Disclosure Control as a Real Option: Contractual Governance in Clinical Trials*

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Abstract

Clinical trial publications are the primary channel through which drug-efficacy evidence reaches physicians, shaping prescribing decisions and patient outcomes. To bolster credibility, pharmaceutical firms outsource trials to independent investigators. Yet the majority of these trials still include embargo clauses granting sponsors manuscript-review and publication-delay rights. We frame the embargo as a real option that grants firms disclosure discretion when results disappoint. Linking over 18,000 U.S. clinical trials to peer-reviewed publications, we show embargo adoption concentrates where option value is highest—when fewer co-sponsors reduce contracting frictions, larger enrollment facilitates statistical power for specification search, and adverse results would cause larger market-value losses (Phase 3 trials). Our core finding concerns statistical reporting: embargoed trials are 60% more likely than non-embargoed trials to report primary outcomes at a significance coined by the FDA as "very statistically persuasive" ($p < 0.0001$)–a level which can qualify their drug for approval without additional replication. Such "very persuasive" significance is moderated by the number of primary outcomes tested in the trial, consistent with selective outcome reporting, and does not appear in non-embargoed trials. Furthermore, among marginally insignificant trials, embargoed studies also show 33 percentage points more positive spin in published abstracts, eliminating 82% of the negative tone associated with marginal significance for non-embargoed trials. We document stratified sophistication: top-tier journals and the FDA penalize embargo-enabled manipulation, whereas lower-tier journals and capital markets do not, allowing manipulated findings to flow into the medical literature that guides prescribing and patient care.

Data Availability: Data used in this study are publicly available. Clinical trial data are obtained from ClinicalTrials.gov. Publication data are obtained from PubMed.

Keywords: Real options; strategic disclosure; clinical trials; embargo clauses; spin; p-hacking; pharmaceutical firms; publication bias; stratified sophistication; information intermediaries

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1 Introduction

Clinical trial disclosures communicate pharmaceutical firms' R&D outcomes to physicians, capital markets, and the broader scientific community. Pharmaceutical firms routinely finance the production of evidence about their own products, giving them a central role in generating information used to evaluate those products' effectiveness. The economic stakes of this information production are substantial: around 60% - 70% of medical research in the U.S. is industry funded (Moynihan et al., 2019; Ahn et al., 2017), with the average late-stage trial costing $35 million and total R&D spending reaching up to $2.6 billion per approved drug (Moore et al., 2018; DiMasi et al., 2016). Because trial results can fundamentally shape regulatory approvals, medical treatment decisions, and valuations of pharmaceutical innovation, the integrity of these disclosures carries profound economic and public health consequences.

Recent reviews of the accounting literature on innovation identify precisely this type of disclosure as an open frontier: Glaeser and Lang (2024) call for research on how firms use contracts to manage the disclosure of innovation outputs, and Barth and Gee (2024) ask whether outside parties receive adequate information about unsuccessful innovation activities or whether firms can shape what reaches the public. To strengthen the credibility of their trial results, pharmaceutical firms routinely outsource trials to independent investigators—yet these same firms commonly negotiate contractual embargo clauses granting rights to review manuscripts, delay submission, and shape how results are communicated (Schulman et al., 2002; Mello et al., 2005).

We study how sponsors use embargo clauses to manage the disclosure of unsuccessful trial results. We theorize that these clauses function as real options over disclosure: acquired ex ante at a potential cost to perceived independence, they grant the right—but not the obligation—to intervene when outcomes disappoint.

Similar tensions between nominal independence and client influence arise in auditing (Teoh,

1992), credit ratings (Jiang et al., 2012), and sell-side research (Lin and McNichols, 1998). In clinical trials, key elements of the disclosure process are observable: the contractual control right is publicly registered, statistical reporting and narrative spin reveal patterns consistent with option exercise, and subsequent gatekeeper outcomes are measurable through FDA approval decisions and journal placement.

Expert intermediaries (e.g., journal editors, reviewers, and FDA evaluators) may view an embargo as a signal that the sponsor retains control over disclosure, potentially lowering the perceived credibility of eventual findings. The firm's ex ante decision to include an embargo clause depends on the expected likelihood and severity of bad outcomes; its ex post decision to exercise control depends on outcome severity and the available channels for managing disclosure. We develop two sets of empirically testable predictions: which trial characteristics predict embargo adoption and, conditional on adoption, how firms strategically frame disappointing results.

Because ClinicalTrials.gov—the publicly accessible clinical trial registry and results database maintained by the National Institutes of Health—requires trial sponsors to disclose whether embargo agreements restrict investigators from discussing or publishing trial results, these contracting choices are observable at scale. Exploiting this, we link industry-sponsored U.S. clinical trials to their peer-reviewed medical journal publications, constructing 58,144 firm–trial–indication observations from 2007–2023 (starting with FDAAA 801's mandatory registration of Phase 2+ trials) and tracking each trial from registration through results posting and FDA approval decision. Our analyses use within-firm, within-indication, within-year variation in embargo adoption to estimate its association with key outcomes: p-values for primary outcomes reported on ClinicalTrials.gov and tone distortion ("spin") between the Results and Conclusions sections of published abstracts (Boutron et al., 2010).[1]

[1]Primary outcome measures (also known as "primary endpoints") are the pre-specified, statistically powered metrics used to define a trial's success. Examples include "overall survival" or "tumor response rates" for a trial testing a cancer drug.

Our empirical tests proceed in three stages. First, we examine the drivers of embargo adoption. In line with the real-options framework, embargo clauses are more common in Phase 2 and Phase 3 trials—where efficacy evidence directly affects regulatory and commercial outcomes—than in post-marketing (Phase 4) studies, in trials enrolling more subjects, and in trials with fewer co-sponsors. These patterns indicate that embargo adoption reflects trial-specific option value rather than fixed firm characteristics.

Second, we study how firms exercise disclosure control when results disappoint. On ClinicalTrials.gov, embargoed trials with multiple primary outcomes concentrate p-values below 0.0001—an extreme significance level relevant to historical single-study approval decisions (Sasinowski and Butler, 2020)—an effect absent at conventional levels ($0.01 < p \leq 0.05$). In published abstracts, embargoed trials with marginally insignificant outcomes ($0.05 < p \leq 0.15$) display about 33 percentage points more positive spin than non-embargoed counterparts, offsetting roughly 82% of the tone penalty that marginal insignificance otherwise imposes. The effect vanishes in both tails: when outcomes achieve significance, the embargo–spin interaction is insignificant, and when results are deeply insignificant ($p > 0.15$), the standalone embargo effect is indistinguishable from zero—consistent with an option exercised only when outcomes are marginal.

These results are consistent with an equilibrium among firms that choose to adopt and exercise embargoes: firms facing higher ex ante risk of unfavorable outcomes purchase disclosure control rights and selectively exercise those rights when realized results fall within a range amenable to credible reframing. We use the Pass-zone ($p < 0.05$) as a placebo to discipline the interpretation of our findings. If embargo status merely proxied for spin-prone firms, the effect would appear even when outcomes achieve significance—it does not, ruling out unconditional differences in framing between embargoed and non-embargoed trials.

Third, we examine who bears the consequences and document stratified sophistication in the clinical evidence supply chain. Top-tier medical journals penalize embargoed manuscripts

with elevated spin, and the FDA discounts embargoed trials whose primary outcomes achieve extreme significance ($p < 0.0001$) when citing pivotal evidence for approval. These gatekeepers distinguish organic optimism—strong results that naturally support positive conclusions—from embargo-enabled reframing that yields positive conclusions from mediocre results. Reviewers at lower-tier journals often lack the expertise or incentives to apply similar scrutiny, so embargoed trials with manipulated framing sort into these outlets largely undetected. Once published, strategically framed results enter the broader clinical evidence base—including systematic reviews and meta-analyses[2]—where the original contractual context is no longer visible to downstream users.

Similar to the lack of embargo framing detection by lower-tier journals, we find no evidence that capital market participants can distinguish between results from embargoed and non-embargoed trials, consistent with work showing that markets have limited attention and cognitive resources (Hirshleifer and Teoh, 2003; Pan et al., 2026). The resulting social costs then fall disproportionately on those least able to scrutinize research: practicing physicians, who often rely on abstracts because of time constraints or lack of full-text access (Barry et al., 2001; Nascimento et al., 2021; Sinopoulou et al., 2024), and ultimately patients whose care depends on a cumulatively distorted evidence base.

