence, we first probe the relationship between competition and clinical trial results disclosure by contrasting responses to competition among private-sector and public-sector clinical trials. For this analysis, we restrict our analysis to the set of clinical trials that are solely privately sponsored and those that are solely publicly sponsored, resulting in 82,233 trial-MeSH observations.[44]

Given the different objectives of private-sector institutions and public-sector institutions (e.g., private-sector institutions may be more profit-oriented while public-sector scientists may be focused on prestige and credit), we expect that private-sector clinical trials may be more responsive to changes in competition relative to public-sector clinical trials. Consistent with our expectations, cumulative distribution functions confirm that the private-sector clinical trials are substantially

[44]Clinical trials that are excluded include trials that are sponsored by academic institutions or are conducted by individual investigators. This follows the methodology of Budish, Roin and Williams (2015).

more likely to delay clinical trial results reporting (Appendix Figure D1). Formally, we estimate:

$$Disclosure_{id} = \beta_1 Competition_{id} \times F_i + \lambda F_i + \beta_2 Competition_{id} + \boldsymbol{\gamma' X_{id}} + \delta_d + \epsilon_{id} \quad (2)$$

where F_i is an indicator for whether clinical trial i is a private-sector trial. The coefficient of interest is β_1 documents whether the competition-disclosure relationship is larger in the sample of private-sector clinical trials. Consistent with the idea that disclosure decisions are profit-driven, Table 3 implies that the effect of competition is more significantly negative for private-sector clinical trials. Columns 1 and 2 examine the correlation between competition and results reporting within two years following clinical trial completion. The estimated coefficient in Column 2 implies that the competition-disclosure correlation is roughly 25 percent ($\approx \frac{-0.02}{-0.02-0.06} \cdot 100$) larger for private-sector clinical trials relative to public-sector clinical trials. The results are similar for time to results reporting (Columns 3 and 4). In particular, Column 4 shows that the competition-time to results reporting correlation is 133 percent ($\approx \frac{0.04}{0.04-0.01} \cdot 100$) larger for private-sector clinical trials relative to public-sector clinical trials. Based on these findings, we focus on private-sector clinical trials for the remainder of this paper.

We explore the role of funding further by examining how the effect of competition on disclosure differs among private-sector firms that are funded by public equity (e.g., shareholders) and those that are funded by private equity (e.g., venture capital). As with public-sector and private-sector firms, the disclosure incentives may differ across firm types: for example, public-equity firms may be more subject to greater regulatory scrutiny and have more formalized disclosure requirements relative to private-equity firms.[45,46] Consistent with the idea that public-equity firms' may be primarily driven by regulatory (and not competitive) concerns, Appendix Figure D2 shows that clinical trials sponsored by public equity-funded firms are less subject to competitive distortions in disclosure, relative to clinical trials sponsored by private equity-funded firms. However, we note that the differences are not statistically significant, likely due to the smaller sample size.[47]

[45] For an overview of how financing may shape innovation, see Kerr and Nanda (2015).

[46] The Securities and Exchange Commission rule Regulation Fair Disclosure requires publicly-listed firms to report material information to shareholders.

[47] We are able to determine whether a private-sector clinical is funded by public equity or private equity for 83 percent of the private-sector clinical trial sample.

Finally, to address concerns that that the types of product markets that the private-sector invests are fundamentally different from the markets invested by the public-sector (David, Hall and Toole, 2000), we document that are results are robust to restricting our analysis to the set of MeSH codes that have both private-sector and public-sector clinical trials (Appendix Table D1). However, one may still be concerned that unobservable factors (for example, market demand) are driving these results. To address these concerns, we now turn to a second empirical test that documents the causal relationship between competition and disclosure.

4.4 Difference in Differences Design

Our second empirical analysis examines how an exogenous increase in competition in the form of a competitor drug approval shapes clinical trial results disclosure. Consistent with the previous empirical evidence, we document that a drug approval for a disease has a quantitatively and statistically significant negative effect on clinical trial results reporting within the same disease.

For this analysis, we use uncertainty in the drug approval process as a source of plausibly exogenous variation in product market competition to examine the effect of competition on results reporting. Variation in competitor shocks (drug approvals) allow not-yet-treated trial-MeSH observations to serve as a plausible control group.[48,49] We focus on competitor priority review drug approvals as they constitute a large positive shock to competition relative to standard competitor drug approvals (Gilchrist, 2016).[50, 51]

A key assumption underlying this analysis is that firms do not anticipate the timing of competitor priority review drug approvals (Krieger, 2021). This view is supported by the large uncertainty in the exact timing in which competitor priority review drugs are approved: the regulatory review period

[48] The control group consists of trial-MeSH observations that are not yet in diseases with a competitor drug approval.

[49] An alternative to competition-increasing events, such as drug approvals, are competition-reducing events, such a drug withdrawals (recall Vioxx). Given the relative rarity of such events, we focus on drug approvals.

[50] Appendix Figure E1 documents the trend in priority review drug approvals over time. Appendix Figure E2 shows that by 2020, 18 percent of trial-MeSH observations experience a competitor priority review drug approval in the same MeSH code.

[51] A natural concern is that a priority review drug approval may make it more difficult for competitors to subsequently enter the same product market (e.g., the newly approved drug may become the standard of care and an active control in future clinical trials). However, the analysis in Section 5.1 suggests that priority review drug approvals has limited effects on rivals' subsequent R&D efforts. Further, the displacement of existing standard of care therapies by newly approved drugs can be relatively rare and likely occurs over a time horizon that exceeds firms' the timing of disclosure responses (which take place over one to two years) (Benjamin et al., 2022).

for a priority review drug average 226 days, with a standard deviation of 74.[52] Further reducing any concerns is that anticipatory effects would attenuate our results and an analysis of pretrends leading up to a competitors' priority review drug approval yields little support for anticipatory effects (Figure 2).

To test the effect of competitor priority drug approvals, we estimate the following specification:

$$Disclosure_{id} = \beta_1 PostCompetitorDrugApproval_{id} + \boldsymbol{\gamma'} \boldsymbol{X_{id}} + \delta_d + \epsilon_{id} \tag{3}$$

where $PostCompetitorDrugApproval_{id}$ is an indicator for whether a competitor priority review drug approval has occurred in MeSH code d by the start of clinical trial i.[53] The remaining variables are as in Equation (1). Our coefficient of interest is β_1 which represents the causal effect of a competitor priority review drug approval on disclosure within the same MeSH code. In particular, β_1 measures the average difference in disclosure in treated and control trial-MeSH before and after a competitor priority review drug approval, conditional on controls. We focus on the set of competitor priority drug approvals that have been approved after 2004 (i.e., within two years of the start of our trial sample) as we want to consider the effects of competitor drug approvals that occur even before the start of our earliest trial.

We present our key DiD results in Table 4. Columns 1-3 shows that competition in the form of a competitor priority review drug approval decreases clinical trial results reporting. In particular, a competitor priority review drug approval decreases the probability of results reporting by roughly 13 percent ($\approx \frac{-0.053}{0.41} \cdot 100$). To explore the timing of the estimated impact on the probability of results reporting, we estimate an event study version of Equation (3) where the single indicator variable $PostCompetitorDrugApproval_d$ is replaced with a vector of indicator variables for two-year bins before and after the first competitor priority review drug approval in the focal MeSH code. Providing evidence for our identification strategy, Panel A of Figure 2 shows that the probability of results reporting does not change differentially across trial-MeSH before the competitor priority review drug approval. However, the probability of results reporting declines differentially for trial-MeSH

[52] Supporting the view that priority and non-priority drug approvals face similar variation in timing uncertainty, the level of efficacy and safety evidence required for priority review approval is the same as that of non-priority review drug approvals.

[53] Trials that are initiated before the competitor drug approval and concluded after it may also respond to the arrival of a competitor drug approval. Our main results are robust to the inclusion of on-going trials evaluating "contemporary" drugs (i.e., those that were previously initiated within one year of the competitor drug approval).

that experience a competitor priority review drug approval and remains lower afterwards. Firms to shift disclosure decisions relatively quickly: firms lower their results reporting within two years of a competitor drug approval. Consistent with these results, Column 6 of Table 4 and Panel B of Figure 2 shows that a competitor priority review drug approval leads to delays in the time to results reporting among disclosing clinical trials.[54]

As a robustness check, we investigate concerns about MeSH-level selection in Appendix Figure E3 by comparing a proxy for disclosure cost—publications—among MeSH codes with early competitor priority review drug approvals (i.e., before the median drug approval date) and MeSH codes with late or no priority review drug approvals between 1990 and 2006. As expected, the figure shows that MeSH codes with early competitor priority review drug approvals are associated with higher publication levels; we control for these differences with MeSH code fixed effects in our regressions. Further, Appendix Figure E3 shows that differences in disclosure costs do not change substantially over time suggesting that when MeSH code fixed effects are included, MeSH-level selection is unlikely to bias our results.

4.5 Signaling Quality of Disclosed Information: Clinical Trial Design

In addition to the likelihood and timeliness of clinical trial disclosure, could competition influence the quality of the disclosed information? Using data on clinical trial design, we document whether competition shapes firms' incentives to provide "useful" signals of the clinically tested drug's quality.

For this analysis, we examine how competitor priority drug approvals shape firm investment in clinical trials with high quality design. Table 5 shows that, across all clinical trial design measures, a competitor priority review drug approval leads to a decline in the likelihood that firms invest in clinical trials with high quality design. For example, the estimated coefficient in Column 1 implies that a competitor priority review drug approval is associated with a 1.6 percent ($\approx \frac{-0.0147}{0.921} \cdot 100$)

[54] A recent literature has shown that difference-in-differences models where the treatment is staggered over time generate a weighted average of all possible pairwise difference-in-differences estimates, with the possibility that observations are already treated are used as a control for observations that are later treated. This can result in negative weights used in the calculation of the treatment effect (de Chaisemartin and D'Haultfoeuille, 2020; Borusyak, Jaravel and Spiess, 2021; Sun and Abraham, 2021). In addition to estimating event study-style specifications, we address these concerns in two additional ways. First, we estimate Equation (3) excluding trial-MeSH that are always treated. Second, in the spirit of Goodman-Bacon (2021), Callaway and Sant'Anna (2021), and Prager and Schmitt (2021), we estimate a separate regression for each cohort (where each cohort is the set of trial-MeSH that experience a competitor priority review drug approval in the same calendar year) and take the weighted average of the cohort-specific estimates, where each weight is the cohort's share of all treated observations. These estimates are consistent with the baseline drug approval estimates (see Appendix Table E1).

decrease in the probability that the clinical trial is randomized. Quantitatively, these estimates are small, likely due to factors (e.g., regulatory expectations) that provide bounds on which firms may shift the quality of their clinical trial design. However, these trial design findings are consistent with our main findings—on the probability and timeliness of results reporting—that competition dampens firms' disclosure incentives.[55,56]

5 Mechanisms

As we discuss in Section 2.2, the negative relationship between competition and product quality disclosure can be driven by several mechanisms: first, competition may lead to a decline in the investment of high quality R&D projects. Second, concerns regarding positive R&D spillovers and market competition effects may cause firms to withhold their clinical trial results, holding project quality fixed. Finally, firm may seek to withhold their clinical trial results in order to minimize lower IP infringement risk. In this section, we analyze each of these mechanisms.

5.1 R&D Project Quality

To study whether competition shapes firms' R&D decision—in particular, the likelihood that they invest in high quality R&D projects—we begin by identify clinical trials that are high and low quality. In the pharmaceutical setting, R&D projects are considered high quality if they successfully advance to the next stage in the development and approval process (Krieger, 2021; Garfinkel and Hammoudeh, 2022). Thus, we construct phase-specific clinical trial advancement measures using our trial-MeSH sample. For example, our measure of a successful Phase II clinical trial is one that successfully advances to Phase III. Similarly, successful Phase III trial advancement is denoted by approval of the trial's drug. All other clinical trials are considered terminated and low quality.[57] Using this data and modifying Equation (3) to include controls for clinical trial design quality, we

[55] Of course, firms may invest in low quality clinical trial design for strategic reasons (e.g., to generate larger treatment effects). While not the focus on the paper, a deeper analysis into firms' strategic decisions to invest in high vs. low quality clinical trial design is a promising avenue for future research.

[56] We cannot rule out that competition may make it more costly to design high quality trials. For example, competition for trial patients may make it more difficult to run randomized trials, which typically require larger patient populations. However, this is of limited concern as our results are robust to controlling for enrollment size and we find impacts on trial design that are unrelated to trial size (e.g., the likelihood that the trial is double-blind).

[57] The algorithm used to construct phase-specific clinical trial advancement measures requires us to rely on the set of clinical trials that are mapped to standardized Cortellis drug and firm names. This results in a final "trial advancement dataset" of 97,438 trial-MeSH observations.

examine how a competitor drug approval shapes the likelihood that a clinical trial successfully advances to the next stage.[58,59]

Consistent with the view that competitor priority review drug approvals do not shift firms' incentives to invest in high quality projects, we find no statistically significant relationship between competition and the likelihood that a clinical trial advances to the next stage (Table 6).[60] Supporting these results, we find that our main findings—that competition leads to a decline in subsequent disclosure—is robust to a disease-level analysis that holds the level of clinical trial investment fixed (Appendix Table F1).[61] This suggests that in our setting, competition has limited effects on firms' R&D decisions. In particular, a competition-driven decline in project quality is unlikely to be a primary channel through which competition shapes disclosure. One reason for this is that competitive pressures are immediate while the decision to shift R&D priorities may operate over longer horizons. For example, we document that competition-driven changes in disclosure can occur within one to two years. In contrast, firms may take more than four years to reach clinical trial testing (from preclinical testing) (DiMasi, Hansen and Grabowski, 2003).

5.2 Strategic Disclosure

We next test whether firms strategically disclose their results, keeping project quality constant. For this analysis, we examine whether competitor priority review drug approvals lead to a decline in results reporting in the sample of low quality projects (R&D projects that are terminated) and the sample of high quality projects (R&D projects that successfully advance). Table 7 shows that

[58] Of course, there may instances where firms may not seek approval for the drug because their primary aim of the trial is to generate clinical evidence to expand off-label drug use (as described in Section 2). However, we expect this to constitute a small portion of the trials in our sample.

[59] One may be concerned that right hand censoring may bias our results. However, our regressions include controls for year fixed effects and we use drug approval data that extends to 2022, thus reducing concerns about biased estimates.

[60] These results contrast the findings of Garfinkel and Hammoudeh (2022), which finds that increases in competition (as measured by the FDA's designation of a rival's drug as a breakthroughs) is associated with the overall decline in the likelihood that a clinical trial advances to the next stage. Our analysis differ from Garfinkel and Hammoudeh (2022) in several key ways: we focus on shocks to competition driven by the *approval* of a rival drug with priority review status (not the designation of drug as a breakthrough); we include disease fixed effects in our models to capture differences in the product category innovativeness and market perceptions; and we examine trial advances for both Phase II and Phase III trials.

[61] We complement this analysis by examining the direct effect of competition on the total number of clinical trials (for brevity, results not shown). Consistent with the findings in Appendix Table F1, we find inconclusive results.

the estimated β_1 coefficients generated from both terminated (Column 1) and successfully advanced (Column 2) R&D projects are negative, statistically significant, and similar in magnitude.[62]

One might be concerned that the reporting of results from low quality projects may be driven by non-strategic considerations, such as cost. For example, small firms may not report the results of a terminated R&D project because of insufficient resources to collect, validate, and analyze trial patient data. While the previous estimates directly control for sponsor experience, we next formally study how the relationship between project quality, competition, and disclosure varies by the level of firm resources. First, we split the sample of clinical trials by those conducted by small and large firms as defined by trial sponsors with below and above, respectively, median levels of prior research experience. Appendix Table F3 confirms that the negative effect of competitor priority review drug approvals holds among terminated and advanced R&D projects for both small and large firms (though the effect among advanced R&D projects conducted by small firms is not statistically significant, likely due to the small sample size).

Taken together, the evidence suggests that the disclosure of product quality information can be a strategic choice. These results support the view that non-disclosure is not simply a signal of low product quality (or bad news); faced with competition, firms may restrict the disclosure of information about both low *and* high quality projects to maintain their competitive advantage.[63]

Although data limitations prevent us from examining how the competition-disclosure relationship varies with continuous measures of project quality, if competition leads to lower disclosure of the lowest quality trials and highest quality trials, the relationship between product quality and disclosure may be an inverted U-relationship. Indeed, on average, higher levels of product quality are associated with more disclosure (see Appendix Table F4). However, the findings in Table 7 suggest that these averages may mask important nonmonotonicities driven by strategic firm decisions.

[62] Appendix Table F2 shows that are results are robust to controlling for drug novelty (Krieger, Li and Papanikolaou, 2022).

[63] A natural next question is: can external parties (e.g., consumers, investors, competitors) infer that a project is not worth pursuing if firms' withhold information from terminated R&D projects? The evidence here suggests that this unclear: competition is not correlated with project quality (recall Table 6). Further, while project continuations are likely correlated with underlying project quality, the signal of project terminations is not always clear (Krieger, 2021). For example, firms may decide to terminate promising R&D projects due to unexpected market conditions. Measuring the marginal effects of non-disclosure on stakeholder perceptions of product quality remains a fruitful area of future research.

5.3 Intellectual Property Infringement Risk

The existing analyses suggest competition plays a direct role in shaping firms' strategic disclosure decisions. In this section, we examine whether firms' concerns around IP infringement risk also creates a link between competition and disclosure. In this analyses, we test the effect of competition on the relative timing of firms' patent filing and clinical trial results disclosure decisions.