A substantial medical literature documents that industry-sponsored studies systematically report more favorable results and conclusions than non-industry research (Lexchin et al., 2003; Lundh et al., 2018). In response, medical editors have acknowledged the limitations of current oversight, emphasizing investigator independence while attempting to distinguish reasonable sponsor review from unacceptable publication delays or veto rights (DeAngelis and Fontanarosa, 2008; Fontanarosa and Bauchner, 2017). Related empirical research examines sponsor control over the research and publication process. Surveys of academic

[2]Systematic reviews and meta-analyses play a distinctive role in medical evidence hierarchies, with no close parallel in accounting or finance: they are among the most cited article types in journals such as *The Lancet*, *New England Journal of Medicine*, and *JAMA*, and are primary inputs to clinical practice guidelines and prescribing recommendations (Sackett et al., 1996).

medical institutions indicate that agreements with industry sponsors often provide investigators with limited protections over data access and publication rights (Schulman et al., 2002; Mello et al., 2005), while a study of 44 industry-initiated trial protocols documents sponsor rights over data and manuscript approval, as well as other publication restrictions that were not disclosed in the corresponding journal publications (Gøtzsche et al., 2006). Taken together, prior medical literature establishes that sponsor publication controls exist, but provides limited evidence on when such contractual rights are adopted or how they shape subsequent scientific reporting.

Building on this foundation, we introduce the study of scientific reporting bias to the accounting literature. While prior research typically examines strategic disclosure within firm-controlled channels or regulated reporting regimes (e.g., Leuz and Wysocki, 2016; Blankespoor et al., 2020; Huang et al., 2014), we apply core accounting concepts—specifically incomplete contracting and strategic disclosure—to an economically meaningful setting outside of traditional financial reporting. Although our setting features third-party information production via external investigators, peer-reviewed journals, and a public registry, sponsors successfully reassert influence through contractual review and delay rights. Because contracts cannot fully specify the interpretation and presentation of every possible trial result, these rights provide valuable bargaining leverage when findings disappoint. Applying a real-options framework to these disclosure choices, we capture this dynamic and organize our predictions about when sponsors retain this discretion and how reporting patterns reflect its selective use.

Empirically, we extend the medical literature by connecting the adoption of contractual disclosure rights to subsequent reporting and evaluation of clinical evidence. Whereas prior studies document restrictions on investigators' dissemination rights, our large-sample analysis examines these restrictions as choices made under different contracting conditions and commercial stakes. This distinction matters because sponsor control need not be a uniform

feature of industry-sponsored research: firms may retain discretion where its anticipated value is greatest. Linking these rights to statistical results posted on ClinicalTrials.gov and narrative framing in journal publications further allows us to examine when, and in what form, reporting patterns are consistent with the selective use of that discretion. We thereby move beyond the average association between industry sponsorship and favorable evidence to investigate variation within sponsored research, distinguishing contractual control from the circumstances in which it is associated with favorable presentation. Finally, by relating these reporting patterns to publication venues and FDA citation of pivotal evidence, we provide evidence on the practical reach of gatekeeper scrutiny beyond statements of editorial safeguards. Together, these analyses connect the contractual arrangements documented in prior medical studies to sponsors' incentives and the reporting and evaluation of the resulting evidence.

Our findings also contribute to the innovation-disclosure literature highlighted by Glaeser and Lang (2024) and Barth and Gee (2024). We document the mirror image of the outward information-flow problem studied in prior work (e.g., Eisfeldt and Papanikolaou, 2013; Erkens, 2011): the sponsor uses contractual rights to pull information *back in-house*, reshaping the framing of independently produced scientific evidence. Unlike patents—where protection and disclosure are bundled into a single act—clinical trial embargoes separate the two, letting firms outsource evidence production while retaining discretion over its communication. Our stratified sophistication results show that the answer to whether outside parties can adequately evaluate a firm's innovation activities depends on who is reading and whether the firm holds contractual rights over the disclosure channel.

Our findings take on added urgency in light of the FDA's announced shift in 2026 toward a single pivotal trial supported by confirmatory evidence as the default basis for drug approval (Prasad and Makary, 2026; U.S. Food and Drug Administration, 2026). Under the traditional two-trial regime, independent replication provided a partial check on embargo-enabled

manipulation—a biased result had to survive a second trial. This new, greater reliance on a single pivotal trial makes the integrity of its analysis and reporting more consequential. Notably, our data show that embargoed trials have reported results concentrated at an extreme significance level ($p < 0.0001$) that has been cited as providing "statistically persuasive evidence" in historical single-study approval decisions. The shift from requiring sponsors to "be lucky twice" to "be lucky once" becomes particularly concerning when the mechanisms we document can help sponsors manufacture the appearance of luck.

2 Background and Related Literature

Clinical trials have four phases: Phase 1 assesses safety, Phase 2 examines efficacy signals, Phase 3—the final stage before FDA approval—tests efficacy in large-scale studies, often against existing treatments, and Phase 4 monitors safety and effectiveness after approval. Although regulations require disclosure of raw results on ClinicalTrials.gov, peer-reviewed publications remain the main channel for revealing the outcomes of R&D investments. Unlike patents, publications are public goods that diffuse knowledge to others while intended to add arm's-length verifiability of a firm's knowledge production (Jaffe, 1989).

Firms publish for several strategic reasons. First, to meet capital-market demand for transparent innovation signals: publishing increases when investor attention to R&D intensifies, reducing information asymmetries and improving market outcomes (Baruffaldi et al., 2024; Glaeser and Lang, 2024). Second, when patenting outcomes are uncertain, firms sometimes use defensive or "preemptive" disclosure to deter rivals (Glaeser and Landsman, 2021; Valentine et al., 2025). Third, to stay visible and connected in scientific networks—accessing external knowledge, bolstering credibility with collaborators, and attracting and retaining talent (Rotolo et al., 2022). Publishing is not costless: revealing unpatentable results about a firm's knowledge assets can invite imitation and entry (Kim and Valentine, 2021; Zhang, 2024). Thus, publication strategy often reflects a tradeoff between building credibility and

avoiding additional competition.

In clinical trials, most approved drugs are protected by at least one patent (e.g., 294 of 313 in Galkina Cleary et al., 2023), limiting immediate generic imitation. Here, scientific publication primarily serves to build credibility and visibility with outside stakeholders—physicians, patients, regulators, and the media. Peer review provides arm's-length verification that new therapies are efficacious and safe, aligning scientific communication with market and policy scrutiny.

Firms also recognize that trial outcomes are uncertain and that poorly framed or poorly timed disclosure of unfavorable results can trigger large negative stock-price reactions, especially around pivotal (Phase 3) milestones. Conversely, sponsors can experience large abnormal returns at publication when primary outcomes are met (Singh et al., 2022). Aware of these stakes, sponsors try to balance credibility with bounded control over timing and narrative, particularly when results are unfavorable.

One mechanism for bounded control is the publication embargo: contractual clauses letting sponsors review, delay, or restrict how external authors share findings. Though framed as aiding regulatory coordination (e.g., FDAAA 801 timing) and intellectual property filings, editors and policy advocates warn that such contracts can undermine researcher independence and slow or bias dissemination (e.g., ICMJE guidance; Chan et al., 2014). In practice, embargoes give firms leverage over when findings appear and how they are framed (e.g., abstract emphasis), enabling favorable narratives when results are marginal, consistent with capital markets evidence that managers positively frame uncertain outcomes in voluntary disclosures (Li, 2008; Davis et al., 2012; Huang et al., 2014).

The scope of this leverage is visible in actual contracts. For example, a clinical trial agreement between AstraZeneca and the University of Texas System requires the principal investigator to submit any proposed manuscript to the sponsor at least 60 days before submission, stipulates that no publication or presentation "shall be made unless and until all of As-

traZeneca's comments ... have been considered," and permits AstraZeneca to request an additional 90-day delay for patent filings.[3] At the restrictive end of the spectrum, some agreements categorically forbid investigators from publishing, claim sole and exclusive right to publish, or impose ten-year confidentiality periods.[4]

The potential for sponsor control to distort published clinical evidence is well documented. In GlaxoSmithKline's Study 329, both pre-specified primary outcomes for paroxetine (Paxil) in adolescent depression failed to achieve statistical significance, yet the published report—ghostwritten by a medical writer retained by the sponsor[5]—concluded that the drug was "generally well tolerated and effective" by emphasizing post-hoc secondary analyses absent from the original protocol (Keller et al., 2001). An independent reanalysis of the same data reached the opposite conclusion: paroxetine demonstrated no efficacy and increased harms (Le Noury et al., 2015). Study 329 predates the ClinicalTrials.gov disclosure regime, but it illustrates precisely the mechanisms—outcome switching, selective reporting, and narrative spin—that embargo clauses formalize as contractual rights. The case underscores a fundamental tension: firms outsource clinical research to independent investigators for credibility, yet retain contractual infrastructure that allows them to reassert control when results disappoint. This credibility-versus-control tension parallels capital-market work on selective disclosure and strategic timing: managers delay or soften bad news when proprietary, litigation, or reputational costs are high and use timing and framing to influence investors and regulators (Verrecchia, 1983; Heflin et al., 2003; Kothari et al., 2009; Beyer et al., 2010). A common theme in accounting and finance is that "independent" assessments are undermined when the assessed party has leverage over the assessor. Teoh (1992) shows this for auditing: the credible threat of dismissal can erode independence when client-specific rents are

[3]Section 17.3, Clinical Study Agreement between AstraZeneca and the University of Texas System. The full clause further specifies that AstraZeneca's proprietary rights provision shall control over any conflicting publication policy in the trial protocol.

[4]See Appendix 6 for a detailed inventory of restrictive provisions.

[5]Sally Laden was the uncredited medical writer, confirmed through litigation documents underlying GSK's $3 billion DOJ settlement in 2012.

at stake, even without actual switching. Similar leverage appears in credit ratings, where the move from investor-pay to issuer-pay led to inflated ratings for bonds with the greatest conflicts (Jiang et al., 2012); and in sell-side research, where underwriting relationships bias analysts' outputs (Lin and McNichols, 1998) and firms steer information through selective analyst access (Kirk and Markov, 2016). Even ESG rating agencies, despite subscriber-pay models, display upward bias when parent-company commercial ties create indirect economic links to rated firms (Li et al., 2024). In all cases, influence arises from some form of economic dependence between assessor and assessed.

Our setting highlights a different lever. Clinical trial investigators are not economically dependent on sponsors in the same way as auditors on client rents or rating agencies on issuer fees. Instead, the embargo clause creates leverage: a contractual right to review, delay, and shape how findings enter the public record. This mechanism substitutes for economic dependence, implying that formal independence of the information producer is weaker protection than previously thought when firms retain dissemination control rights. Our clinical trials setting is also distinctive in its observability: the control right is explicitly recorded, its exercise is visible in protocol amendments and publication delays, and its effects are measurable in public scientific records. Clinical-trial embargoes therefore offer a transparently governed, outcomes-observable testbed for theories of "independent opinion under issuer influence." Section 3 explains how we use these features to test when sponsors adopt and exercise control.

3 Hypothesis Development

We view the embargo clause as a real option. Real options logic has been applied to pharmaceutical R&D investment decisions (McGrath and Nerkar, 2004) and to explicit contractual call options in joint ventures (Reuer and Tong, 2005); our setting extends this reasoning to contractual rights over disclosure. At the contracting stage, the sponsoring firm decides

whether to include an embargo provision in its agreement with the third-party principal investigator. If it does, the firm pays an upfront reputational cost—sophisticated observers recognize that embargoes signal a desire for control over disclosure—in exchange for the right, but not the obligation, to delay publication and attempt to reframe the narrative if trial results are unfavorable. The core mechanism—using contractual control to obtain a second evaluation of the same underlying information—has a close analogue in the auditing literature. Teoh (1992) shows that a firm receiving an unfavorable audit opinion may switch auditors not to coerce a more lenient report, but simply to obtain a fresh draw from a different evaluator's assessment distribution, a strategy she demonstrates is "observationally equivalent to obtaining a second drawing by the switching firm of an auditor's assessment" (p. 12). In our setting, specification search serves the same function: the sponsor does not fabricate data but instead redraws from the statistical distribution of possible test specifications, seeking one that crosses the significance threshold. Like auditor switching, this strategy requires no fraud—only the contractual right to try again. In Appendix 6 we develop a simple illustrative example to help us motivate our empirical predictions, which we describe here in words.

The key insight is that the embargo option has value only when the firm can credibly use it. Trial outcomes fall into three zones. In the *Pass* zone (roughly, p-value ≤ 0.05), the primary outcome target is met and no reframing is needed. In the *Fail* zone (roughly, p-value > 0.15), the trial has clearly failed and no amount of narrative reframing can plausibly bridge the gap between actual and desired results. The option has value only in the *Marginal* zone (roughly, $0.05 < p$-value ≤ 0.15), where results narrowly missed significance and the gap between actual and desired outcomes is small enough that specification search or narrative spin may credibly close it. This three-zone structure generates predictions about when firms purchase the option, when they exercise it, and who detects the resulting manipulation.

3.1 When Do Firms Adopt Embargo Clauses?

The decision to include an embargo clause depends on comparing its expected benefits against its costs. The primary benefit is flexibility: if trial results fall in the *Marginal* zone, the firm can exercise embargo control rights to rerun analyses or reframe their findings. The contract bears a reputational cost, as embargo agreements are publicly disclosed and signal to informed outsiders that the firm seeks control over the publication process, potentially reducing the credibility of whatever results are eventually published. This tradeoff yields three testable comparative statics. First, embargo clauses should be more common in trials where the payoff from successful manipulation is larger. Phase 3 trials—where FDA approval hangs in the balance—are the highest-stakes setting in drug development (Singh et al., 2022), so the value of converting a marginal failure into a perceived success is greatest. Phase 2 trials also carry high stakes because they have the highest failure rates of all four phases (Wong et al., 2019) and because strong results can support accelerated approvals, especially in oncology (Chabner, 2012). By contrast, Phase 4 trials occur after approval, so the value of reframing is lower. Second, embargo clauses should be more common when manipulation is more feasible. Larger trials permit more subgroup analysis and specification search, increasing the likelihood of successful reframing. More experienced sponsors—measured by cumulative prior trials—have deeper knowledge of outcome behavior and analytical degrees of freedom. Third, embargo clauses should be less common when reputational costs are higher. Trials with more co-sponsors create coordination frictions and expose the firm to scrutiny from additional parties, raising the effective cost of reduced transparency.

H1 (Embargo Adoption): *Embargo clauses are more prevalent in trials where commercial stakes are higher (Phase 2 and Phase 3), manipulation is more feasible (larger sample sizes, greater sponsor experience), and reputational costs are lower (fewer co-sponsors).*

An observable implication of this prediction is that not all trials carry embargo clauses. If the option were costless, universal adoption would dominate. The incomplete adoption

we document—approximately 25% of industry-sponsored trials with external principal investigators lack embargo clauses—is itself revealed-preference evidence that sponsors face real frictions in contracting for disclosure control.[6] These frictions operate primarily at the contracting stage: investigators at prestigious research institutions may demand higher compensation or resist participation when sponsors insist on publication control, and co-sponsors introduce negotiation costs and reputational exposure to additional parties (Mello et al., 2005). We do not observe these contracting frictions directly, but the cross-sectional variation in adoption (Section 5.2) reveals the trial characteristics that shift the cost-benefit margin—fewer co-sponsors, higher commercial stakes, and greater analytical degrees of freedom all predict adoption, consistent with costs borne at the negotiation table.

3.2 How Do Firms Exercise Disclosure Control?

Once a firm includes an embargo clause, the question is when it exercises the option. The framework predicts exercise only when two conditions hold simultaneously: (i) the trial result falls in the *Marginal* zone, and (ii) the expected gain from reframing exceeds its costs. In the *Pass* zone, the trial met its primary outcome and the marginal benefits to spin are minimal. In the *Fail* zone, the gap between actual and desired outcomes is too large for credible reframing, and the expected gain from manipulation turns negative.

We expect the firm to exercise control through multiple channels. First, sponsors can engage in specification search, selecting from among the analytical degrees of freedom available in a complex clinical dataset to identify results that cross conventional significance thresholds. We hypothesize that creating additional primary outcomes on ClinicalTrials.gov serves effectively as specification search, as it allows the firm to use alternative metrics in their statistical analyses of trial results. Second, sponsors can influence the narrative framing of the publication abstract to present a more optimistic interpretation than the underlying results

[6] This logic parallels the inference in the real options literature that the failure to exercise an apparently in-the-money option reveals unobserved costs. Here, the failure to *purchase* the option reveals that C_{rep} is binding for a substantial fraction of trials.

warrant. The clinical trials literature refers to this practice as "spin" (Boutron et al., 2010).