We obtain relevant method-of-use patents from the FDA's Orange Book.[64] Next, we obtain patent filing dates from the United States Patent and Trademark Office (USPTO) and patent characteristics from Cortellis Competitive Intelligence.[65] Firms typically file patents for drugs and their uses (not clinical trials), so our preferred specification will be at the trial-MeSH-drug-patent (rather than the trial-MeSH) level. For comprehensiveness, we also show results at the trial-MeSH level and observe similar findings. To identify settings where the threat of patent challenges from rivals is most salient, we switch from a dynamic concept of recent competition to, instead, a static concept of historical (pre-2000) competition based on the level of competitor clinical trial activity within the focal disease.

We begin by comparing trial disclosure-patent delays (between the clinical trial results reporting date and patent filing date) across low (below median) and high (above median) competition settings. High levels of competition are associated with greater delays between patent filing and clinical trial results reporting. Panel A in Figure 3 shows that, within our preferred (trial-MeSH drug-patent) level analysis, clinical trial results are reported 23 months, on average, later in high competition settings relative to low competition settings. Panel B in Figure 3 shows that our results are similar if we perform the analysis at the trial-MeSH level and examine the average time between patent filing and clinical trial results reporting.

To study more formally how competition relates to the relative timing of patent filing and clinical trial results reporting, we construct an indicator variable for whether a clinical trial's result are reported before its patent is filed. Column 1 in Appendix Table F5 implies that clinical trial

[64] The FDA's Approved Drug Products with Therapeutic Equivalence Evaluation (the Orange Book) provides a census of patents associated with each approved drug. Under the Hatch-Waxman Act of 1984, firms are required to report all patents for approved drugs. As a result, we limit this analysis to the set of clinical trials testing approved drugs.

[65] We focus on the patent priority date (sometimes called the "effective filing date"), which is the first date that the patent applicant seeks IP protection and the date that the obviousness and novelty of the patent is assessed. For simplicity, we refer to the "patent priority date" as the "filing date."

disclosure-patent delays are on the order of 70 percent ($\approx \frac{-0.0108}{0.0153} \cdot 100$) greater in high competition settings. Taken together, this evidence provides support for the idea that that firms' patenting strategies are a mechanism through which competition shapes clinical trial results reporting.

6 Conclusion

This paper considers the impact of market structure on firms' product quality disclosure decisions. Using the pharmaceutical industry as our setting, we document causal evidence that competition hinders the probability and timeliness of product quality information disclosure. These findings are supported by two tests. First, the effect of competition on subsequent clinical trial results reporting is driven by private-sector clinical trials. Second, a competitor drug approval lowers the likelihood that clinical trials results are reported by 13 percent. Providing additional support for the view that competition lowers disclosure, we show that competition leads to a decline in the signaling quality of the disclosed clinical information.

Using detailed data on clinical trial advancements and patents, we provide several sources of evidence which together are consistent with the view that disclosure is a strategic decision that increases in relevance in the presence of competition. We find that firms may selectively disclose information in response to the threat of positive knowledge spillovers, product market competition, and IP enforcement challenges. We find limited evidence that non-strategic considerations shift firms' disclosure incentives: competition has little effect on the overall quality of subsequent projects, suggesting that declines in project quality are unlikely to be the primary channel through which competition leads to declines in product quality disclosure. Taken together, these findings represent a significant step towards a deeper understanding of the mechanisms that shape the relationship between competition and the complete and timely disclosure of product quality information.

Our analysis has several limitations and points to several opportunities for future research. For example, we primarily focus on how competition shapes disclosure on the extensive margin—i.e., the decision of firms to disclose *any* clinical trial results. However, competition may shape disclosure decisions regarding the *amount* of information that firms choose to report. For example, firms may selectively collect and disclose information on a narrow set of critical clinical trial outcomes, rather than the complete set of FDA-recommended clinical endpoints. In addition, while trial

sponsors have strong incentives to register their clinical trials on ClinicalTrials.gov (recall the clinical trial registration requirements discussed in Section 2.1.1), there may be incomplete clinical trial registration. To the extent that this incomplete registration is correlated with our competition measures, our estimates may not fully capture the competition-driven shifts in firms' R&D decisions. Even though we also examine how competition shapes the signaling quality of the information disclosed, data limitations prevent us from characterizing extensive margin disclosures at scale and from identifying clinical trials that are not registered. Accordingly, these data limitations should be taken into account when interpreting the implications of our findings.

Further, while we focus on clinical trial reporting across several platforms (e.g., ClinicalTrials.gov, in scientific journals, and at a major medical conference), disclosure can take place through many other communication channels—for example, via firm websites, press releases, financial filings, or social media. What are the unique incentives associated with results reporting across these channels? In general, is the model of industry results disclosure (which may prioritize disclosure in financial filings) different from academic results disclosure (which may prioritize disclosures in publications and at conferences)? We hope future work can incorporate reporting across alternative communication channels and shed light on these topics.

While a full welfare analysis is beyond the scope of our study, our finding that competition leads to a strategic decline in product quality disclosure has important managerial and regulatory implications.[66] A simple back-of-the-envelope calculation shows that if there was no effect of competition, there would have been 1,374 private-sector trials that would have publicly reported their results within two years following clinical trial completion. This translates into clinical trial results reporting from $20.6 billion investments in clinical trials.[67] Our results suggests that in

[66] A complete welfare analysis that explores the relationship between competition, results reporting, product quality, pricing, and firm outcomes and considers the optimal amount of results disclosure remains a promising area for future research. There is a broad literature in economics, finance, and accounting that studies optimal disclosure. See Healy and Palepu (2001) for a review and Szydlowski (2021) for a recent contribution.

[67] We calculate these estimates using the number of private-sector trials that were "treated" by the priority review competitor drug approvals. There were 21,141 trial-MeSH observations that were tested in a MeSH code where a competitor priority review drug was previously approved. Table 4 shows that a competitor drug approval lowers the likelihood that a trial reports its results within two years following clinical trial completion by 13 percent. This suggests that 2,748 ($\approx$21,141 $\times$ 0.13) trial-MeSh observations will not disclose results. To convert this to the trial level, we note that trials are typically associated with 2 MeSH codes. Converting trial-MeSH observations to the trial level gives 1,374 trials. To estimate the dollar value associated with these 1,374 trials we take the average of the reported Phase II and Phase III costs ($15 million per trial) from Martin et al. (2017), which results in an estimated $20.6 billion.

competitive markets, firms' disclosure strategies play an important role in minimizing the risk of knowledge spillovers, competition effects, and patent invalidation.

Indeed, firms can design disclosure strategies that maintain their competitive position while taking into account the environment's regulatory requirements. To illustrate, we compute a back-of-the-envelope calculation for an estimate of the fines associated with missing reporting on ClinicalTrials.gov: at $10,000/day, the penalty for withholding results of a clinical trial for one year is $3.65 million. This yearly penalty is small in comparison to potential yearly drug revenues lost through disclosure: the 2021 revenues for AbbVie's Humira is $20.7 billion, Merck and Co's Keytruda is $17.2 billion, and Bristol Myers Squibb's Revlimid is $12.8 billion.[68] Against this backdrop, managers should convey the strategic nature of their disclosure decisions to employees and investors.

In additional to their strategic disclosure decisions, R&D managers can draw insights to improve their R&D practices. Given the substantial costs and uncertainties in the R&D process, the ability of R&D managers to effectively incorporate external knowledge is essential (Cohen and Levinthal, 1990; Cockburn, Henderson and Stern, 2000). R&D managers considering whether to initiate, terminate, or advance a research project may look to competitors' R&D outcomes (Krieger, 2021). To the extent that R&D managers rely on external information generated from clinical trials, these findings demonstrate that R&D managers may want to consider the fact that the set of publicly available clinical evidence is strategically determined, and that in some contexts, deviations from competitors' revealed R&D outcomes may be more optimal.

For regulators, the impact of disclosure policies depends on the strategic and competitive environment in which firms operate. In particular, the impact of disclosure policies may be reduced in highly competitive settings. Concerns around transparency are widespread in the healthcare industry (for a recent example, see Chao and Larkin (2022)). For example, the Centers for Medicare and Medicaid Services (CMS) launched the Physician Compare website in 2010 in response to concerns about consumer access to information about physician quality and performance. However, despite the low cost of reporting, only 23% of physicians reported quality information. Our findings

[68] A complete analysis that incorporates the full set of potential fines (e.g., fines associated violating consumer protection laws) and the probability of receiving a fine remains an important area for future research.

suggest that competition may be an important factor in explaining low physician participation (Li, Das and Chen, 2019).

Though the pharmaceutical industry makes an ideal setting for our analysis, these results have important implications for how regulators encourage information disclosure in any innovation-driven setting with high uncertainty. Examples of limited voluntary disclosure of product quality information are widespread in health care and other industries (for example, food, electricity, finance, politics).[69,70] As policymakers consider how best to incentivize the voluntary disclosure of proprietary information, incorporating the effects of market structure on firms' disclosure strategies is essential.

[69]See Li, Das and Chen (2019) (physician quality); Mathios (2000) (nutrition labeling); Bae (2014) (environmental performance among electric utilities); Jiang et al. (2022) (finance); Hoffmann, Inderst and Ottaviani (2020) (politics).

[70]That said, policymakers should exercise caution when designing transparency policies. If the goal is to increase stakeholder access to product quality information, blanket policies on disclosures (such as mandatory results reporting) may be ineffective.

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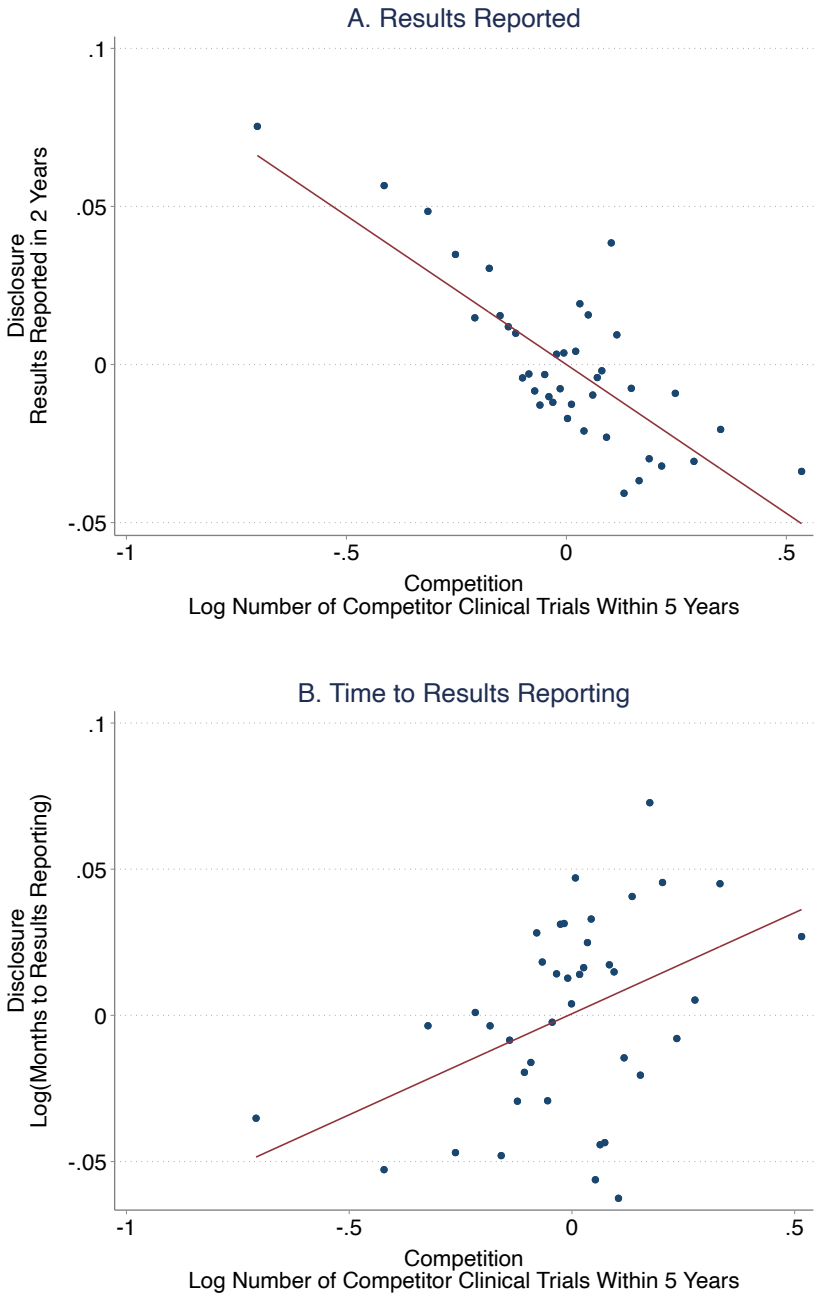
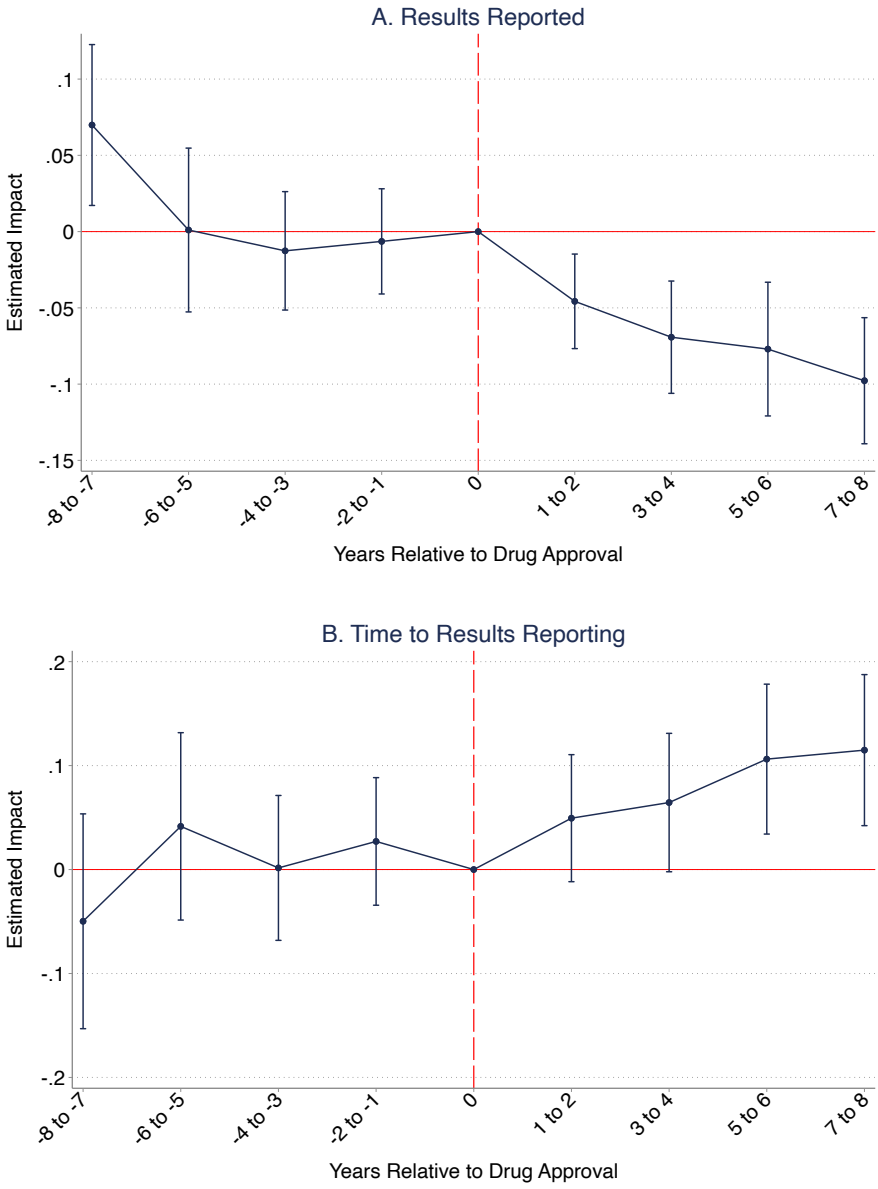
FIGURE 1: COMPETITION AND DISCLOSURE



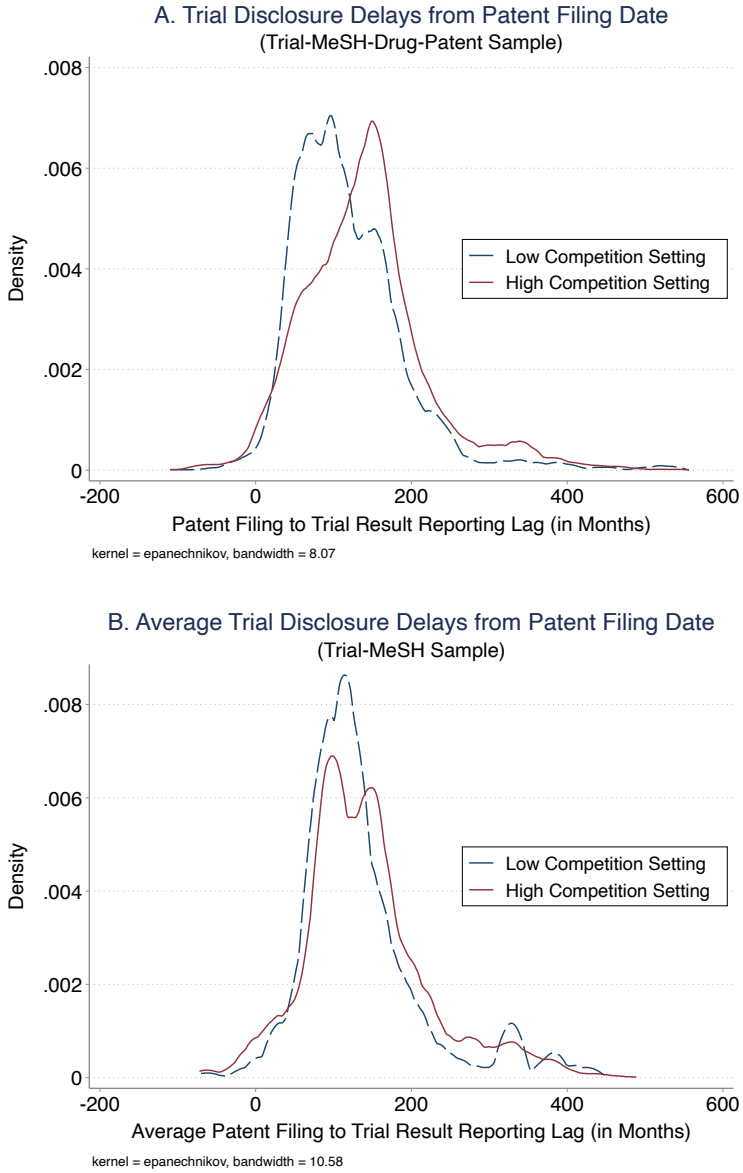
NOTES: This figure shows the relationship between competition and clinical trial results reporting. The sample consists of clinical trials initiated on/after 2007 and completed by 2019. The level of observation is at the trial-MeSH. Competition for a trial-MeSH is measured by the log of the number of competitor clinical trials initiated in the same MeSH code within the previous five years. Panel A shows a binscatter plot of the residualized likelihood results reporting in ClinicalTrials.gov within two years of the clinical trial completion date against the trial-MeSH's residualized competition. Panel B shows a binscatter plot of the residualized time to results reporting in ClinicalTrials.gov from the clinical trial completion date against the trial-MeSH's residualized competition. Residuals are conditional on the year fixed effects, MeSH code fixed effects, sponsor experience, trial phase, clinical trial duration, number of patients diagnosed in the clinical trial's diseases, and number of patients enrolled. For more detailed data and variable descriptions, see Section 3.