The specification search prediction can be sharpened by considering *where* sponsors target their efforts. The p-hacking literature documents that the conventional threshold of $p \leq 0.05$ serves as the de facto gatekeeping standard for journal acceptance in both economics (Brodeur et al., 2016, 2020) and medicine (Dwan et al., 2008). Investigators whose primary career incentive is publication therefore face strong returns to nudging borderline results just below this cutoff but limited incentive to push further.

Industry sponsors face a different payoff structure. FDA guidance permits reliance on a *single* adequate, well-controlled trial when results are *"statistically very persuasive"* ($p \leq 0.0001$) (U.S. Food and Drug Administration, 1998; Sasinowski and Butler, 2020), creating strong incentives to report at this threshold. Doing so can enable one-study approval, boosting profits through lower trial costs and extended patent life. Sponsors using embargo-enabled specification search therefore target this more stringent threshold because the marginal return to extremely significant results ($p \leq 0.0001$) is regulatory approval, not just publication.

H2a (Differential Targeting): *The effect of embargo status on statistical significance concentrates at different thresholds depending on who controls the specification search. Embargoed trials—where sponsors direct the analysis—exhibit an excess concentration of p-values at the* $p \leq 0.0001$ *level and a reduced concentration in the two-star band (*$0.04 < p \leq 0.05$*). Non-embargoed trials—where investigators retain control—exhibit the reverse pattern, consistent with targeting the conventional journal publication threshold.*

Specification search operates on the reported test statistic; narrative spin operates on the language used to interpret it. This prediction carries a sharp empirical implication: any *incremental* effect of embargo status on disclosure manipulation should concentrate among marginally insignificant trials. The Pass zone offers a direct placebo test. If embargoes merely proxied for the type of firm that manipulates, embargoed trials would exhibit elevated spin

even when results are favorable. If instead embargoes function as real options, the embargo–spin association should be confined to the Marginal zone, where the option has positive exercise value.[7] Thus, our identification rests on the contrast between the Marginal zone (where the embargo interaction should be large and positive) and the Pass zone (where it should be indistinguishable from zero).

H2b (Conditional Exercise): Embargoed trials exhibit elevated spin, but only when primary outcomes are *Marginal*. The embargo–spin association is absent when results are already significant (the option is unneeded). Thus, the *Pass* zone serves as a placebo test: if embargo status merely proxied for firm-level spin propensity, the effect would appear regardless of outcome significance.

3.3 Who Detects the Manipulation?

The framework predicts that the consequences of embargo-enabled manipulation depend on the sophistication of the audience. Published results pass through gatekeepers before reaching end-users, and these gatekeepers vary in their ability to detect manipulation.

Sophisticated gatekeepers. Top-tier medical journals demand strict transparency regarding underlying trial data and employ reviewers with deep clinical expertise. These reviewers can compare the published abstract against the registered protocol, identify specification searches, and recognize when conclusions are more optimistic than the reported results warrant. We therefore expect top journals to penalize embargoed manuscripts that carry elevated spin: the interaction of embargo status and spin should predict a *lower* probability of publication in a top journal. Similarly, the FDA evaluates drug applications using

[7]The framework's prediction on the Fail zone is more nuanced. While the option to rescue statistical significance is clearly worthless when results are far from any threshold, the option to shape *how* the failure is presented—emphasizing the safety profile of the drug, framing the trial as informative for future trials—may make the trial results more publishable, and hence retain value. To the extent that investigators with an incentive to publish failed trials already engage in such reframing in the Fail zone, embargo control may have little additional effect at the margin—as these drugs will clearly not be commercializable.

the complete clinical dossier—including raw patient-level data—rather than relying on published abstracts alone. FDA evaluators can identify when unusually strong p-values from embargoed trials reflect specification search rather than genuine efficacy. We therefore expect the FDA to apply larger discounts to highly significant results from embargoed trials when making approval decisions.

H3 (Sophisticated Detection): *Top journal reviewers and FDA evaluators detect embargo-enabled manipulation: (i) embargoed trials with elevated spin are less likely to appear in top journals, and (ii) the FDA discounts suspiciously significant results from embargoed trials in approval decisions.*

Importantly, the penalties predicted by H3—top journals penalizing embargoed manuscripts with elevated spin, the FDA discounting suspiciously significant embargoed results—do not imply that the embargo option is costless when results are favorable. These penalties constitute additional, probability-weighted costs that the firm anticipates ex ante when deciding whether to purchase the option. Even though the penalties are realized only conditional on manipulation, the firm incorporates their expected value across all outcome states at t_0. The fact that penalties are state-contingent is a property of any option: the cost of purchasing a put option is paid upfront regardless of whether the underlying asset declines.[8]

4 Research Design

4.1 Data and sample selection

Our primary data source is ClinicalTrials.gov, a public database where trial sponsors must (1) register clinical trials within 21 days after enrolling the first participant and (2) report

[8]More precisely, the ex-ante cost of the embargo option includes both the direct contracting friction C_{rep} and the probability-weighted expected penalty $\rho_M \cdot \rho_m \cdot d_H \cdot L_{detect}$, where ρ_M is the probability of landing in the Marginal zone, ρ_m is the probability of successful manipulation conditional on marginal results, d_H is the probability that a sophisticated gatekeeper detects it, and L_{detect} is the loss from detection (journal sorting to a lower-tier outlet, FDA discounting). See Appendix A.

results within one year after the trial's primary completion date. Registration records include sponsor, phase, medical condition, eligibility criteria, trial dates, study design (protocol with outcome measures), and trial status. Results disclosures include information on trial efficacy (including p-values for primary outcomes) and safety (adverse events).

We collect AACT data[9] for all interventional studies registered on ClinicalTrials.gov between 2007-2023. Our sample starts in 2007, when registration of Phase 2 and later trials became mandatory under Section 801 of the Food and Drug Administration Amendments Act (FDAAA). We exclude Phase 1 trials, which are not subject to FDAAA, and keep only studies with at least one industry sponsor (hereafter, "firm"). Because therapeutic areas differ in trial success rates, competition, and regulatory scrutiny—which may affect disclosure—we assign each trial to a therapeutic area (indication) and include indication fixed effects throughout. One caveat applies: because sponsors must answer questions about embargo agreements only when they submit results and report that not all PIs are employees, our sample includes only trials with results disclosed on ClinicalTrials.gov and external PIs. Importantly, although embargo information is submitted alongside trial results, the embargo contract is typically formed at the onset of the trial—before outcomes are realized—meaning adoption reflects an ex-ante contracting choice rather than an ex-post response to unfavorable findings.

Although our main tests use a binary *Embargo* indicator, the underlying agreements vary widely. Among 18,630 trials with recorded agreement text, provisions range from time-limited review to outright publication bans.[10] We use a binary specification for two reasons.

[9]Aggregate Analysis of ClinicalTrials.gov (AACT) is a publicly available relational database containing all information (trial protocol and result data elements) for every study registered on ClinicalTrials.gov. See: `https://aact.ctti-clinicaltrials.org/`.

[10]Appendix C provides examples; we highlight several here. At the strictest end, 149 trials categorically forbid the PI from discussing or publishing results. In 11 trials, the sponsor claims "the sole and exclusive right to publish," stating that the PI "has no right to publish [but] may be invited to publish." One Merck agreement assigns the sponsor ownership of "all documentation, research data, records, raw data, [and] other work product," treating the PI's work as the sponsor's intellectual property. Thirty-six trials impose ten-year confidentiality, and the most common template (462 trials) conditions publication on "prior written approval" plus a waiting period—often two years—after the sponsor's disclosure of pooled results. Another 7,112 embargoed trials were coded in AACT's legacy format, which records the restriction type but not the

First, provisions such as prohibition, delay, veto, and ownership differ qualitatively and lack a natural ordering; imposing one (e.g., ranking an outright ban above a ten-year confidentiality clause) would introduce unknown measurement error. Second, the binary indicator is conservative: pooling blanket bans with time-limited review biases estimates toward zero relative to a measure isolating only the most restrictive agreements.[11]

Our second major data source is PubMed, a National Library of Medicine repository with over 38 million biomedical abstracts. For clinical trial–based articles, PubMed provides a trial registration ID (`NCT_ID`), which we use to merge with AACT, along with journal titles, publication dates, and abstracts. Our final sample includes 58,144 firm–trial–indication observations with non-missing values for key variables, the level at which firms make disclosure decisions and interact with external PIs.