FIGURE 2: EVENT STUDY ESTIMATES: IMPACT OF COMPETITOR DRUG APPROVALS



NOTES: This figure plots the change in clinical trial results reporting following a competitor priority review drug approval in the eight years before and after approval. Each dot corresponds to coefficients for 2-year lead and lag indicators prior to or following the year before a competitor priority review drug approval, from a regression where these indicators replace the single $PostCompetitorDrugApproval$ variable in Equation (3). The outcome variable in Panel A is a binary indicator for whether the clinical trial results are reported in ClinicalTrials.gov within two years of trial completion. The outcome variable in Panel B is the log of the time to results reporting in ClinicalTrials.gov. Shown are 95 percent confidence intervals (corresponding to robust standard errors, clustered at the MeSH code level). The specification is based on trial-MeSH observations, the coefficients are estimates from OLS models, and the sample includes private-sector trials initiated on/after 2007 and completed by 2019. Regressions include year fixed effects and MeSH code fixed effects, as well as controls for sponsor experience, trial phase, clinical trial duration, number of patients diagnosed in the clinical trial's diseases, and number of patients enrolled. For more detailed data and variable descriptions, see Section 3.

FIGURE 3: TIMING OF PATENTING AND CLINICAL TRIAL RESULTS REPORTING



NOTES: This figure plots the kernel density estimates of patent filing to clinical trial results reporting lag. The sample consists of private-sector clinical trials in the trial advancement dataset that are initiated on/after 2007 and completed by 2019 and linked to the patent data. Panel A uses trial-MeSH-drug-patent level data to plot the patent filing to results reporting lag calculated as the patent filing date minus the results reporting date in months. Panel B uses trial-MeSH level data to plot the patent filing to results reporting lag, averaged across all linked drug and patent pairs. "Low Competition Setting" denotes the set of observations that are in MeSH codes with low levels of historical competition (below median number of clinical trials initiated prior to 2000). "High Competition Setting" denotes the set of observations that are in MeSH codes with high levels of historical competition (above median number of clinical trials initiated prior to 2000). For more detailed data and variable descriptions, see Section 5.3.

TABLE 1: SUMMARY STATISTICS

	Mean	Median	SD	Min	Max	Count
A. Disclosure						
0/1: Results Reported on ClinicalTrials.gov	0.34	0	0.47	0	1	147,413
0/1: Results Reported in Publications	0.06	0	0.23	0	1	147,413
Months to Results Reporting on ClinicalTrials.gov	26.24	16.95	23.11	0	163	78,215
Months to results Reported in Publications	25.75	23.00	15.82	0	119	11,666
B. Competition						
# Competitor Clinical Trials (Past 5 Years)	176.29	96.00	207.11	0	1,510	147,413
0/1: Competitor Priority Review Drug Approval in MeSH	0.29	0	0.45	0	1	147,413
C. Trial Characteristics						
# of Diagnoses in Disease (1,000s)	7,532.04	2,313.79	10,812.40	11	68,497	113,840
Sponsor Experience (# Clinical Trials, Past 5 Years)	1.85	0	4.44	0	51	147,413
0/1: Private-sector Sponsor	0.54	1	0.50	0	1	147,413
0/1: Public-sector Sponsor	0.03	0	0.17	0	1	147,413
0/1: Other Sponsor	0.44	0	0.50	0	1	147,413
# of Patients	304.57	84.00	1589.22	0	204,438	147,208
Trial Length in Months	27.12	21.97	20.21	0	143.00	147,413
0/1: Phase 2	0.55	1	0.50	0	1	147,413
0/1: Phase 2/3	0.06	0	0.24	0	1	147,413
0/1: Phase 3	0.39	0	0.49	0	1	147,413

NOTES: This table shows summary statistics at the trial-MeSH code level. "Months to Results Reporting" refers to the number of months between trial completion and results reporting for trials that report results. "# of Diagnoses in Disease" denotes the number of patients diagnosed with the trial's diseases. "Sponsor Experience" denotes the number of clinical trials initiated by the clinical trial sponsor in the previous five years. "Other Sponsor" is an indicator for whether the trial is sponsored by a non-private-sector and non-public-sector institution (e.g., academic institution, hospital, independent investigator). Missing data accounts for observations lower than 147,413. For more detailed data and variable descriptions, see Section 3.

TABLE 2: COMPETITION AND DISCLOSURE

Dependent Variable:	Results Reported			log(Months to Reporting)		
	(1)	(2)	(3)	(4)	(5)	(6)
log(Competition)	-0.119***	-0.122***	-0.0941***	0.0618***	0.0811***	0.0725***
	(0.00859)	(0.00859)	(0.00845)	(0.0178)	(0.0180)	(0.0185)
log(Disease Market Size)		0.00408**	0.00122		0.00505	-0.0103***
		(0.00188)	(0.00144)		(0.00329)	(0.00280)
log(Sponsor Experience)			0.157***			-0.0583***
			(0.00309)			(0.00609)
Mean of Dep. Var.	0.336	0.336	0.336	3.025	3.025	3.025
Observations	147,283	147,283	147,283	77,991	77,991	77,991
R-squared	0.062	0.085	0.153	0.118	0.138	0.183
Start Yr FE	YES	YES	YES	YES	YES	YES
Mesh 9 FE	YES	YES	YES	YES	YES	YES
Trial Controls	NO	YES	YES	NO	YES	YES

NOTES: This table shows the relationship between competition and clinical trial results reporting. Competition for a trial-MeSH is measured by the log of the number of competitor clinical trials initiated in the same MeSH code within the previous five years. The sample consists of clinical trials initiated on/after 2007 and completed by 2019. The level of observation is at the trial-MeSH. Estimates are from OLS models. Columns 1 to 3 regress an indicator for clinical trial results reporting in ClinicalTrials.gov within two years of clinical trial completion. Columns 4 to 6 regress the log of the time from clinical trial completion to results reporting in ClinicalTrials.gov. "Disease Market Size" denotes the number of patients diagnosed with the trial's diseases. "Sponsor Experience" denotes the number of clinical trials initiated by the clinical trial sponsor in the previous five years. "Trial Controls" denotes controls for trial phase, trial duration, and number of patients enrolled. All columns include year fixed effects and MeSH code fixed effects. Robust standard errors, clustered at the MeSH code level, are shown in parentheses. Singleton observations are dropped in fixed effects specifications, which accounts for the smaller number of observations. For more detailed data and variable descriptions, see Section 3.

*p <0.10

**p <0.05

***p <0.01

Table 3: Disclosure and Clinical Trial Funding Type

Dependent Variable:	Results Reported		log(Months to Reporting)	
	(1)	(2)	(3)	(4)
log(Competition) × Private-sector	0.00539	-0.0231***	0.00915	0.0404***
	(0.00674)	(0.00640)	(0.0121)	(0.0120)
log(Competition)	-0.127***	-0.0639***	0.0192	-0.00989
	(0.0142)	(0.0127)	(0.0274)	(0.0272)
Private-sector	-0.274***	-0.197***	0.211***	0.0830
	(0.0303)	(0.0314)	(0.0508)	(0.0569)
log(Disease Market Size) × Private-sector		-0.00547***		-0.000427
		(0.00112)		(0.00200)
log(Disease Market Size)		0.00222		0.00247
		(0.00217)		(0.00466)
log(Sponsor Experience) × Private-sector		0.0879**		-0.0896
		(0.0433)		(0.0709)
log(Sponsor Experience)		0.0408		0.0146
		(0.0438)		(0.0708)
Mean of Dep. Var.	0.419	0.419	3.044	3.044
Observations	83,104	83,104	54,876	54,876
R-squared	0.092	0.194	0.134	0.211
Start Yr FE	YES	YES	YES	YES
Mesh 9 FE	YES	YES	YES	YES
Trial Controls	NO	YES	NO	YES

Notes: This table shows how clinical trial results reporting among public-sector and private-sector clinical trials varies with competition. Competition for a trial-MeSH is measured by the log of the number of competitor clinical trials initiated in the same MeSH code within the previous five years. The sample consists of clinical trials initiated on/after 2007 and completed by 2019 that are either solely sponsored by the private-sector or the public-sector. The level of observation is at the trial-MeSH. Estimates are from OLS models. Columns 1 and 2 regress an indicator for clinical trial results reporting in ClinicalTrials.gov within two years of clinical trial completion. Columns 3 and 4 regress the log of the time from clinical trial completion to results reporting in ClinicalTrials.gov. "Disease Market Size" denotes the number of patients diagnosed with the trial's diseases. "Sponsor Experience" denotes the number of clinical trials initiated by the clinical trial sponsor in the previous five years. "Trial Controls" denotes controls for trial phase, trial duration, and number of patients enrolled. All columns include year fixed effects and MeSH code fixed effects. Robust standard errors, clustered at the MeSH code level, are shown in parentheses. Singleton observations are dropped in fixed effects specifications, which accounts for the smaller number of observations. For more detailed data and variable descriptions, see Section 3.

*p <0.10

**p <0.05

***p <0.01

Table 4: Impact of Competitor Drug Approvals on Disclosure

Dependent Variable:	Results Reported			log(Months to Reporting)		
	(1)	(2)	(3)	(4)	(5)	(6)
Post Competitor Drug Approval	-0.0537***	-0.0525***	-0.0525***	0.0415	0.0454*	0.0476**
	(0.0194)	(0.0192)	(0.0142)	(0.0254)	(0.0254)	(0.0223)
log(Disease Market Size)		-0.000217	-0.00476**		0.00141	0.00529
		(0.00228)	(0.00200)		(0.00423)	(0.00403)
log(Sponsor Experience)			0.131***			-0.0761***
			(0.00317)			(0.00699)
Mean of Dep. Var.	0.408	0.408	0.408	3.058	3.058	3.058
Observations	78,781	78,781	78,781	51,073	51,073	51,073
R-squared	0.132	0.144	0.188	0.178	0.205	0.212
Start Yr FE	YES	YES	YES	YES	YES	YES
Mesh 9 FE	YES	YES	YES	YES	YES	YES
Trial Controls	NO	YES	YES	NO	YES	YES

Notes: This table reports difference-in-differences estimates of the effect of competitor priority review drug approvals on clinical trial results reporting. The sample consists of private-sector clinical trials initiated on/after 2007 and completed by 2019. The level of observation is at the trial-MeSH. Estimates are from OLS models. Columns 1 to 3 regress an indicator for clinical trial results reporting in ClinicalTrials.gov within two years of clinical trial completion. Columns 4 to 6 regress the log of the time from clinical trial completion to results reporting in ClinicalTrials.gov. *PostCompetitorDrugApproval* switches from 0 to 1 when a competitor drug is approved in a MeSH code. "Disease Market Size" denotes the number of patients diagnosed with the trial's diseases. "Sponsor Experience" denotes the number of clinical trials initiated by the clinical trial sponsor in the previous five years. "Trial Controls" denotes controls for trial phase, trial duration, and number of patients enrolled. All columns include year fixed effects and MeSH code fixed effects. Robust standard errors, clustered at the MeSH code level, are shown in parentheses. Singleton observations are dropped in fixed effects specifications, which accounts for the smaller number of observations. For more detailed data and variable descriptions, see Section 3.

*p <0.10

**p <0.05

***p <0.01

TABLE 5: IMPACT OF COMPETITOR DRUG APPROVALS ON CLINICAL TRIAL DESIGN QUALITY

Dependent Variable:	Randomized	Double Blind	Double Blind and Randomized	Controlled
	(1)	(2)	(3)	(4)
Post Competitor Drug Approval	-0.0147**	-0.0247*	-0.0252*	-0.0261**
	(0.00714)	(0.0133)	(0.0132)	(0.0108)
Mean of Dep. Var.	0.921	0.619	0.616	0.325
Observations	66,886	78,519	78,437	77,639
R-squared	0.130	0.274	0.274	0.130
Start Yr FE	YES	YES	YES	YES
Mesh 9 FE	YES	YES	YES	YES
Trial Controls	YES	YES	YES	YES

NOTES: This table shows the relationship between competition and clinical trial design quality. The sample consists of private-sector clinical trials initiated on/after 2007 and completed by 2019 that are linked to trial advancement data. The level of observation is at the trial-MeSH. Estimates are from OLS models. *PostCompetitorDrugApproval* switches from 0 to 1 when a competitor drug is approved in a MeSH code. "Disease Market Size" denotes the number of patients diagnosed with the trial's diseases. "Sponsor Experience" denotes the number of clinical trials initiated by the clinical trial sponsor in the previous five years. "Trial Controls" denotes controls for trial phase, trial duration, number of patients enrolled, disease market size, and sponsor experience. All columns include year fixed effects and MeSH code fixed effects. Robust standard errors, clustered at the MeSH code level, are shown in parentheses. The smaller number of observations is due to missing data and singleton observations which are dropped in fixed effects specifications. For more detailed data and variable descriptions, see Section 3.

*p <0.10

**p <0.05

***p <0.01

TABLE 6: IMPACT OF COMPETITOR DRUG APPROVALS ON R&D PROJECT QUALITY

Dependent Variable:	Advanced Trial (Mean = 0.233)	
	(1)	(2)
Post Competitor Drug Approval	0.00170	0.00399
	(0.0187)	(0.0164)
log(Disease Market Size)		-0.0106***
		(0.00280)
log(Sponsor Experience)		0.0973***
		(0.00549)
Observations	68,360	68,360
R-squared	0.095	0.155
Start Yr FE	YES	YES
Mesh 9 FE	YES	YES
Trial Controls	NO	YES

NOTES: This table reports how difference-in-differences estimates of the effect of competitor priority review drug approvals on R&D project quality. The sample consists of private-sector clinical trials in the trial advancement dataset that are initiated on/after 2007 and completed by 2019. The level of observation is at the trial-MeSH. Estimates are from OLS models. All columns regress an indicator for whether the clinical trial successfully advances to the next stage (i.e., whether Phase II trials advance to Phase III, whether Phase III trials test an intervention that is subsequently approved). *PostCompetitorDrugApproval* switches from 0 to 1 when a competitor drug is approved in a MeSH code. "Disease Market Size" denotes the number of patients diagnosed with the trial's diseases. "Sponsor Experience" denotes the number of clinical trials initiated by the clinical trial sponsor in the previous five years. "Trial Controls" denotes controls for trial phase, trial duration, number of patients enrolled, disease market size, sponsor experience, and trial design. All columns include year fixed effects and MeSH code fixed effects. Singleton observations are dropped in fixed effects specifications, which accounts for the smaller number of observations. Robust standard errors, clustered at the MeSH code level, are shown in parentheses. For more detailed data and variable descriptions, see Sections 3 and 5.1.

*p <0.10

**p <0.05

***p <0.01

Table 7: Impact of Competitor Drug Approvals on Disclosure, by R&D Project Quality

	Dependent Variable: Results Reported	
	Terminated Trials Sample (1)	Advanced Trials Sample (2)
Post Competitor Drug Approval	-0.0624***	-0.0636*
	(0.0168)	(0.0330)
log(Disease Market Size)	0.00347	-0.00834*
	(0.00243)	(0.00461)
log(Sponsor Experience)	0.132***	0.112***
	(0.00364)	(0.00506)
Mean of Dep. Var.	0.418	0.488
Observations	52,402	15,782
R-squared	0.158	0.318
Start Yr FE	YES	YES
Mesh 9 FE	YES	YES
Trial Controls	YES	YES

Notes: This table reports how difference-in-differences estimates of the effect of competitor priority review drug approvals on clinical trial results reporting varies by R&D project quality. The sample consists of private-sector clinical trials in the trial advancement dataset that are initiated on/after 2007 and completed by 2019. Columns 1 consists of projects that were terminated. Column 2 consists of projects that successfully advanced to the next stage. The level of observation is at the trial-MeSH. Estimates are from OLS models. All columns regress an indicator for clinical trial results reporting in ClinicalTrials.gov within two years of clinical trial completion. *PostCompetitorDrugApproval* switches from 0 to 1 when a competitor drug is approved in a MeSH code. "Disease Market Size" denotes the number of patients diagnosed with the trial's diseases. "Sponsor Experience" denotes the number of clinical trials initiated by the clinical trial sponsor in the previous five years. "Trial Controls" denotes controls for trial phase, trial duration, number of patients enrolled, disease market size, sponsor experience, and trial design. All columns include year fixed effects and MeSH code fixed effects. Singleton observations are dropped in fixed effects specifications, which accounts for the smaller number of observations. Robust standard errors, clustered at the MeSH code level, are shown in parentheses. For more detailed data and variable descriptions, see Sections 3 and 5.1.