4.2 Determinants of embargo adoption (test of H1)

To test H1, we examine firm- and trial-level characteristics associated with embargo adoption by estimating the following regression at the firm–trial–indication level, where subscripts i, j, and k denote firm, trial, and indication:

$$\begin{aligned} Embargo_{i,j,k} = \alpha + \beta_1 N_sponsors_{i,j,k} + \beta_2 Phase_2_{i,j,k} + \beta_3 Phase_3_{i,j,k} \\ + \beta_4 N_subjects_{i,j,k} + \beta_5 Previous_trials_i + \text{FE} + \varepsilon_{i,j,k} \end{aligned} \tag{1}$$

where *Embargo* equals one if the trial features an embargo agreement between the firm and the external PI. *N_sponsors* captures the number of co-sponsors, reflecting coordination complexity and bargaining dynamics; *N_subjects* (the logarithm of enrolled subjects) proxy for trial size and complexity; and *Phase_3* and *Phase_2* (with Phase 4 omitted) capture differ-

contract language, so these figures are a lower bound on such provisions.

[11] Purdue Pharma illustrates the extreme: all 35 of its trials include restrictive agreements—a 100% adoption rate—across opioid formulations studied during a period of rising addiction evidence and crisis-level litigation, consistent with our model's prediction that sponsors facing uniformly high disclosure costs will purchase the embargo option across their entire portfolio.

ences in regulatory and commercial stakes. At the firm level, *Previous_trials* (the logarithm of count of prior trials) measures sponsor experience. H1 predicts $\beta_1 < 0$ and $\beta_2, \beta_3, \beta_4, \beta_5 > 0$.

We estimate Equation (1) under progressively restrictive fixed-effects specifications, building from year fixed effects to indication and year, firm and year, and finally—indication, firm and year fixed effects. The last specification—our preferred one—exploits within-firm, within-indication, within-year variation. Standard errors are clustered at the firm level throughout.

4.3 Conditional exercise of disclosure control (tests of H2a, H2b)

4.3.1 Primary outcome multiplicity and p-value significance

We conduct two analyses for the main venues where trial results are disclosed: ClinicalTrials.gov and scientific journals. First, we study how embargo status relates to the distribution of p-values for primary outcomes, which sponsors must report on ClinicalTrials.gov. We also test whether the reporting of multiple primary outcomes moderates this association. We estimate the following OLS regression for each trial, where subscripts i, j, and k denote firm, trial, indication:

$$\begin{aligned} Sig_{i,j,k} = \alpha + \beta_1 Embargo_{i,j,k} + \beta_2 N_outcomes_{i,j,k} \\ + \beta_3 Embargo_{i,j,k} \times N_outcomes_{i,j,k} + \mathbf{X}'\boldsymbol{\gamma} + \text{FE} + \varepsilon_{i,j,k} \end{aligned} \tag{2}$$

We estimate Equation (2) using two distinct significance thresholds for the primary outcome p-values reported on ClinicalTrials.gov (hereafter, "p-values"). Specifically, we construct two indicator variables that equal one if the smallest p-values fall into a specific significance bin, and zero otherwise: *Sig_0_0001* for extremely significant outcomes ($0 < p \leq 0.0001$) and *Sig_04_05* for barely significant outcomes ($0.04 < p \leq 0.05$). *N_outcomes* is the count of primary outcomes reported on ClinicalTrials.gov.[12] The vector $\mathbf{X}'$ contains the same controls as Equation (1), and we include year, indication, and firm fixed effects.

[12] 80% of observations of our sample report only one primary outcome, hence for robustness we also use an indicator *Multi_outcomes* that equals one when *N_outcomes* is larger than one.

H2a predicts positive signs for β_1 and β_3 in Equation (2) when *Sig_0_0001* is the dependent variable: embargoed trials should show greater concentrations of p-values below 0.0001—the FDA's historical single-study approval threshold (Sasinowski and Butler, 2020), moderated by primary-outcome multiplicity. We complement the regressions with graphical analysis of the p-value distribution for embargoed versus non-embargoed trials (Figure 2 and Figure 3), providing a nonparametric view of the distributional shifts predicted by H2a.

4.3.2 Abstract spin and the Marginal zone test

Second, we test whether embargo status is associated with narrative spin, and whether this association concentrates among marginally insignificant rather than clearly significant or clearly insignificant results:

$$\begin{aligned} Spin_{i,j,k} = \alpha &+ \beta_1 Embargo_{i,j,k} + \beta_2 Pass_{i,j,k} \\ &+ \beta_3 Embargo_{i,j,k} \times Pass_{i,j,k} + \beta_4 Marginal_{i,j,k} \\ &+ \beta_5 Embargo_{i,j,k} \times Marginal_{i,j,k} + \mathbf{X}'\boldsymbol{\gamma} + \text{FE} + \varepsilon_{i,j,k} \end{aligned} \tag{3}$$

Following Boutron et al. (2010), our spin measure targets the Conclusion section of the abstract. Medical journal abstracts separately label Results and Conclusions sections. The Conclusions section is generally considered the most interpretive part of a scientific abstract—it provides space for framing effects: emphasizing strengths, downplaying limitations, or projecting broader significance (Boutron et al., 2010). The Results section, by contrast, reports effect sizes, p-values, and confidence intervals in a standardized format subject to editorial scrutiny, leaving less room for influence. Thus, we control for results tone and define *Spin* as the difference between conclusion tone and results tone—capturing how much more optimistically authors frame conclusions relative to reported evidence. We measure tone using Linguistic Inquiry and Word Count (LIWC) 2015 (Pennebaker et al., 2015), a validated text analysis program that classifies words into psychologically meaningful categories including positive and negative affect. LIWC is widely used to assess tone in scientific publications

and to analyze deceptive language (Hauch et al., 2015; Rathee et al., 2025), and its affect categories were developed to capture dimensions of language that shape reader perceptions (Tausczik and Pennebaker, 2010)—making it well suited to a setting where the mechanism of interest is how narrative framing influences physicians' and investors' interpretation of disappointing results.[13]

We classify primary-outcome p-values posted on ClinicalTrials.gov into three zones: Pass ($p \leq 0.05$), Marginal ($0.05 < p \leq 0.15$), and Fail ($p > 0.15$).[14] *Pass* equals one if the trial's most significant primary outcome p-value falls into the Pass zone. *Marginal* equals one if the trial's most significant primary outcome p-value falls into the Marginal zone. The Fail zone is the omitted category. Accordingly, β_1 measures the embargo–spin association among deeply insignificant trials, β_2 and β_4 measure spin differences across zones for non-embargoed trials relative to the Fail baseline, and β_3 and β_5 capture the incremental embargo effect in each zone.

Equation (3) decomposes spin into two components–a baseline effect of independent scientific researchers to publish their studies, and any additional effect owing to embargo contractual control. The zone indicators (β_2, β_4) capture investigator incentives: the tendency to frame conclusions more optimistically than reported results as a function of outcome severity. The interaction coefficients (β_3, β_5) capture the *incremental* effect of sponsor control in each zone—*the margin along which the real option operates*. H2b predicts $\beta_5 > 0$ (embargo clauses increase spin in the Marginal zone), $\beta_3 \approx 0$ (no embargo effect in the Pass zone). The Pass-zone interaction serves as a placebo test: if embargo status merely proxied for spin-prone firms, the effect would appear even when endpoints achieved significance.

[13]For robustness, we use a modified LIWC-based *Spin* measure that adjusts the positive and negative word lists following Vinkers et al. (2015), who specifically analyze scientific PubMed abstracts.

[14]We follow Elliott et al. (2022), who find sizable mass points in the p-value distribution up to 0.15, above which results are too insignificant to be plausibly manipulated. For robustness, we also show results using 0.20 as an alternative cutoff between the Marginal and Fail zones.

4.4 Detection of embargo-enabled manipulation (tests of H3)

We test H3 by separately examining how results from embargoed trials are perceived by sophisticated gatekeepers—top medical journals and the FDA—and by less sophisticated audiences—capital market participants.

4.4.1 Journal sorting

We estimate the following OLS regression at the firm–trial–indication level:

$$\begin{aligned} FirstPub_top_{i,j,k} = \alpha + \beta_1 Embargo_{i,j,k} + \beta_2 Spin_{i,j,k} \\ + \beta_3 Embargo_{i,j,k} \times Spin_{i,j,k} + \mathbf{X}'\boldsymbol{\gamma} + \text{FE} + \varepsilon_{i,j,k} \end{aligned} \tag{4}$$

where *FirstPub_top* equals one if the trial's first publication appeared in a top-10 medical journal, as ranked by the McGill University Department of Medicine.[15] More prestigious journals employ more rigorous peer review and are therefore better positioned to detect strategic framing.