*p <0.10

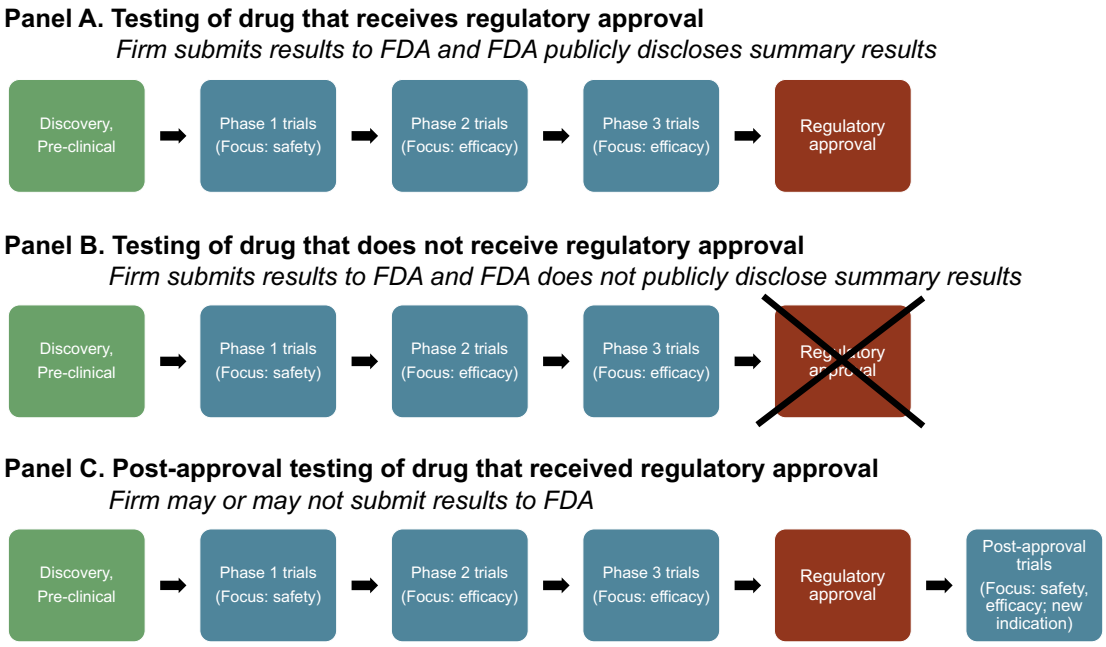
**p <0.05

***p <0.01

Appendix for
Information Disclosure in the Presence of Competition: Evidence from the Pharmaceutical Industry

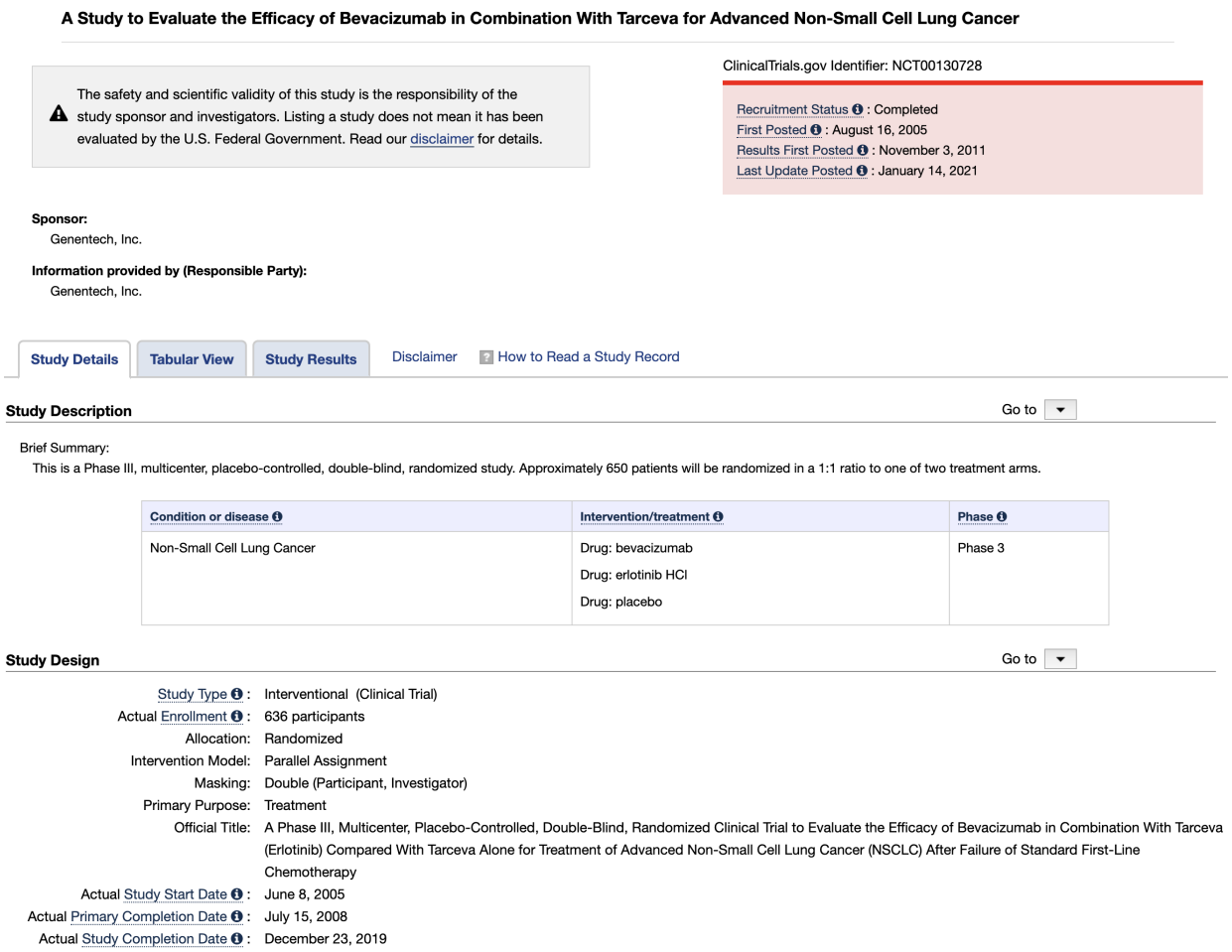
Appendix A
Drug Development and ClinicalTrials.gov

FIGURE A1: CLINICAL TRIALS IN DRUG DEVELOPMENT AND RESULTS REPORTING TO THE FDA



NOTES: This figure provides an overview of clinical trials in drug development and FDA results reporting policies. These policies are distinct from ClinicalTrials.gov clinical trial results reporting requirements, which are outlined in Section 2.1.1.

Figure A2: Basic Clinical Trial Registration Characteristics



A Study to Evaluate the Efficacy of Bevacizumab in Combination With Tarceva for Advanced Non-Small Cell Lung Cancer

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

ClinicalTrials.gov Identifier: NCT00130728

Recruitment Status : Completed
First Posted : August 16, 2005
Results First Posted : November 3, 2011
Last Update Posted : January 14, 2021

Sponsor:
Genentech, Inc.

Information provided by (Responsible Party):
Genentech, Inc.

Study Details | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Study Description Go to

Brief Summary:
This is a Phase III, multicenter, placebo-controlled, double-blind, randomized study. Approximately 650 patients will be randomized in a 1:1 ratio to one of two treatment arms.

Condition or disease	Intervention/treatment	Phase
Non-Small Cell Lung Cancer	Drug: bevacizumab Drug: erlotinib HCl Drug: placebo	Phase 3

Study Design Go to

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	636 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Masking:	Double (Participant, Investigator)
Primary Purpose:	Treatment
Official Title:	A Phase III, Multicenter, Placebo-Controlled, Double-Blind, Randomized Clinical Trial to Evaluate the Efficacy of Bevacizumab in Combination With Tarceva (Erlotinib) Compared With Tarceva Alone for Treatment of Advanced Non-Small Cell Lung Cancer (NSCLC) After Failure of Standard First-Line Chemotherapy
Actual Study Start Date :	June 8, 2005
Actual Primary Completion Date :	July 15, 2008
Actual Study Completion Date :	December 23, 2019

Notes: This figure shows the basic trial registration characteristics reported in ClinicalTrials.gov for trial NCT00130728.

FIGURE A3: CLINICALTRIALS.GOV RESULTS TEMPLATES

More details available in the Results Data Element Definitions. April 2017

Outcome Measure Template ***ClinicalTrials.gov***

* Outcome Measure Type	(Select One) Primary Secondary Other Pre-specified Post-Hoc
* Outcome Measure Title	
[*] Outcome Measure Description	
* Outcome Measure Time Frame	

* Arm/Group Title						
*§ Arm/Group Description ①						
* Overall Number of Participants Analyzed ②						
[*] Analysis Population Description						
* Measure Type	* Measure of Dispersion/Precision					
(Select One) Count of Participants ③ Mean Median Least Squares Mean (LSM) Geometric Mean Geometric LSM Number Count of Units ③	(Select One) Not Applicable ④ Standard Deviation Standard Error Inter-Quartile Range Full Range _____ % Confidence Interval Geometric Coefficient of Variation					
[*] Row/Category Title ⑤			③④		③④	③④
[*] Row/Category Title ⑤			③④		③④	③④
* Unit of Measure						

* Required *§ Required if Primary Completion Date is on or after January 18, 2017 [*] Conditionally required

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Participants/Units Analyzed. The percentage can be hidden (display is optional).
④ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion/precision value is needed if Measure of Dispersion is Not Applicable.
⑤ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Outcome Measure Data are required for each row. Row/Category Titles are only required if more than one row.

More details available in the Results Data Element Definitions. April 2017

All-Cause Mortality and Serious Adverse Events Template ***ClinicalTrials.gov***

*§ Time Frame	
[*] Adverse Event Reporting Description	
Source Vocabulary Name for Table Default ①	
*§ Collection Approach for Table Default ①	(Select One) Systematic Non-Systematic

* Arm/Group Title						
*§ Arm/Group Description ②						
*§ All-Cause Mortality						
	*§ Number Participants Affected	*§ Number Participants at Risk	*§ Number Participants Affected	*§ Number Participants at Risk	*§ Number Participants Affected	*§ Number Participants at Risk
*§ Total						

* Serious Adverse Events										
	* Number Participants Affected	* Number Participants at Risk	Number Events	* Number Participants Affected	* Number Participants at Risk	Number Events	* Number Participants Affected	* Number Participants at Risk	Number Events	
* Total										
* Adverse Event Term	* Organ System									
	③		④[*]			④[*]			④[*]	
	③		④[*]			④[*]			④[*]	
	③		④[*]			④[*]			④[*]	
	③		④[*]			④[*]			④[*]	
	③		④[*]			④[*]			④[*]	
	③		④[*]			④[*]			④[*]	

* Required *§ Required if Primary Completion Date is on or after January 18, 2017 [*] Conditionally required

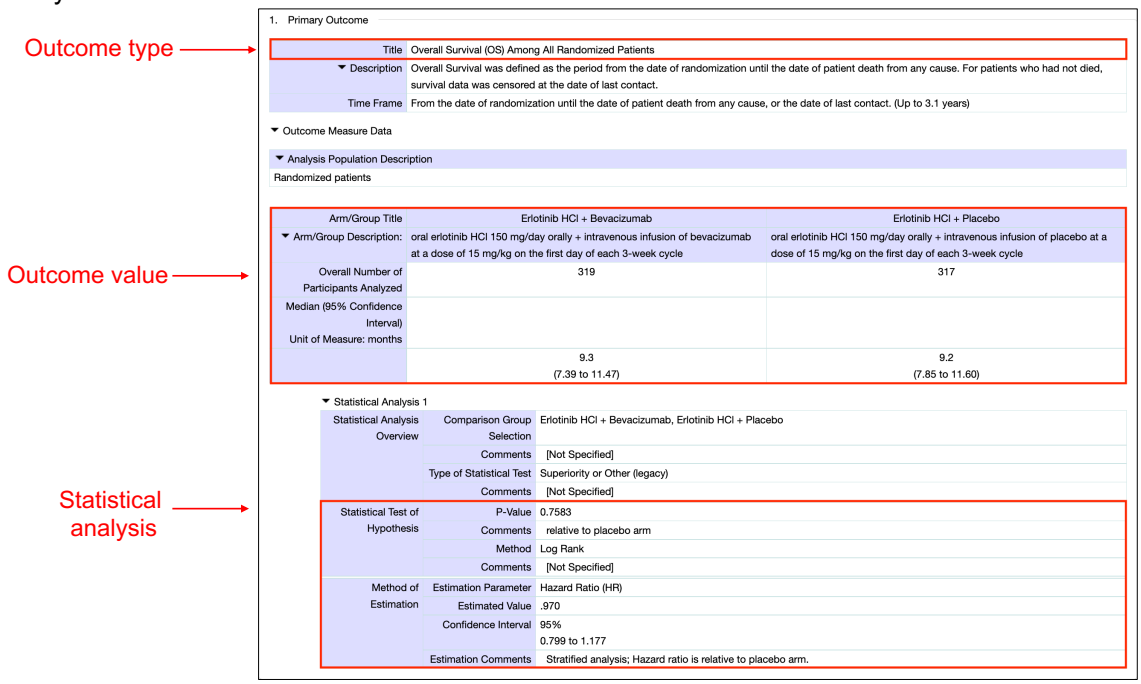
① If entered, the table default values apply to all Adverse Event Terms. The values may be changed for any single Adverse Event, if different from the table default.
② Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
③ Organ System must be selected from a pick-list of high-level categories. See the Results Data Element Definitions for details.
④ Number of Participants at Risk for an Adverse Event Term is only required when the value differs from the Total Number of Participants at Risk.

NOTES: This figure shows a template clinical trial sponsors use to submit clinical trial outcome measures, statistical analyses, and adverse events to ClinicalTrials.gov.

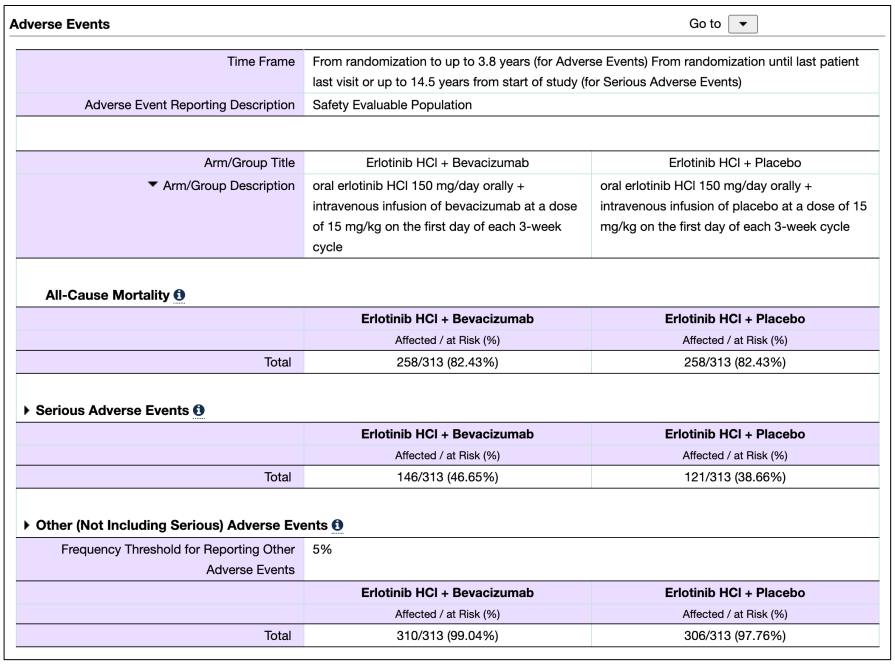
Source: https://prsinfo.clinicaltrials.gov/results_table_layout/ResultSimpleForms.html

FIGURE A4: CLINICAL TRIAL RESULTS FOR TRIAL NCT00130728

Efficacy Outcomes:



Safety Outcomes:



NOTES: This figure shows the clinical trial results reported in ClinicalTrials.gov for trial NCT00130728.

Appendix B
Competition-Disclosure Correlations: Extensions and Robustness

This Appendix provides a detailed discussion of the extensions and robustness checks on the competition-disclosure correlations presented in Section 4.

Additional Disclosure Channels. Our primary analysis examines trial sponsors' decisions to disclose the results of completed clinical trials on ClinicalTrials.gov. We explore disclosure along two additional dimensions of disclosure: disclosure earlier in the R&D process (before the trial's completion) and disclosure on different platforms (publications, scientific conferences). Appendix Table B1 shows that competition is associated with a significant decrease in the probability that clinical trials are registered within the registration deadline mandated by the FDAAA.[i] To examine disclosure across platforms, we collect additional disclosure data on clinical trial results that are published in a scientific journals in PubMed. In addition, for the clinical trials testing anticancer drugs, we determine whether (and if so, when) clinical trial results are presented at the world's largest cancer conference, the American Society of Clinical Oncology (ASCO) Annual Meetings. ASCO is the primary professional society for medical oncologists and major research groups present clinical trial findings at its annual conference. We obtain abstracts accepted to the ASCO Annual Meetings between 2004 and 2017. Appendix Figure B1 and Table B2 show that the correlations between competition and disclosure are robust to incorporating clinical trial disclosure within publications and at scientific conferences. Appendix Figure B2 shows sharp increase in results reporting on ClinicalTrials.gov in the year after the primary approval (which is the FDAAA results reporting deadline) relative to reporting in publications and scientific conferences, which is consistent with the view that trial sponsors' disclosure decisions are strongly shaped by financial incentives.

Heterogeneity Across Phases. As described in Section 2, clinical trial phases vary substantially in size, risk, and cost. Appendix Figure B3 shows that the negative relationship between competition and disclosure is found across all clinical trial phases, though the effects are more pronounced among clinical trials in Phase II and II-III. These patterns are likely to be explained by factors such as differences in public scrutiny and risk (for example, given the clinical requirements necessary to proceed to Phase III, drugs tested in Phase III may have higher ex-ante drug quality and be lower risk relative to drugs tested in Phase II).

Alternative Measures of Competition. We examine whether the competition-disclosure correlations are robust to alternative measures of competition. Appendix Table B3 measures competition using the log of one plus number of firms testing clinical trials in the same MeSH in the previous five years. Appendix Table B4 uses a more direct measure of product market competition: the number of competitor drugs previously approved in the same MeSH. Confirming our main results, the relationship between competition and results reporting is relatively stable across these alternative competition measures. We also find that the correlation between competition and time to disclosure is positive, though imprecisely estimated. We prefer the trial-based measure of trial-MeSH competition over the firm-based measure since it better captures the level of research intensity and competitive pressure within a particular MeSH code. We further explore the role of competition from approved drugs in Section 4.4.

Alternative Trial Sample and Trial-Disease Linkages. Our main results relies on a trial-MeSH code dataset where a clinical trial may be linked to multiple MeSH codes. This one-to-many linkage may occur for three reasons: first, the focal trial may be investigating multiple conditions. Second, the MeSH codes—which we use at the 9-digit level—may be individually too granular to fully

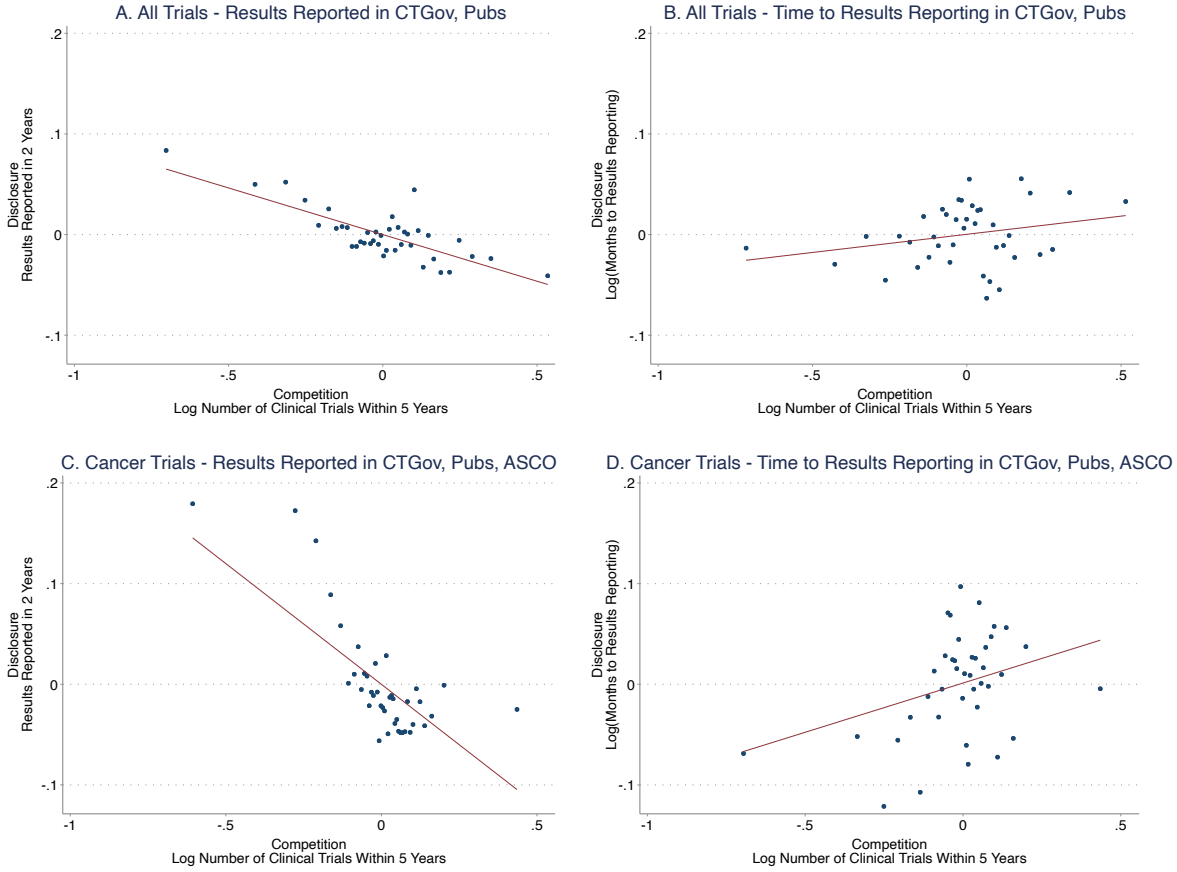
[i]The FDAAA requires trial sponsors register trials on ClinicalTrials.gov within 21 days after the enrollment of the first clinical trial participant.

encompass the trial's condition. Third, due to the hierarchical nature of the MeSH tree structure, a disease may be linked to multiple 9-digit MeSH codes (e.g., "Pneumonia, viral" is linked to 3 distinct 9-digit MeSH codes). To address concerns that one-to-many trial-MeSH linkage may distort our empirical results, Appendix Table B5 shows our results are robust to restricting our analysis to trials that map to a single 9-digit MeSH code (Column 1). Next, we show that our results are robust to using alternative disease categorizations that are more comprehensive and provide a more conservative mapping between trials and diseases: 6-digit MeSH codes (Column 2) and International Classification of Diseases, 9th Edition (ICD-9 codes) (Column 3). To provide a sense of this alternative trial-disease linkage: the median trial is linked to one ICD-9 code. Finally, we use a weighted regression that incorporates the number of 9-digit MeSH codes that a trial is linked to (in other words, a trial-MeSH associated with a trial that is linked to N MeSH codes receives a weight of 1/N).

Heterogeneity in Disclosure Costs. One might be concerned that responses to competition might be driven by differences in disclosure costs that are not sufficiently controlled for in Equation (1). For example, drug manufacturers are increasingly outsourcing the management of their clinical trials to contract research organizations (CROs), which may change drug manufacturers' clinical trial reporting costs (Mirowski and Van Horn, 2005). Appendix Table B6 shows that competition-disclosure correlations are robust to including controls and interaction terms for CROs.

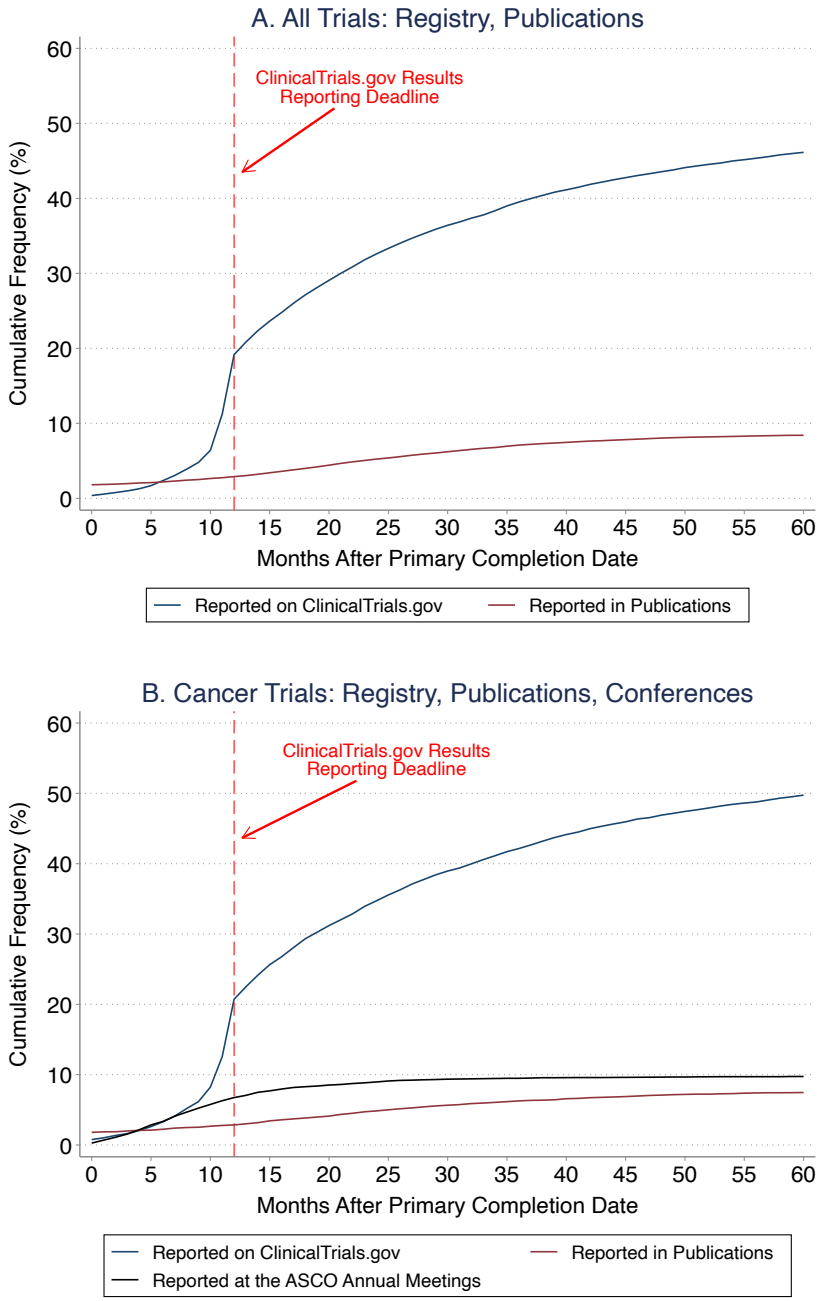
Placebo Tests. To demonstrate that the estimated correlations between competition and disclosure are unlikely to be statistical noise, we run 2,000 placebo experiments where we randomly reassign trial-based competition levels across different trial-MeSH. We then re-estimate Equation (1), where the outcome is the probability of results reporting within two years of clinical trial completion. Appendix Figure B4 plots the distribution of estimated t-statistics across the 2,000 placebo experiments. The estimated t-statistic from original data (as shown in Column 3 of Table 2) is substantially more negative than all placebo test estimates.

FIGURE B1: COMPETITION AND DISCLOSURE: COMPARISON ACROSS PLATFORMS



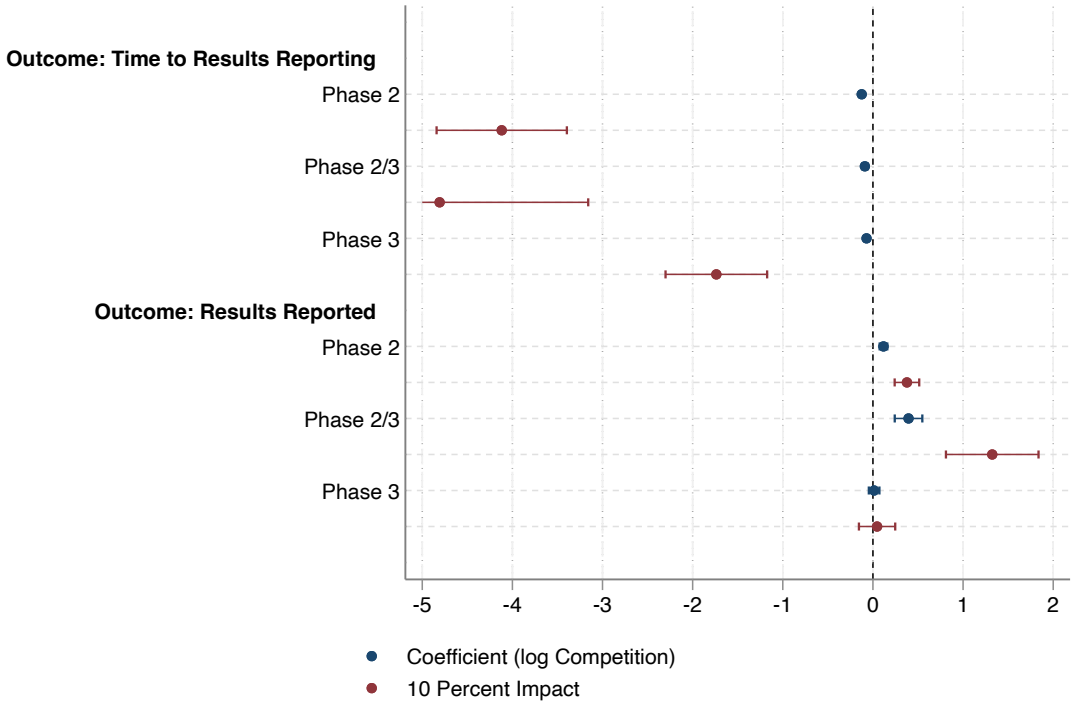
NOTES: This figure shows the relationship between competition and clinical trial results reporting across different platforms: ClinicalTrials.gov, publications, and medical conferences. The sample consists of clinical trials initiated on/after 2007 and completed by 2019. The level of observation is at the trial-MeSH. Competition for a trial-MeSH is measured by the log of the number of competitor clinical trials initiated in the same MeSH code within the previous five years. Panels A and B describe results reporting on ClinicalTrials.gov and in publications for all clinical trials. Panels C and D describe results reporting on ClinicalTrials.gov, in publications, and at the ASCO Annual Meetings for oncology clinical trials. Panels A and C show binscatter plots of the residualized likelihood results reporting in ClinicalTrials.gov within two years of the clinical trial completion date against the trial-MeSH's residualized competition. Panels B and D show binscatter plots of the residualized time to results reporting in ClinicalTrials.gov from the clinical trial completion date against the trial-MeSH's residualized competition. Residuals are conditional on year fixed effects, MeSH code fixed effects, sponsor experience, trial phase, trial duration, number of patients diagnosed with the trial's diseases, and number of patients enrolled. For more detailed data and variable descriptions, see Section 3.

FIGURE B2: CUMULATIVE SHARE OF TRIALS REPORTING RESULTS: COMPARISON ACROSS PLATFORMS



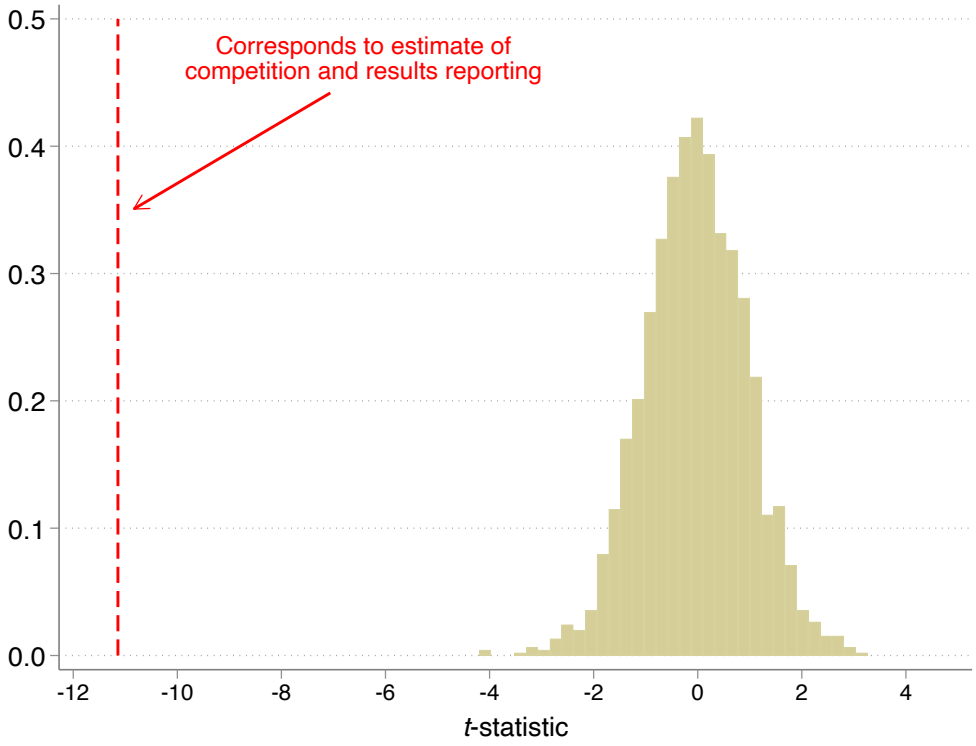
NOTES: This figure compares the cumulative share of clinical trials reporting results across different platforms: ClinicalTrials.gov, publications, and medical conferences. Panel A shows the cumulative share of clinical trials reporting results on ClinicalTrials.gov and in publications for all clinical trials initiated on/after 2007 and completed by 2019. Panel B shows the cumulative share of clinical trials reporting results on ClinicalTrials.gov, in publications, and at the ASCO Annual Meetings for oncology clinical trials initiated on/after 2007 and completed by 2019. The unit of observation is at the trial-level. The red line indicates the one year mark after the trial completion date and corresponds to the FDAAA ClinicalTrials.gov one year results reporting deadline.

FIGURE B3: COMPETITION AND DISCLOSURE: HETEROGENEITY ACROSS PHASES



NOTES: This figure reports coefficient and percent impact estimates of the relationship between competition and clinical trial results reporting across clinical trial phases. The level of observation is the trial-MeSH. Estimates are from OLS models where results reporting measures are regressed on the log of the number of competitor clinical trials initiated in the same MeSH code within the previous five years, for subsets (by trial phase) of clinical trials initiated on/after 2007 and completed by 2019. Point estimates in the "Coefficients" panel correspond to coefficients on the competition measure. Regressions include year fixed effects, MeSH code fixed effects, as well as controls for sponsor experience, trial phase, trial duration, number of patients diagnosed in the trial's diseases, and number of patients enrolled. 95% confidence intervals were constructed from standard errors clustered at the MeSH code level. "Percent Impacts" point estimates correspond to a percent change in the outcome variable associated with a 10 percent increase in competition. Some confidence intervals were truncated to ease visualization. For more detailed data and variable descriptions, see Section 3.