4.4.2 FDA approval

We examine FDA approval decisions using the following specification:

$$\begin{aligned} FDA_Decision_{i,j,k} = \alpha + \beta_1 Embargo_{i,j,k} + \beta_2 Sig_0_0001_{i,j,k} \\ + \beta_3 Embargo_{i,j,k} \times Sig_0_0001_{i,j,k} + \mathbf{X}'\boldsymbol{\gamma} + \text{FE} + \varepsilon_{i,j,k} \end{aligned} \tag{5}$$

where *FDA_Decision* captures the FDA's regulatory response to the drug tested in a given trial and is empirically measured using two indicator variables: *Approval_Pivotal* and *Approval*. *Approval_Pivotal* equals one if the FDA approved the trial's associated drug and explicitly cited the trial as pivotal evidence in its approval letter, and zero otherwise. *Approval* equals one if the drug tested in the trial is approved by the FDA i.e., the experimental

[15] See top 10 list at `https://www.mcgill.ca/deptmedicine/research/research-publications/top-10-medical-journals-list`.

arm of that trial tests the same active ingredient, or combination of active ingredients, as a drug that received the FDA's New Drug Application (NDA) approval, and zero otherwise.

The primary advantage of *Approval_Pivotal* is that it provides direct evidence of whether the FDA *relied on a specific trial* to justify a drug's approval. However, systematic data identifying the exact "pivotal trial" behind an FDA approval decision is only available for the subsample of oncology trials completed between 2017 and 2022, whereas *Approval* can be constructed for the full sample.[16]

Sig_0_0001 is an indicator that equals one if the smallest p-values for the trial's primary outcomes falls below 0.0001. We emphasize the $p < 0.0001$ threshold because the FDA has historically accepted such "statistically very persuasive" evidence to justify single-study approvals (Sasinowski and Butler, 2020).

H3 predicts $\beta_3 < 0$ in both Equations (4) and (5): top journals penalize embargoed trials with elevated spin, and the FDA—evaluating applications with raw, patient-level data and in-house biostatisticians—is less susceptible to specification search, making it less likely to cite significant results from embargoed trials as pivotal for drug approval.

5 Empirical Results

5.1 Descriptive statistics

Table 1 reports descriptive statistics (variable definitions are in Appendix B). All continuous variables are winsorized at the 1st and 99th percentiles. Three-quarters of sample trials

[16]The FDA began systematically disclosing `NCT_ID` (the unique trial identifier on ClinicalTrials.gov) in approval announcements for cancer drugs from 2018 onward, and we collect this data from `https://www.fda.gov/drugs/resources-information-approved-drugs/oncology-cancerhematologic-malignancies-approval-notifications`. Note that the complete set of trials submitted in New Drug Application is not publicly available. To identify this set of trials, we require that the trial's primary completion date falls between 2017 and 2022, the indication is in cancer (first level of MeSH term equals "C04"), and the trial phase is either 2 or 3—we include Phase 2 trials because it is common for Phase 2 data to support accelerated approvals in oncology (Chabner, 2012). Because only Phase 2 and Phase 3 trials enter this subsample, Phase 3 serves as the omitted category.

feature embargo agreements (*Embargo* mean = 0.75). Conclusions sections of published abstracts are notably more optimistic than Results sections: *Tone_conclusion* averages 58% positive words versus 30% for *Tone_results*, producing a mean *Spin* of 0.27 with substantial variation (0 at the 25th percentile, 0.64 at the 75th). Among trials with reported p-values, 23% include at least one primary outcome achieving extreme significance ($p \leq 0.0001$), while only 3% fall in the barely significant range ($0.04 < p \leq 0.05$). Two-thirds of trials have primary outcomes that achieve significance at the 5% level (*Pass* = 0.67), 8% have primary outcomes in the *Marginal* zone ($0.05 < p \leq 0.15$), and 81% report a single primary outcome.

Figure 1 plots the prevalence of embargo agreements over time. Embargo use declined steadily from approximately 84% in the late 2000s to roughly 64% by 2020, consistent with escalating transparency norms.[17]

5.2 Determinants of embargo adoption (test of H1)

Panel A of Table 2 presents univariate comparisons: embargoed trials have fewer co-sponsors, are more likely to be Phase 3 (and less likely to be Phase 2), enroll more participants, and are conducted by more experienced sponsors.

Panel B estimates Equation (1) with progressively saturated fixed effects across Columns (1) through (5). Both Phase 2 and Phase 3 trials are significantly more likely to include embargo clauses relative to Phase 4 post-marketing studies, with Phase 3 carrying the largest coefficient—consistent with commercial stakes being highest at the final milestone before FDA approval. Trials enrolling more subjects are also more likely to be embargoed. Sponsor experience (*Previous_trials*) predicts embargo adoption in Columns (1)–(3) but is absorbed by firm fixed effects in Columns (4)–(5), indicating cross-firm rather than within-firm variation. The number of co-sponsors is negatively associated with adoption, consistent with

[17]These norms include the AllTrials campaign (2013), PhRMA/EFPIA data-sharing principles (2013), ICMJE data-sharing requirements (2018), and enforcement of the FDAAA Final Rule (2017). The trough around 2019–2020 may additionally reflect the pandemic-era shift toward decentralized trial designs that reduced reliance on traditional PI–sponsor contracting arrangements.

transaction costs and reputational risks scaling with the number of parties involved.

Consistent with H1, sponsors adopt embargoes when commercial stakes are higher and reputational costs are lower. The adjusted R^2 in Column (5) is 0.474, meaning just over half the variation remains unexplained by observables and fixed effects—supporting our claim that adoption contains meaningful firm–trial-specific information rather than reflecting fixed institutional norms.

5.3 Conditional exercise of disclosure control (tests of H2a, H2b)

5.3.1 Primary outcome multiplicity and p-value significance

Figure 2 illustrates the distribution of minimum reported p-values for primary outcome measures. Embargoed trials are 11% more likely to fall in the $p \leq 0.1$ bin. Figure 3 zooms in around two key reporting thresholds, revealing distinct patterns of differential bunching. In the left subpanel, embargoed trials are 60% more likely to report "$p < 0.0001$"—the FDA's "statistically very persuasive" threshold for single-study drug approval (Sasinowski and Butler, 2020; Prasad and Makary, 2026)—at 22.8% versus 14.2% ($z = 6.72$). In the right subpanel, embargoed trials are 83% less likely to report "$p < 0.05$" ($z = -8.26$) and 59% less likely to report "$p = 0.05$" ($z = -2.75$). Around both thresholds, surrounding bins show no significant differences (Bonferroni-corrected), indicating that the bunching is concentrated at the reporting thresholds rather than reflecting a distributional shift. These patterns are consistent with the two groups catering to different institutional audiences: industry-sponsored embargoed trials cluster at the threshold relevant to FDA approval, while non-embargoed trials cluster at the $p \leq 0.05$ threshold governing academic publication.

We next test H2a by examining the relation between embargoes, outcome multiplicity, and p-value significance. Table 3 Panel A confirms the patterns in Figure 3 with regression controls and firm, indication and year fixed effects. The coefficient on *Embargo* is positive and significant for *Sig_0_0001* ($\beta = 0.071$, $t = 2.85$) and negative and significant for *Sig_04_05*

($\beta = -0.036$, $t = -3.09$). Panel B introduces the interaction with outcome multiplicity. *Embargo* × *N_outcomes* is positive and significant for *Sig_0_0001* ($\beta = 0.051$, $t = 4.00$), and the binary *Multi_outcomes* yields a similar pattern ($\beta = 0.093$, $t = 3.16$). The null interaction with *Sig_04_05* in all four columns confirms that multiplicity increases bunching only at the ultra-low threshold. Embargoed trials with multiple primary outcomes are disproportionately likely to report extreme significance—consistent with additional outcomes providing more degrees of freedom for specification search, but only when the sponsor holds contractual control over disclosure.

5.3.2 Abstract spin and the Marginal zone test

Table 4 examines the baseline embargo–spin association. Panel A shows that embargoed trials display more spin than non-embargoed trials (0.284 vs. 0.208). Panel B confirms this with firm, indication, year, and journal fixed effects: embargoed trials produce publications whose abstracts contain Conclusion sections that are substantially more optimistic, both overall (column 3) and relative to their Results sections (column 1), reflecting sponsor firms' desire for positive framing. The tone on the entire abstract is unimpacted by embargo, as the positive tone on the conclusion is offset by the negative tone on results, with the tone of other passages (methods, results, background) likely being neutral.