FIGURE B4: COMPETITION AND DISCLOSURE: PLACEBO EXPERIMENTS



NOTES: This figure plots the distribution of estimated t-statistics across 2,000 placebo experiments. In each placebo experiment, we randomly shuffle the trial-MeSH competition measures across all trial-MeSH observations and estimate Equation (1). The dotted red line on the left denotes the t-statistic using the original data (as shown in Column 3 of Table 2). All of the coefficients produced by the placebo experiments generate t-statistics that are more positive than the primary empirical estimates.

TABLE B1: COMPETITION AND REGISTRATION

Dependent Variable:	Registered Early (mean = 0.752)		
	(1)	(2)	(3)
log(Competition)	-0.0681***	-0.0666***	-0.0518***
	(0.00750)	(0.00726)	(0.00695)
log(Disease Market Size)		0.00452**	-0.000725
		(0.00203)	(0.00158)
log(Sponsor Experience)			0.0822***
			(0.00306)
Observations	147,283	147,283	147,283
R-squared	0.065	0.074	0.096
Start Yr FE	YES	YES	YES
Mesh 9 FE	YES	YES	YES
Trial Controls	NO	YES	YES

NOTES: This table shows the relationship between competition and clinical trial registration. Competition for a trial-MeSH is measured by the log of the number of competitor clinical trials initiated in the same MeSH code within the previous five years. The sample consists of clinical trials initiated on/after 2007 and completed by 2019. The level of observation is at the trial-MeSH. Estimates are from OLS models. The outcome is an indicator for whether clinical trials are registered on ClinicalTrials.gov within 21 days after the enrollment of the first human participant ("Registered Early"). "Disease Market Size" denotes the number of patients diagnosed with the trial's diseases. "Sponsor Experience" denotes the number of clinical trials initiated by the trial sponsor in the previous five years. "Trial Controls" denotes controls for trial phase, trial duration, and number of patients enrolled. All columns include year fixed effects and MeSH code fixed effects. Singleton observations are dropped in fixed effects specifications, which accounts for the smaller number of observations. Robust standard errors, clustered at the MeSH code level, are shown in parentheses. For more detailed data and variable descriptions, see Section 3.

*p <0.10

**p <0.05

***p <0.01

TABLE B2: COMPETITION AND DISCLOSURE: ADDITIONAL PLATFORMS

Dependent Variable:	Results Reported			log(Months to Reporting)		
	(1)	(2)	(3)	(4)	(5)	(6)
A. All Trials: Reporting in ClinicalTrials.gov, Publications						
log(Competition)	-0.116***	-0.119***	-0.0927***	0.0275	0.0435**	0.0376**
	(0.00845)	(0.00839)	(0.00826)	(0.0171)	(0.0172)	(0.0174)
log(Disease Market Size)		0.00152	-0.00156		0.00886***	-0.00612**
		(0.00188)	(0.00142)		(0.00328)	(0.00285)
log(Sponsor Experience)			0.151***			-0.0445***
			(0.00293)			(0.00607)
Mean of Dep. Var.	0.366	0.366	0.366	2.987	2.987	2.987
Observations	147,283	147,283	147,283	81,199	81,199	81,199
R-squared	0.055	0.079	0.142	0.095	0.113	0.158
Start Yr FE	YES	YES	YES	YES	YES	YES
Mesh 9 FE	YES	YES	YES	YES	YES	YES
Trial Controls	NO	YES	YES	NO	YES	YES
B. Cancer Trials: Reporting in ClinicalTrials.gov, Publications, ASCO Annual Meetings						
log(Competition)	-0.255***	-0.251***	-0.240***	0.108***	0.120***	0.100***
	(0.0307)	(0.0310)	(0.0303)	(0.0359)	(0.0375)	(0.0362)
log(Disease Market Size)		-0.00411	-0.00572		0.0257***	0.0256***
		(0.00464)	(0.00445)		(0.00842)	(0.00812)
log(Sponsor Experience)			0.147***			-0.0360***
			(0.00567)			(0.0117)
Mean of Dep. Var.	0.421	0.421	0.421	2.809	2.809	2.809
Observations	30,091	30,091	30,091	18,383	18,383	18,383
R-squared	0.040	0.046	0.111	0.053	0.059	0.111
Start Yr FE	YES	YES	YES	YES	YES	YES
Mesh 9 FE	YES	YES	YES	YES	YES	YES
Trial Controls	NO	YES	YES	NO	YES	YES

NOTES: This table shows the relationship between competition and clinical trial results reporting across different platforms: ClinicalTrials.gov, publications, and medical conferences. The sample consists of clinical trials initiated on/after 2007 and completed by 2019. The level of observation is at the trial-MeSH. Estimates are from OLS models. Competition for a trial-MeSH is measured by the log of the number of competitor clinical trials initiated in the same MeSH code within the previous five years. Panel A describes results reporting on ClinicalTrials.gov and in publications for all clinical trials. Panel B describes results reporting on ClinicalTrials.gov, in publications, and at the ASCO Annual Meetings for oncology clinical trials. "Disease Market Size" denotes the number of patients diagnosed with the trial's diseases. "Sponsor Experience" denotes the number of clinical trials initiated by the trial sponsor in the previous five years. "Trial Controls" denotes controls for trial phase, trial duration, and number of patients enrolled. All columns include year fixed effects and MeSH code fixed effects. Singleton observations are dropped in fixed effects specifications, which accounts for the smaller number of observations. Robust standard errors, clustered at the MeSH code level, are shown in parentheses. For more detailed data and variable descriptions, see Section 3.

*p <0.10

**p <0.05

***p <0.01

TABLE B3: COMPETITION AND DISCLOSURE—FIRM-BASED COMPETITION MEASURE

Dependent Variable:	Results Reported			log(Months to Reporting)		
	(1)	(2)	(3)	(4)	(5)	(6)
log(Competition)	-0.0339***	-0.0365***	-0.0384***	0.00371	0.00604	0.00174
	(0.00657)	(0.00628)	(0.00630)	(0.0157)	(0.0156)	(0.0156)
log(Disease Market Size)		0.00392**	0.00105		0.00493	-0.0103***
		(0.00188)	(0.00143)		(0.00330)	(0.00280)
log(Sponsor Experience)			0.158***			-0.0592***
			(0.00308)			(0.00608)
Mean of Dep. Var.	0.336	0.336	0.336	3.025	3.025	3.025
Observations	147,283	147,283	147,283	77,991	77,991	77,991
R-squared	0.059	0.083	0.152	0.118	0.138	0.183
Start Yr FE	YES	YES	YES	YES	YES	YES
Mesh 9 FE	YES	YES	YES	YES	YES	YES
Trial Controls	NO	YES	YES	NO	YES	YES

NOTES: This table shows the relationship between firm-based measures of competition and clinical trial results reporting. Competition for a trial-MeSH is measured by the log of the number of firms initiating clinical trials in the same MeSH code within the previous five years. The sample consists of clinical trials initiated on/after 2007 and completed by 2019. The level of observation is at the trial-MeSH. Estimates are from OLS models. Columns 1 to 3 regress an indicator for clinical trial results reporting in ClinicalTrials.gov within two years of clinical trial completion. Columns 4 to 6 regress the log of the time from clinical trial completion to results reporting in ClinicalTrials.gov. "Disease Market Size" denotes the number of patients diagnosed with the trial's diseases. "Sponsor Experience" denotes the number of clinical trials initiated by the trial sponsor in the previous five years. "Trial Controls" denotes controls for trial phase, trial duration, and number of patients enrolled. All columns include year fixed effects and MeSH code fixed effects. Singleton observations are dropped in fixed effects specifications, which accounts for the smaller number of observations. Robust standard errors, clustered at the MeSH code level, are shown in parentheses. For more detailed data and variable descriptions, see Section 3.

*p <0.10

**p <0.05

***p <0.01

Table B4: Competition and Disclosure—Drug Approval-Based Competition Measure

Dependent Variable:	Results Reported			log(Months to Reporting)		
	(1)	(2)	(3)	(4)	(5)	(6)
log(Drug Competition)	-0.0303	-0.0184	-0.0293**	0.0645**	0.0658**	0.0235
	(0.0216)	(0.0185)	(0.0127)	(0.0291)	(0.0265)	(0.0244)
log(Disease Market Size)		0.00381**	0.000905		0.00498	-0.0103***
		(0.00188)	(0.00143)		(0.00330)	(0.00280)
log(Sponsor Experience)			0.159***			-0.0593***
			(0.00306)			(0.00608)
Mean of Dep. Var.	0.336	0.336	0.336	3.025	3.025	3.025
Observations	147,283	147,283	147,283	77,991	77,991	77,991
R-squared	0.059	0.082	0.151	0.118	0.138	0.183
Start Yr FE	YES	YES	YES	YES	YES	YES
Mesh 9 FE	YES	YES	YES	YES	YES	YES
Trial Controls	NO	YES	YES	NO	YES	YES

Notes: This table shows the relationship between competition and clinical trial results reporting, where competition is measured by the log number of competitior priority review drug approvals that were previously approved in the same MeSH code. The sample consists of clinical trials initiated on/after 2007 and completed by 2019. The level of observation is at the trial-MeSH. Estimates are from OLS models. Columns 1 to 3 regress an indicator for clinical trial results reporting in ClinicalTrials.gov within two years of clinical trial completion. Columns 4 to 6 regress the log of the time from clinical trial completion to results reporting in ClinicalTrials.gov. "Disease Market Size" denotes the number of patients diagnosed with the trial's diseases. "Sponsor Experience" denotes the number of clinical trials initiated by the trial sponsor in the previous five years. "Trial Controls" denotes controls for trial phase, trial duration, and number of patients enrolled. All columns include year fixed effects and MeSH code fixed effects. Singleton observations are dropped in fixed effects specifications, which accounts for the smaller number of observations. Robust standard errors, clustered at the MeSH code level, are shown in parentheses. For more detailed data and variable descriptions, see Section 3.

*p <0.10

**p <0.05

***p <0.01

TABLE B5: ALTERNATIVE TRIAL SAMPLE AND TRIAL-DISEASE LINKAGES

	Dependent Variable: Results Reported			
	One 9-digit MeSH Sample (1)	6-digit MeSH Sample (2)	ICD-9 Sample (3)	Weighted Regression (4)
log(Competition)	-0.0987**	-0.0797***	-0.0471***	-0.0669***
	(0.0442)	(0.0182)	(0.0149)	(0.0140)
Mean of Dep. Var.	0.296	0.320	0.349	0.322
Observations	5,899	106,188	35,903	147,283
R-squared	0.162	0.133	0.129	0.143
Start Yr FE	YES	YES	YES	YES
Disease FE	YES	YES	YES	YES
Trial Controls	YES	YES	YES	YES

NOTES: This table provides more restricted analysis samples and alternative methods for linking trials to diseases. Column 1 restricts the final sample of trial-MeSH 9 observations to the set of trials that map to a single 9-digit MeSH code. Column 2 uses 6-digit MeSH disease categorization. Column 3 uses ICD-9 disease categorizations. Column 4 uses a weighted regression where each trial is weighed by the number of diseases it maps to. Competition is measured by the log of the number of firms initiating clinical trials in the same disease within the previous five years. The sample consists of clinical trials initiated on/after 2007 and completed by 2019. Estimates are from OLS models where the outcome is an indicator for clinical trial results reporting in ClinicalTrials.gov within two years of clinical trial completion. "Trial Controls" denotes controls for trial phase, trial duration, number of patients enrolled, disease market size, and sponsor experience. All columns include year fixed effects and disease fixed effects. Singleton observations are dropped in fixed effects specifications, which accounts for the smaller number of observations. Robust standard errors, clustered at the disease level, are shown in parentheses. For more detailed data and variable descriptions, see Section 3.

*p <0.10

**p <0.05

***p <0.01

TABLE B6: CONTROLLING FOR CONTRACT RESEARCH ORGANIZATIONS AFFILIATION

Dependent Variable:	Results Reported		log(Months to Reporting)	
	(1)	(2)	(3)	(4)
log(Competition) × CRO	-0.0406***	-0.0251***	0.110***	0.112***
	(0.0108)	(0.00953)	(0.0199)	(0.0204)
log(Competition)	-0.114***	-0.0921***	0.0691***	0.0775***
	(0.00856)	(0.00849)	(0.0177)	(0.0182)
CRO	0.228***	0.0599	-0.399***	-0.269**
	(0.0529)	(0.0548)	(0.0872)	(0.110)
log(Disease Market Size) × CRO		0.00969***		-0.00677
		(0.00247)		(0.00478)
log(Disease Market Size)		-0.000536		-0.0118***
		(0.00138)		(0.00282)
log(Sponsor Experience) × CRO		-0.0673***		-0.0451
		(0.0234)		(0.0283)
log(Sponsor Experience)		0.155***		-0.0601***
		(0.00312)		(0.00607)
Mean of Dep. Var.	0.336	0.336	3.025	3.025
Observations	147,283	147,283	77,991	77,991
R-squared	0.074	0.156	0.122	0.187
Start Yr FE	YES	YES	YES	YES
Mesh 9 FE	YES	YES	YES	YES
Trial Controls	NO	YES	NO	YES

NOTES: This table shows how the relationship between clinical trial results reporting and competition varies across trials based on their affiliation with contract research organizations. Competition for a trial-MeSH is measured by the log of the number of competitor clinical trials initiated in the same MeSH code within the previous five years. The sample consists of clinical trials initiated on/after 2007 and completed by 2019. The level of observation is at the trial-MeSH. Estimates are from OLS models. Columns 1 and 2 regress an indicator for clinical trial results reporting in ClinicalTrials.gov within two years of clinical trial completion. Columns 3 and 4 regress the log of the time from clinical trial completion to results reporting in ClinicalTrials.gov. CRO is an indicator for whether the trial's sponsor or collaborator is a contract research organization. "Disease Market Size" denotes the number of patients diagnosed with the trial's diseases. "Sponsor Experience" denotes the number of clinical trials initiated by the trial sponsor in the previous five years. "Trial Controls" denotes controls for trial phase, trial duration, and number of patients enrolled. The smaller number of observations is due to missing data and singleton observations which are dropped in fixed effects specifications. All columns include year fixed effects and MeSH code fixed effects. Robust standard errors, clustered at the MeSH code level, are shown in parentheses. For more detailed data and variable descriptions, see Section 3.

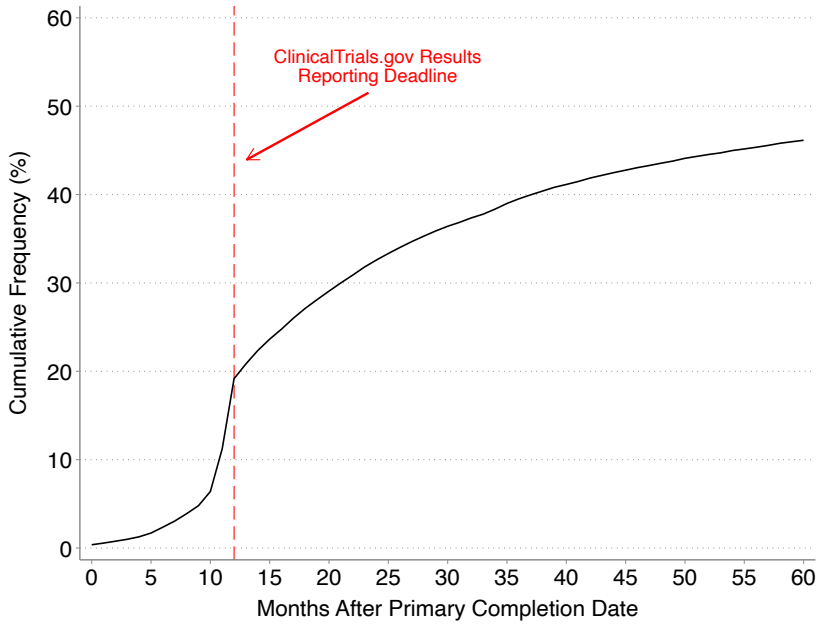
*p <0.10

**p <0.05

***p <0.01

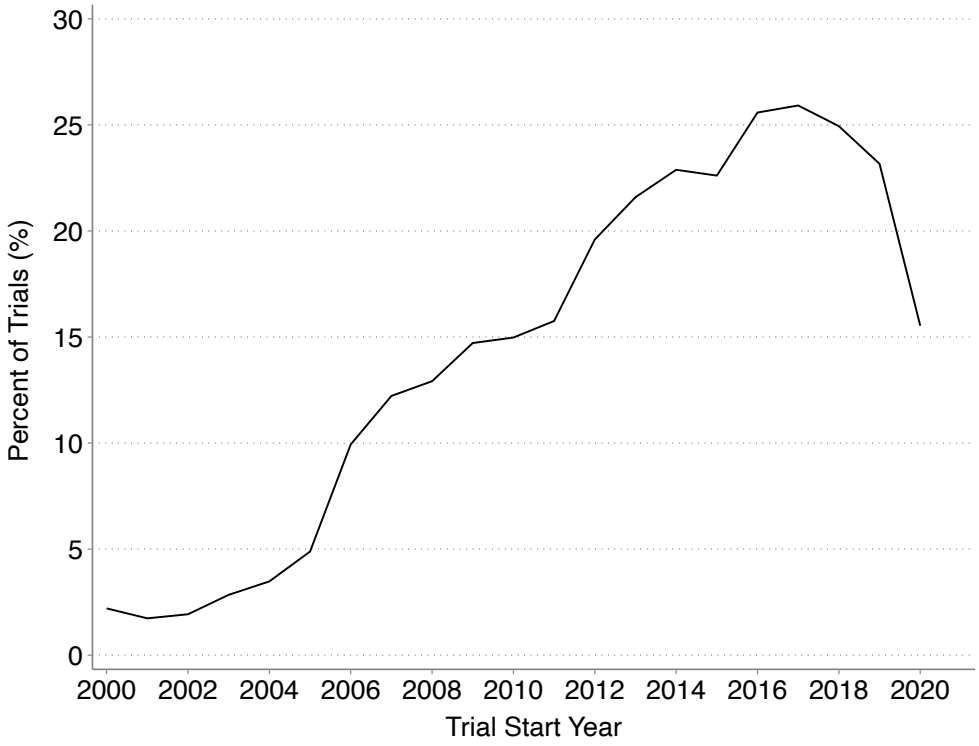
Appendix C
Trends in Disclosure and Competition

FIGURE C1: CUMULATIVE SHARE OF CLINICAL TRIALS REPORTING RESULTS



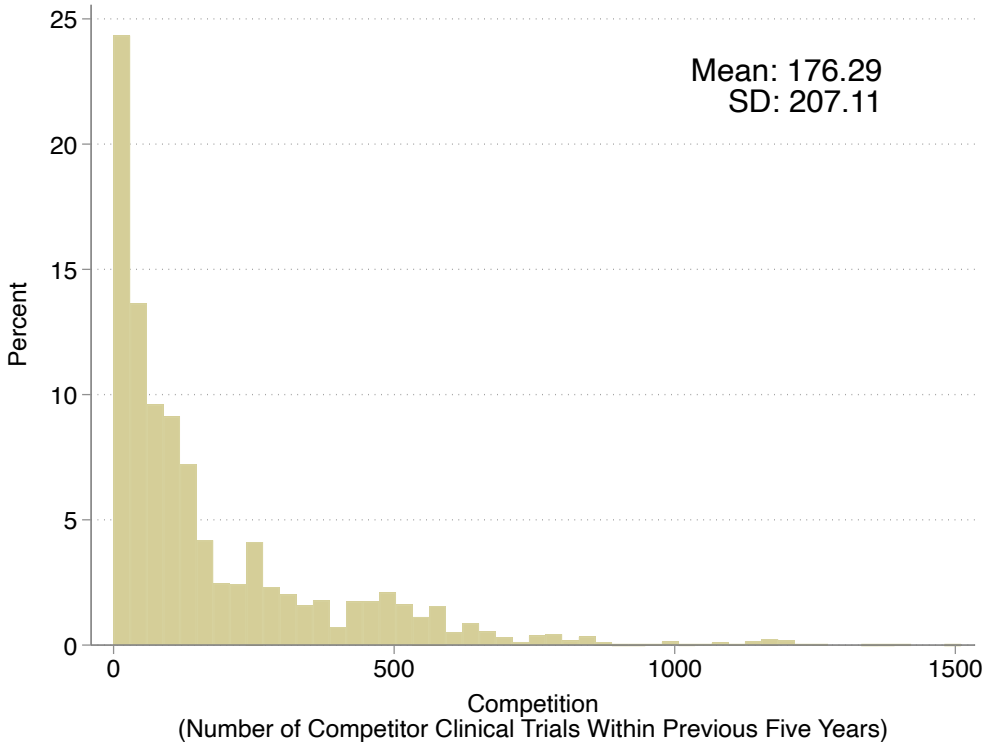
NOTES: This figure shows the cumulative share of clinical trials reporting results in ClinicalTrials.gov. The sample consists of clinical trials initiated on/after 2007 and completed by 2019. The unit of observation is at the trial-level. The red line indicates the one year mark after the clinical trial completion date and corresponds to the FDAAA ClinicalTrials.gov one year results reporting deadline.

FIGURE C2: SHARE OF TRIALS DISCLOSING RESULTS WITHIN ONE YEAR



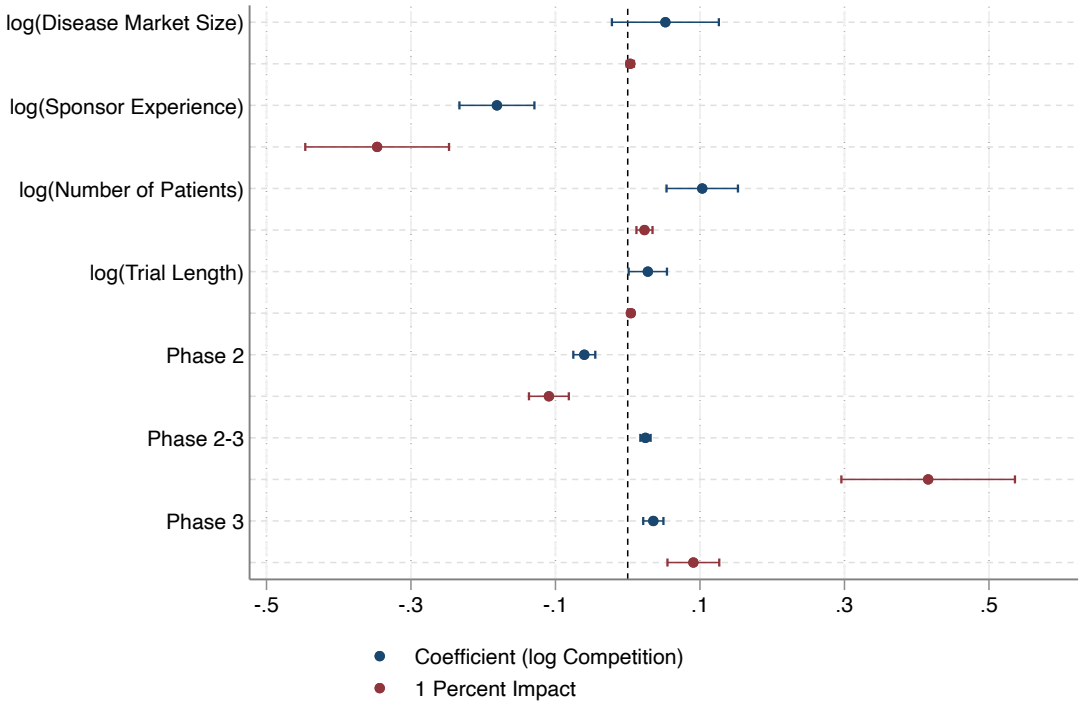
NOTES: This figure plots the yearly percent of clinical trials reporting results to ClinicalTrials.gov within one year of clinical trial completion. The period of analysis is 2000-2020. The unit of observation is at the trial-level.

FIGURE C3: VARIATION IN COMPETITION



NOTES: This figure shows a histogram of competition for clinical trials initiated on/after 2007 and completed by 2019. Competition for a trial-MeSH is measured by the log of the number of competitor clinical trials initiated in the same MeSH code within the previous five years. The level of observation is the trial-MeSH.

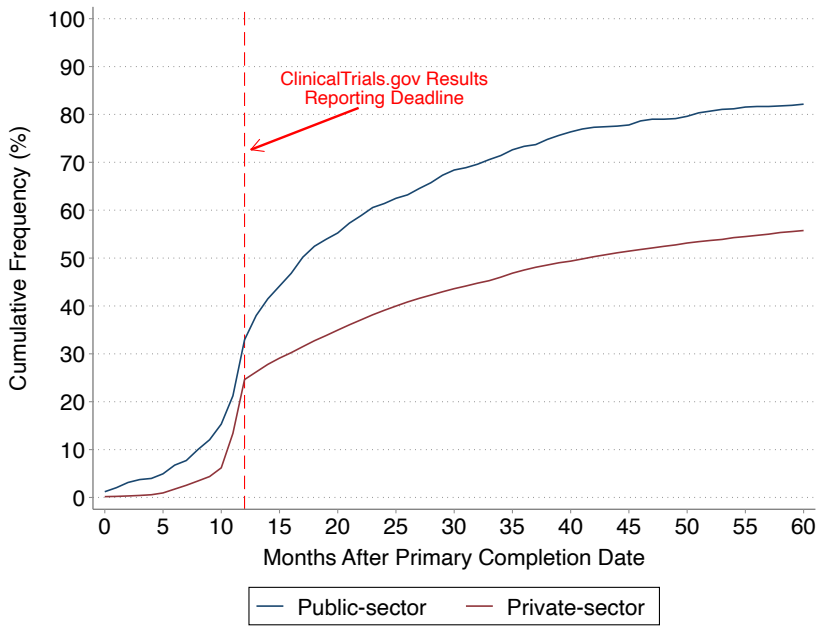
FIGURE C4: TRIAL CHARACTERISTICS BY COMPETITION



NOTES: This figure reports coefficient and percent impact estimates of the relationship between competition and clinical trial characteristics. The level of observation is the trial-MeSH. Estimates are from OLS models where clinical trial characteristics are regressed on the log of the number of competitor clinical trials initiated in the same MeSH code within the previous five years. The sample consists of clinical trials initiated on/after 2007 and completed by 2019. Point estimates in the "Coefficients" panel correspond to coefficients on the competition measure. Regressions include year fixed effects and MeSH code fixed effects. 95% confidence intervals were constructed from standard errors clustered at the MeSH code level. "Percent Impacts" point estimates correspond to a one percent change in the outcome variable associated with a one percent increase in competition. "Disease Market Size" denotes the number of patients diagnosed with the trial's diseases. "Sponsor Experience" denotes the number of clinical trials initiated by the trial sponsor in the previous five years. For more detailed data and variable descriptions, see Section 3.

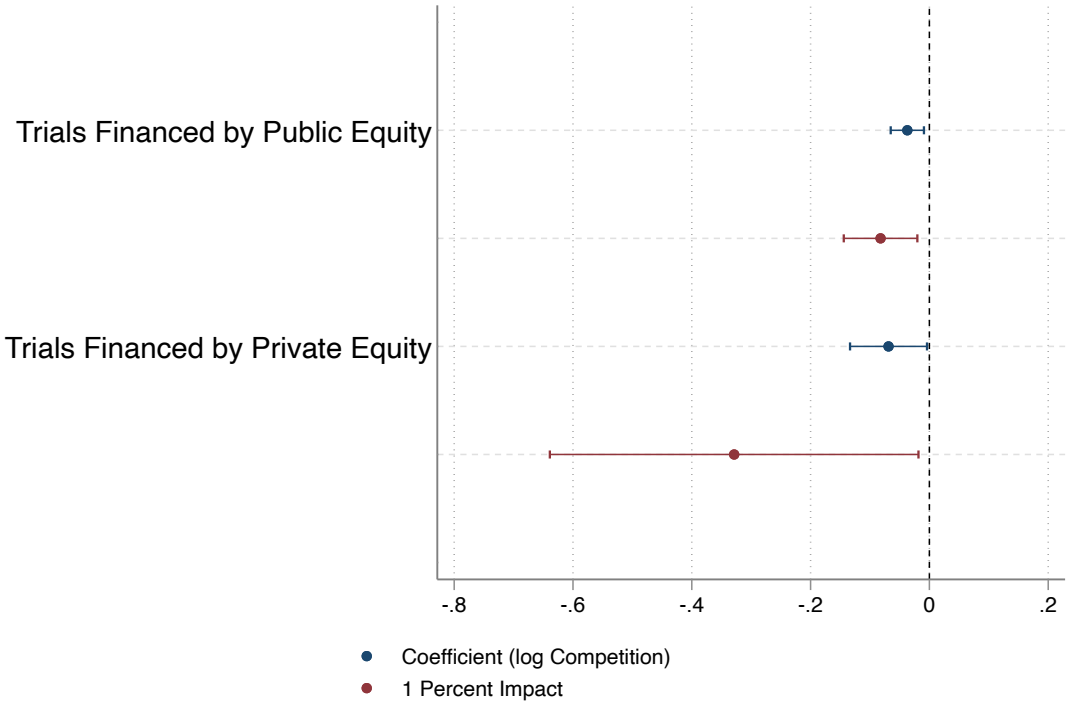
Appendix D
Clinical Trial Funding: Additional Figures and Tables

FIGURE D1: CUMULATIVE SHARE OF TRIALS REPORTING RESULTS AMONG PUBLIC-SECTOR AND PRIVATE-SECTOR TRIALS



NOTES: This figure compares the cumulative share of clinical trials reporting results in ClinicalTrials.gov across public-sector and private-sector trials. The sample consists of clinical trials initiated on/after 2007 and completed by 2019 that are either solely sponsored by the private-sector or the public-sector. The unit of observation is at the trial-level. The red line indicates the one year mark after the trial completion date and corresponds to the FDAAA ClinicalTrials.gov one year results reporting deadline.

FIGURE D2: COMPETITION AND PRIVATE-SECTOR FINANCING TYPE



NOTES: This figure reports coefficient and percent impact estimates of the relationship between competition and clinical trial results reporting across private-sector trials with public equity financing and private equity financing. Information on financing type comes from Cortellis Competitive Intelligence. The sample consists of private-sector clinical trials initiated on/after 2007 and completed by 2019. The level of observation is the trial-MeSH. Estimates are from OLS models where results reporting measures are regressed on the log of the number of competitor clinical trials initiated in the same MeSH code within the previous five years, for subsets (by private-sector financing type) of clinical trials initiated on/after 2007 and completed by 2019. Point estimates in the "Coefficients" panel correspond to coefficients on the competition measure. Regressions include year fixed effects, MeSH code fixed effects, as well as controls for sponsor experience, trial phase, trial duration, number of patients diagnosed in the trial's diseases, and number of patients enrolled. 95% confidence intervals were constructed from standard errors clustered at the MeSH code level. "Percent Impacts" point estimates correspond to a percent change in the outcome variable associated with a one percent increase in competition. For more detailed data and variable descriptions, see Section 3.

TABLE D1: DISCLOSURE AND FINANCING OF CLINICAL TRIALS: MESH WITH BOTH PUBLIC-SECTOR AND PRIVATE-SECTOR CLINICAL TRIALS

Dependent Variable:	Results Reported		log(Months to Reporting)	
	(1)	(2)	(3)	(4)
log(Competition) × Private-sector	0.00671	-0.0225***	0.00776	0.0400***
	(0.00688)	(0.00644)	(0.0125)	(0.0125)
log(Competition)	-0.105***	-0.0359**	-0.0422	-0.0740**
	(0.0163)	(0.0140)	(0.0308)	(0.0298)
Private-sector	-0.285***	-0.260***	0.227***	0.0953*
	(0.0307)	(0.0302)	(0.0520)	(0.0534)
log(Sponsor Experience) × Private-sector		0.0977**		-0.0931
		(0.0435)		(0.0698)
log(Sponsor Experience)		0.0323		0.0162
		(0.0440)		(0.0697)
log(Disease Market Size)		-0.00677***		0.00157
		(0.00224)		(0.00444)
Mean of Dep. Var.	0.425	0.425	3.036	3.036
Observations	73,602	73,602	48,931	48,931
R-squared	0.088	0.195	0.137	0.215
Start Yr FE	YES	YES	YES	YES
Mesh 9 FE	YES	YES	YES	YES
Trial Controls	NO	YES	NO	YES

NOTES: This table shows how the relationship between clinical trial results reporting and competition varies across public-sector and private-sector trials, among MeSH that include both public-sector and private-sector trials. The sample consists of clinical trials initiated on/after 2007 and completed by 2019 that are either solely sponsored by the private-sector or the public-sector. Competition for a trial-MeSH is measured by the log of the number of competitor clinical trials initiated in the same MeSH code within the previous five years. The level of observation is at the trial-MeSH. Estimates are from OLS models. Columns 1 and 2 regress an indicator for clinical trial results reporting in ClinicalTrials.gov within two years of clinical trial completion. Column 3 and 4 regress the log of the time from clinical trial completion to results reporting in ClinicalTrials.gov. "Disease Market Size" denotes the number of patients diagnosed with the trial's diseases. "Sponsor Experience" denotes the number of clinical trials initiated by the trial sponsor in the previous five years. "Trial Controls" denotes controls for trial phase, trial duration, and number of patients enrolled. All columns include year fixed effects and MeSH code fixed effects. Singleton observations are dropped in fixed effects specifications, which accounts for the smaller number of observations. Robust standard errors, clustered at the MeSH code level, are shown in parentheses. For more detailed data and variable descriptions, see Section 3.