Table 5 reports the results with the *Fail* zone as the reference category. The zone indicator main effects capture baseline investigator incentives to frame failed trials positively. Trials led by investigators without sponsor control show the most spin in the *Fail* zone, likely because these scientists emphasize favorable aspects such as safety or future research directions to publish failed trials.[18] Spin is lower in the *Pass* zone ($\beta = -0.148$, $t = -2.75$) and lowest in the *Marginal* zone ($\beta = -0.407$, $t = -4.22$): independent investigators reporting near-miss

[18] In untabulated results, we find this pattern to be attributable to differences in results tone across the zones. Boutron et al. (2010) notes that results sections report effect sizes, p-values, and confidence intervals in a standardized format that has little flexibility for discretionary tone, and thus tone will be naturally lower in the *Fail* zone. If authors of both failed and marginal trials aim for similarly optimistic conclusions, *Spin* will be largest for outright failures.

results adopt a cautious tone, hedging rather than overclaiming.

The embargo interactions isolate the incremental effect of sponsor editorial control. The key result is *Embargo* × *Marginal* ($\beta = 0.336$, $t = 3.05$): sponsor-enabled spin offsets 83% (= 0.336/0.407) of the cautious tone that independent investigators adopt when reporting near-miss results, nearly closing the gap to the Fail-zone baseline. The *Embargo* × *Pass* interaction is positive but insignificant ($\beta = 0.097$, $t = 1.45$), consistent with limited exercise value when results are favorable. A linear combination test confirms that the Marginal-zone embargo effect significantly exceeds the Pass-zone effect ($p = 0.02$), ruling out the interpretation that embargoes raise spin uniformly across outcome zones.[19] The embargo main effect is economically and statistically zero ($\beta = -0.004$, $t = -0.06$): in the Fail zone, investigators already reframe aggressively to salvage publishability, and sponsors whose drugs will not reach commercialization have no incremental incentive to intervene. Sponsors exercise their option precisely where it is most valuable—the Marginal zone, where investigator restraint creates the largest gap between what the results say and what the firm would like the abstract to convey.

Panel B of Table 5 presents additional specifications of the Marginal zone in Column (1) and tonal sentiment in Column (2). Widening the Marginal zone to $0.05 < p \leq 0.20$ attenuates the interaction but it remains significantly positive ($\beta = 0.201$, $t = 2.18$). Using a refined LIWC-based *Spin* measure with word lists adjusted following Vinkers et al. (2015) yields consistent results ($\beta = 0.255$, $t = 2.77$), confirming that the finding is not an artifact of a particular sentiment dictionary.

[19] Because Table 3 shows that embargo status shifts the p-value distribution, conditioning on p-value zone raises a potential collider concern. However, narrative spin operates on the *reported* result, not the counterfactual result absent specification search. A firm observing a reported p-value of 0.08 faces the same reframing decision regardless of whether that value reflects the first specification attempted or the residual after failed specification search. We condition on the reported zone because it constitutes the firm's information set at the moment it decides whether to exercise editorial control over the abstract. To the extent that specification search depletes the embargoed Marginal cell of its strongest trials, the remaining embargoed-Marginal trials have weakly worse underlying results, biasing the interaction coefficient toward zero—making our estimate conservative.

Our findings have direct implications for clinical practice. Physicians under time pressure rely heavily on abstracts—often as their sole information source for treatment decisions—yet frequently lack the statistical literacy to see through strategic framing. Prior evidence documents "collective statistical illiteracy" among even experienced clinicians, where spin systematically distorts perceptions of drug efficacy (Gigerenzer et al., 2008; Boutron et al., 2014). Embargo clauses may facilitate this distortion, driving a wedge between the published evidence base and optimal patient care.

5.4 Detection of embargo-enabled manipulation (tests of H3)

5.4.1 Journal sorting

Panel A of Table 6 regresses indicators of journal prestige on *Embargo*. Embargoed trials are 1.8 percentage points less likely to appear in top-10 journals ($t = -3.25$). Against base rates of 5.8% (mean of *Top_pub* in Table 1), these represent relative declines of 31%. Panel B estimates Equation (4). The coefficient on *Spin* is positive ($\beta = 0.061$, $t = 1.79$): a one-standard-deviation increase ($\approx$0.4) raises the probability of top-10 publication by 2.4 percentage points, a 41% increase over the base rate. *Embargo* $\times$ *Spin* is negative and of greater magnitude ($\beta = -0.115$, $t = -2.95$), more than fully offsetting the main effect—top journals reward optimistic framing in non-embargoed manuscripts but see through it entirely when an embargo clause is present.

The non-top journal results confirm the mirror image: *Embargo* $\times$ *Spin* is positive ($\beta = 0.138$, $t = 3.14$), fully offsetting the negative main effect. Embargoed manuscripts with elevated spin that top journals filter out are absorbed by lower-ranked outlets. Combined with the spin results in Tables 4 and 5, embargo-enabled framing enters the mainstream medical literature through lower-tier journals.

5.4.2 FDA approval decision

Our second test of H3 examines FDA approval decisions, which are captured by whether a trial was cited as providing "pivotal evidence" in the FDA's approval letter (*Approval_Pivotal*, which is only available for a subsample of oncology drug trials), or more broadly, whether the drug tested in the trial received FDA approval (*Approval*).

Panel A of Table 7 shows that unconditionally, embargoed trials have higher rate of being cited as "pivotal" in approval letters (22.5% vs. 15.7%, $t = -2.10$) and higher approval rates (31.5% vs. 23.9%, $t = -9.58$).[20] Panel B estimates Equation (5), with columns 1 and 2 having *Approval_Pivotal* and *Approval* as the dependent variable, respectively. The coefficient on *Embargo* is positive across both columns: on average, embargoed trials are 8.4 percentage points more likely to be the pivotal evidence leading to approval, and the drugs tested in them are 3.7 percentage points more likely to receive approval, consistent with embargo adoption correlating with trial quality and commercial importance. Extreme significance is strongly associated with approval: trials achieving $p \leq 0.0001$ on at least one primary outcome are 64.7 percentage points more likely to be cited as pivotal and 8.7 percentage points more likely to test a drug that became FDA-approved. However, *Embargo* × *Sig_0_0001* is significantly negative in column 1 ($\beta = -0.227$, $t = -2.55$): when identifying pivotal evidence, the FDA discounts extreme significance from embargoed trials by 22.7 percentage points—an effect exceeding the unconditional pivotal designation rate of 21% (mean of *Approval_Pivotal* in Table 1). This discount more than offsets the baseline embargo advantage, rendering embargoed trials with suspiciously extreme p-values less likely to be cited as pivotal than non-embargoed trials at the same threshold (net premium of 50.4 pp vs. 64.7 pp).[21] Similarly, in column 2, the FDA discounts extreme significance

[20] Note that *Approval* generally have higher values than *Approval_Pivotal*, for two reasons: 1) firms typically submit multiple trials in New Drug Application, and only a subset of them are later cited as providing "pivotal evidence" by the FDA, and 2) oncology drugs are known to have lower likelihood of receiving FDA approval (Wong et al., 2019).

[21] Compared with non-embargoed trials without extremely significant results ($p \leq 0.0001$), embargoed trials with extremely significant results have a 50.4% (=0.084+0.647-0.227) higher rate of pivotal designation, whereas non-embargoed trials with extremely significant results have 64.7% (=coefficient for *Sig_0_0001*)

from embargoed trials by 8.1 percentage points, which again more than offsets the baseline embargo advantage of 3.7 percentage points. Taken together, these results are consistent with the incentive of embargoed firms to influence FDA approval decisions with "statistically persuasive evidence", as well as the FDA's measured skepticism in its regulatory response — the FDA reduces the pivotal designation premium of embargoed trials' extremely low p-values by approximately 35% ($= 0.227/0.647$) and the approval premium of such extreme results by approximately 93% ($= 0.081/0.087$).

5.4.3 Capital market reaction to disclosure events

Having established that lower-ranked journals do not screen out embargo-enabled framing, we extend the analysis to capital markets. Markets face significant costs acquiring and processing information, even in the presence of arbitrageurs and market competition(Blankespoor et al., 2020). The value of knowledge-specific expertise is well documented—analysts with relevant pre-career industry experience produce more accurate forecasts (Bradley et al., 2017)—implying that generalists in capital markets covering pharmaceutical firms will face significant disadvantages in evaluating trial results.