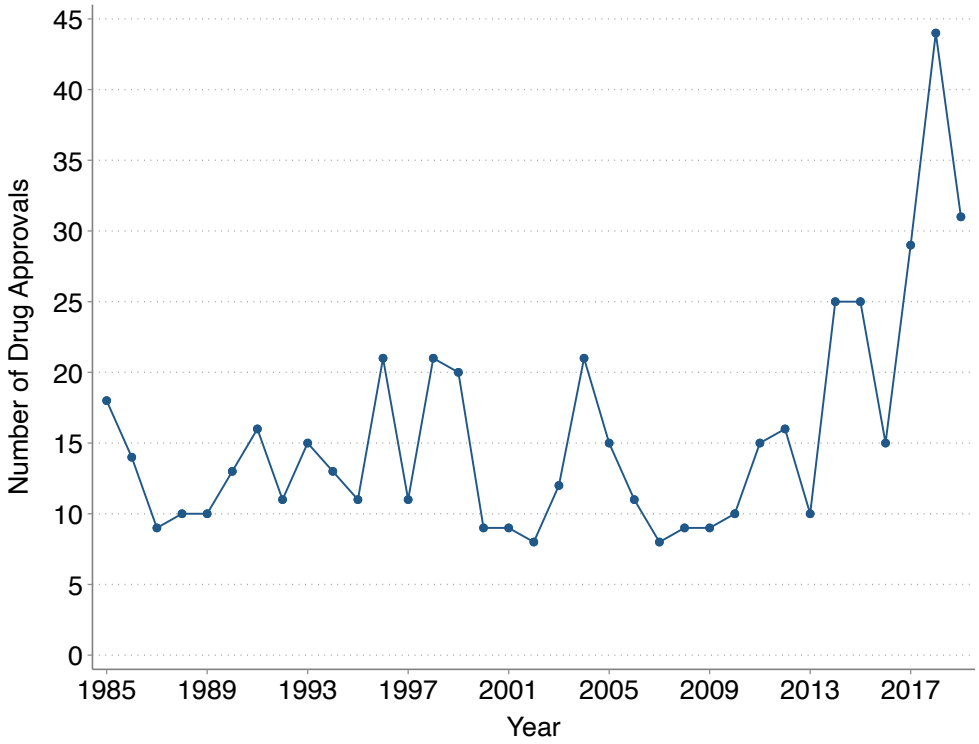
*p <0.10

**p <0.05

***p <0.01

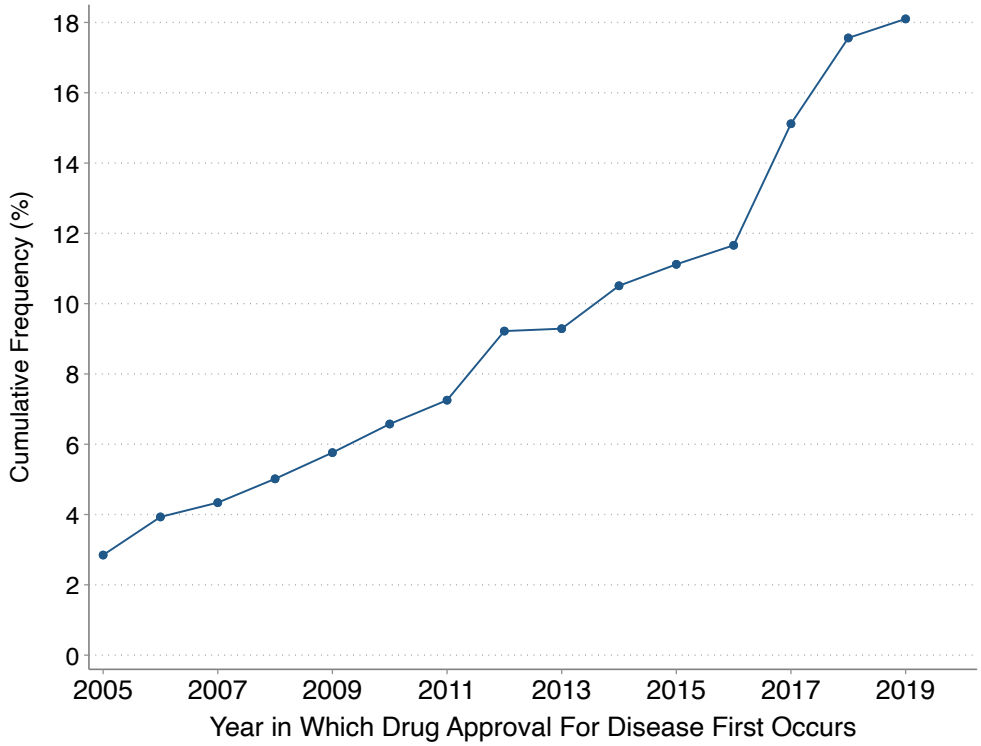
Appendix E
Difference in Differences: Additional Figures and Tables

FIGURE E1: TREND IN DRUG APPROVALS



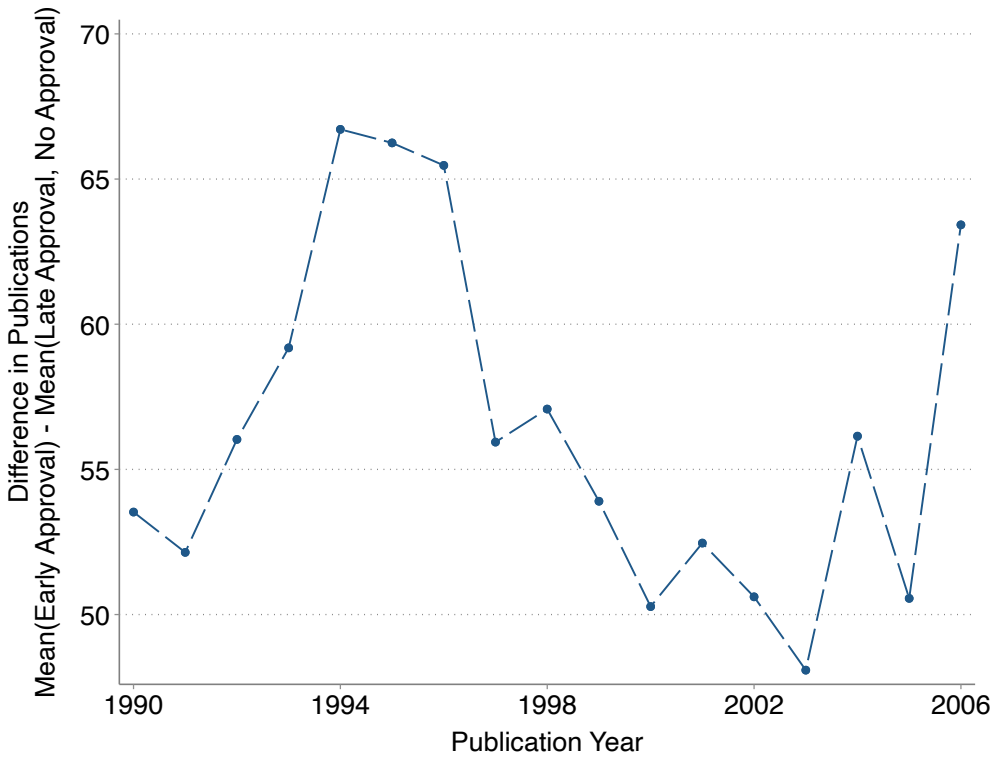
NOTES: This figure plots the total number of priority review drug approvals from 1985 to 2018, inclusive. The unit of observation is at the drug-level. In 2018, the FDA approved a record number of novel drugs (new molecular entities or new therapeutic biologics), which is reflected by the increase in priority review drug approvals (Munos, 2019). While this increase is unlikely to influence our results, our empirical models account for shifts in agency priorities (e.g., towards drug approval) and resources with controls with year fixed effects.

FIGURE E2: CUMULATIVE SHARE OF DISEASES WITH COMPETITOR DRUG APPROVALS



NOTES: This figure plots the cumulative share of MeSH codes with a priority review drug approval, for the unique MeSH codes associated with private-sector clinical trials initiated on/after 2007 and completed by 2019. For more detailed data and variable descriptions, see Section 3.

FIGURE E3: INVESTIGATING SELECTION INTO COMPETITOR DRUG APPROVAL



NOTES: This figure explores selection into competitor priority review drug approvals and compares the difference in average yearly publications among MeSH codes where there was a priority review drug approval early (on/before the median year in the priority review drug approval distribution) and MeSH codes where there was a priority review drug approval late (after the median) or no priority review drug approval.

TABLE E1: COMPETITOR DRUG APPROVAL ESTIMATES: EXCLUDING ALWAYS TREATED AND COHORT-BY-COHORT ESTIMATION

	Main Text	Excluding Always Treat	Wgt. Av. of Cohort by Cohort
	(1)	(2)	(3)
Results Reported	-0.0525	-0.0548	-0.0641
log(Months to Reporting)	0.0476	0.0433	0.0314

NOTES: Column 1 repeats and reports difference-in-differences estimates for the coefficient on *PostCompetitorDrugApproval* (as shown in Column 3 of Table 4). Column 2 reports the results obtained by excluding the set of trial-MeSH observations that are always treated. Column 3 reports the results obtained by estimating the difference-in-differences separately for each cohort and reweighting the cohort-specific estimated treatment effects by cohort size (in the spirit of Goodman-Bacon (2021) and Callaway and Sant'Anna (2021), and following Prager and Schmitt (2021).)

Appendix F
Mechanisms: Additional Figures and Tables

TABLE F1: MESH-LEVEL: COMPETITION AND SHARE DISCLOSED

Dependent Variable:	Share of Trials with Results Reported (mean = 0.315)			
	(1)	(2)	(3)	(4)
log(Competition)	-0.0659***	-0.0693***		
	(0.0182)	(0.0183)		
Post Approval			-0.0868***	-0.0865***
			(0.0233)	(0.0232)
log(Disease Market Size)		0.00995***		0.00946***
		(0.00320)		(0.00320)
Observations	7,248	7,248	7,248	7,248
R-squared	0.221	0.223	0.221	0.223
Start Yr FE	YES	YES	YES	YES
Mesh 9 FE	YES	YES	YES	YES

NOTES: This table examines the relationship between competition and clinical trial results reporting, at the MeSH-year level. The outcome is the share of clinical trials whose results are reported in ClinicalTrials.gov within two years of clinical trial completion. By focusing on a MeSH-year level analysis, this table estimates the competition-disclosure relationship, keeping the level of R&D fixed. To increase consistency across trials, we focus on the set of Phase II private-sector clinical trials initiated on/after 2007 and completed by 2019. Estimates are from OLS models. In Columns 1 and 2, competition is measured by the log of the number of competitor clinical trials initiated in the same MeSH code within the previous five years. In Columns 3 and 4, *PostCompetitorDrugApproval* switches from 0 to 1 when a drug is approved in a MeSH code. "Disease Market Size" denotes the number of patients diagnosed with the MeSH's associated trials. Robust standard errors, clustered at the MeSH code level, are shown in parentheses. For more detailed data and variable descriptions, see Section 3.

*p <0.10

**p <0.05

***p <0.01

TABLE F2: IMPACT OF COMPETITOR DRUG APPROVALS ON DISCLOSURE, BY R&D PROJECT QUALITY AND CONTROLLING FOR DRUG NOVELTY

	Dependent Variable: Results Reported	
	Terminated Trials Sample (1)	Advanced Trials Sample (2)
Post Competitor Drug Approval	-0.0624***	-0.0625*
	(0.0167)	(0.0332)
log(Disease Market Size)	0.00352	-0.00853*
	(0.00242)	(0.00466)
log(Sponsor Experience)	0.131***	0.111***
	(0.00366)	(0.00503)
Mean of Dep. Var.	0.418	0.488
Observations	52,402	15,782
R-squared	0.158	0.318
Start Yr FE	YES	YES
Mesh 9 FE	YES	YES
Trial Controls	YES	YES

NOTES: This table reports how difference-in-differences estimates of the effect of competitor priority review drug approvals on clinical trial results reporting, controlling for drug novelty. The estimates are derived from regressions that include indicators for whether the trial-MeSH tests a novel drug—defined as a drug whose biological mechanism of action has never been previously clinically tested. The sample consists of private-sector clinical trials in the trial advancement dataset that are initiated on/after 2007 and completed by 2019. Columns 1 consists of trials that were terminated. Column 2 consists of trials that successfully advanced. The level of observation is at the trial-MeSH. Estimates are from OLS models. All columns regress an indicator for clinical trial results reporting in ClinicalTrials.gov within two years of clinical trial completion. *PostCompetitorDrugApproval* switches from 0 to 1 when a competitor drug is approved in a MeSH code. "Disease Market Size" denotes the number of patients diagnosed with the trial's diseases. "Sponsor Experience" denotes the number of clinical trials initiated by the clinical trial sponsor in the previous five years. "Trial Controls" denotes controls for trial phase, trial duration, number of patients enrolled, disease market size, sponsor experience, and trial design. All columns include year fixed effects and MeSH code fixed effects. Singleton observations are dropped in fixed effects specifications, which accounts for the smaller number of observations. Robust standard errors, clustered at the MeSH code level, are shown in parentheses. For more detailed data and variable descriptions, see Sections 3 and 5.1.

*p <0.10

**p <0.05

***p <0.01

TABLE F3: IMPACT OF COMPETITOR DRUG APPROVALS ON DISCLOSURE, BY R&D PROJECT QUALITY AND FIRM SIZE

	Dependent Variable: Results Reported			
	Terminated Trials Sample		Advanced Trials Sample	
	Small Firms	Large Firms	Small Firms	Large Firms
	(1)	(2)	(3)	(4)
Post Competitor Drug Approval	-0.0610***	-0.0617**	-0.0451	-0.0685*
	(0.0141)	(0.0290)	(0.0463)	(0.0409)
log(Disease Market Size)	0.000293	0.0115***	-0.0101	-0.00134
	(0.00247)	(0.00427)	(0.00801)	(0.00618)
log(Sponsor Experience)	0.0810***	0.128***	0.0127	0.143***
	(0.0196)	(0.00665)	(0.0391)	(0.0106)
Mean of Dep. Var.	0.322	0.521	0.344	0.538
Observations	27,164	25,091	3,930	11,741
R-squared	0.121	0.188	0.325	0.340
Start Yr FE	YES	YES	YES	YES
Mesh 9 FE	YES	YES	YES	YES
Trial Controls	YES	YES	YES	YES

NOTES: This table reports how difference-in-differences estimates of the effect of competitor priority review drug approvals on clinical trial results reporting varies by R&D project quality and firm size (as measured by research experience). The sample consists of private-sector clinical trials in the trial advancement dataset that are initiated on/after 2007 and completed by 2019. Columns 1 and 3 consists of private-sector trials whose sponsoring firms have low (below median) prior research experience. Columns 2 and 4 consists of private-sector trials whose sponsoring firms have high (above median) prior research experience. The sample in Columns 1 and 2 consist of trials that were terminated. The sample in Columns 3 and 4 consist of trials that successfully advanced. The level of observation is at the trial-MeSH. Estimates are from OLS models. All columns regress an indicator for clinical trial results reporting in ClinicalTrials.gov within two years of clinical trial completion. *PostCompetitorDrugApproval* switches from 0 to 1 when a competitor drug is approved in a MeSH code. "Disease Market Size" denotes the number of patients diagnosed with the trial's diseases. "Sponsor Experience" denotes the number of clinical trials initiated by the clinical trial sponsor in the previous five years. "Trial Controls" denotes controls for trial phase, trial duration, number of patients enrolled, disease market size, sponsor experience, and trial design. All columns include year fixed effects and MeSH code fixed effects. Singleton observations are dropped in fixed effects specifications, which accounts for the smaller number of observations. Robust standard errors, clustered at the MeSH code level, are shown in parentheses. For more detailed data and variable descriptions, see Sections 3 and 5.1.

*p <0.10

**p <0.05

***p <0.01

TABLE F4: R&D PROJECT QUALITY AND DISCLOSURE

Dependent Variable:	Results Reported (mean = 0.434)		
	(1)	(2)	(3)
Advanced Trial	0.0470***	0.0731***	0.0253***
	(0.00717)	(0.00677)	(0.00483)
log(Disease Market Size)		0.00394	-0.000973
		(0.00245)	(0.00218)
log(Sponsor Experience)			0.126***
			(0.00312)
Observations	68,360	68,360	68,360
R-squared	0.089	0.154	0.192
Start Yr FE	YES	YES	YES
Mesh 9 FE	YES	YES	YES
Trial Controls	NO	YES	YES

NOTES: This table shows how the relationship between R&D project quality and disclosure. The sample consists of private-sector clinical trials in the trial advancement dataset that are initiated on/after 2007 and completed by 2019. The level of observation is at the trial-MeSH. Estimates are from OLS models where the outcome is an indicator for clinical trial results reporting in ClinicalTrials.gov within two years of clinical trial completion. For Phase II trials, "Advanced Trial" denotes an indicator for whether intervention subsequently advances to Phase III. For Phase II/III and Phase III trials, "Advanced Trial" denotes an indicator for whether the trial intervention is subsequently approved. "Disease Market Size" denotes the number of patients diagnosed with the trial's diseases. "Sponsor Experience" denotes the number of clinical trials initiated by the clinical trial sponsor in the previous five years. "Trial Controls" denotes controls for trial phase, trial duration, number of patients enrolled, and trial design. All columns include year fixed effects and MeSH code fixed effects. Robust standard errors, clustered at the MeSH code level, are shown in parentheses. Singleton observations are dropped in fixed effects specifications, which accounts for the smaller number of observations. For more detailed data and variable descriptions, see Sections 3 and 5.1.

*p <0.10

**p <0.05

***p <0.01

TABLE F5: PATENTING, COMPETITION, AND RESULTS DISCLOSURE

Dependent Variable:	Trial Results Reported Bf. Patent Filing	Trials Results Reported Bf. Any Patent Filing
	Trial-MeSH-Drug-Patent Sample	Trial-MeSH Sample
	(1)	(2)
High Competition Setting	-0.0108*	-0.0558**
	(0.00652)	(0.0223)
Advanced Trial	0.00754***	0.0473***
	(0.00184)	(0.00631)
Mean of Dep. Var.	0.0153	0.0480
Observations	109,473	20,968
R-squared	0.074	0.177
Start Yr FE	YES	YES
Mesh 9 FE	YES	YES
Trial Controls	YES	YES

NOTES: This table shows the relationship between competition and timing of patent filing and results disclosure. The sample consists of private-sector clinical trials testing initiated on/after 2007 and completed by 2019 that are linked to trial advancement data and patent data. Column 1 uses trial-MeSH-drug-patent level data and regresses an indicator for whether the trial results are reported prior to the focal patent filing date. Column 2 uses trial-MeSH level data and regresses an indicator for whether the trial results are reported prior to any of its focal patent filing dates. Estimates are from OLS models. "High Competition Setting" is an indicator for whether the observation is a MeSH code with high levels of historical competition (above median number of clinical trials initiated prior to 2000). "Advanced Trial" denotes an indicator for whether the trial successfully advances to Phase III (for Phase II trials) or to approval (for Phase III trials). "Trial Controls" denotes controls for trial phase, trial duration, number of patients enrolled, disease market size, sponsor experience, and trial design. All columns include year fixed effects and MeSH code fixed effects. Robust standard errors, clustered at the MeSH code level, are shown in parentheses. The smaller number of observations is due to missing data and singleton observations which are dropped in fixed effects specifications. For more detailed data and variable descriptions, see Sections 3 and 5.3.

*p <0.10

**p <0.05

***p <0.01

Appendix References

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