For publicly listed sponsoring firms, we examine capital market reactions to trial disclosures:

$$CAR_{i,t} = \alpha + \beta_1 Embargo_{i,j,k} + \beta_2 MarketCap_{i,t} + \beta_3 BM_{i,t} + \mathbf{X}'\boldsymbol{\gamma} + \text{FE} + \varepsilon_{i,j,k,t} \qquad (6)$$

where CAR is the cumulative abnormal return over the $(0, 2)$ window, calculated as the sum of daily raw returns minus the CRSP value-weighted market return. Day 0 corresponds to one of three disclosure events: posting of results on ClinicalTrials.gov (*CAR_result*), first journal publication (*CAR_Fpub*), first publication in a top-10 journal (*CAR_Ftop*). *MarketCap* and *BM* (book-to-market ratio) are measured as of day 0.

Table 8 reports that β_1 is insignificant across all three windows—capital markets react sim-

higher rate of pivotal designation.

ilarly to disclosure events from embargoed and non-embargoed trials. Testing the null from the earliest regulatory posting through top-journal publication ensures that the result does not depend on the stage of the information chain at which prices incorporate trial outcomes.

Why would markets not discount embargoed publications by the ex-ante probability of manipulation? Three features of the setting explain this. First, embargo status is recorded in ClinicalTrials.gov metadata and not prominently disclosed at publication, reducing its salience. Second, the base rate of embargo adoption is high (roughly 75%) but only a small fraction of embargoed trials land in the Marginal zone where the option is exercised, making a blanket discount noisy and costly. Third, identifying *which* publications were manipulated requires clinical expertise—comparing conclusions against registered protocols, evaluating the opportunism of trials with multiple primary outcomes and assessing p-value plausibility. Our evidence suggests that markets lack both the ability to detect manipulation ex post and the information or awareness to price it ex ante.

Together, Tables 6–8 illustrate *stratified sophistication*: the same manipulation is detected and discounted by expert gatekeepers but missed by less specialized audiences. Given we find that journal sorting redirects manipulated publications to lower-tier outlets, the implications extend beyond capital markets. Trial-based publications inform regulators, physicians, and patients, and if embargo-enabled framing degrades the published record—for example through pooled meta-analyses—it could affect prescribing decisions and patient outcomes (e.g., Dranove et al., 2003; Huang et al., 2020). We do not test these downstream channels directly but view the contractual governance of scientific disclosure as a bridge between firm-level incentives and the broader public-interest stakes motivating clinical trial transparency requirements.

6 Conclusion

This paper brings a disclosure-rights lens to scientific communication. We show that pharmaceutical firms use contractual embargo clauses—present in 75% of industry-sponsored trials with external investigators—to acquire real options over the publication of clinical trial results. Firms acquire these options when commercial stakes are highest and exercise them selectively: when primary endpoints narrowly miss significance, embargoes generate a 33-percentage-point increase in narrative spin, offsetting 82% of the negative tone associated with insignificant results. While our analysis faces certain scope conditions—relying on formally registered embargoes, measuring spin via abstract tone, and the inherent challenge of eliminating all trial-level confounds—the absence of an embargo effect among trials with clearly significant results provides a robust falsification test, confirming that this framing is strategic rather than indiscriminate.

Expert gatekeepers—FDA evaluators and top-tier journal reviewers—detect and penalize this framing, but manipulated manuscripts are redirected to lower-tier outlets rather than suppressed entirely. Capital markets, lacking the domain expertise to distinguish manipulated from honest findings, fail to differentially price these embargoed disclosures. Because manipulated publications ultimately enter the broader medical literature through lower-tier journals, the social costs extend beyond capital markets to the quality of clinical evidence informing prescribing decisions and patient care (Boutron et al., 2010; Dranove et al., 2003).

Following Grossman and Hart (1986) and Hart and Moore (1990), our findings suggest that when contracts are incomplete, the party holding residual control rights over dissemination can fundamentally shape the output of ostensibly independent assessments. Consequently, formal independence is a weaker safeguard than previously understood whenever the assessed party retains control over how findings enter the public record. While there are natural analogies to other capital market settings involving outsourced information production (e.g., auditing, credit ratings), our findings underscore that even in a domain disciplined by

rigorous scientific norms, contractual design allows firms to reassert influence exactly when independent disclosure is most informative—when results disappoint.

These concerns are amplified by the FDA's announced shift in 2026 toward a *single* pivotal trial as the default evidentiary standard (Prasad and Makary, 2026; U.S. Food and Drug Administration, 2026), which eliminates independent replication as a check on the mechanisms we document. This regulatory shift from requiring sponsors to "be lucky twice" to "be lucky once" is particularly concerning when contractual control over disclosure can help sponsors manufacture the appearance of luck.

Appendix A. Framework for Embargo Decisions

A.1 Overview

This appendix develops a stylized illustration to build intuition and generate testable predictions. It is not a full equilibrium model.[22] We model a pharmaceutical firm's choice to include a publication embargo clause in clinical trial contracts with third-party investigators. We treat the embargo as an *option*: the firm pays an upfront reputational cost for the right—but not the obligation—to reclaim control over the publication process if results are unfavorable. The setting satisfies the boundary conditions for real options reasoning identified by Adner and Levinthal (2004): the embargo is a discrete contractual right with identifiable exercise decisions, observable payoff states (Pass/Marginal/Fail), and a clear non-exercise rule in the Fail zone. A summary of all notation is provided in Section A.9 for reference.

The firm exercises its option through two sequential channels. *Specification search* operates on the reported test statistic before public disclosure and can shift a trial's reported significance level. *Narrative spin* reframes interpretive language at the publication stage and is credible only when the reported result remains in the Marginal zone. The favorable-outcome null serves as the primary placebo test.[23]

A.2 Timeline

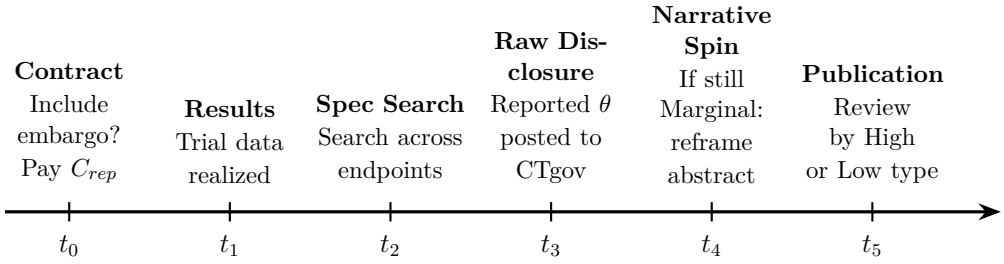


Figure 1: Timeline of Embargo Decision and Use.

- t_0 **(Contract):** The firm decides whether to include an embargo clause, paying C_{rep} if it does.
- t_1 **(Results):** The trial data are realized.
- t_2 **(Specification Search):** Because the sponsor is responsible for submitting initial results to ClinicalTrials.gov, we assume embargoed firms have greater latitude to select among specifications when reporting.

[22] We assume risk-neutral sponsors maximizing expected firm value. Adding risk aversion would not change any comparative static.

[23] Non-embargoed investigators may also engage in specification search, but their career incentives target the conventional $p \leq 0.05$ publication threshold rather than the $p \leq 0.0001$ regulatory threshold. The model's predictions concern the *differential* targeting of thresholds, not the presence or absence of search.

- t_3 **(Raw Disclosure):** The reported result θ (reflecting the selected specification) is posted to ClinicalTrials.gov.
- t_4 **(Narrative Spin):** If the reported result falls in the Marginal zone, sponsors with control rights can reframe the findings in the abstract.
- t_5 **(Publication):** The study is submitted to a journal and evaluated by a reviewer of type H (sophisticated) or L (less sophisticated).

A.3 Setup

We define the state space first, followed by the actions and costs.

Trial Outcomes. Let θ measure the strength of the trial's reported primary outcome, as posted to ClinicalTrials.gov at t_3. Throughout, θ and the p-value move in opposite directions: higher θ = lower p = stronger result. We partition outcomes into three zones using thresholds θ^P and θ^F ($\theta^F < \theta^P$):

- **Pass (P):** $\theta \geq \theta^P$ (i.e., $p \leq 0.05$). The trial met its primary outcome. No manipulation needed.
- **Marginal (M):** $\theta^F \leq \theta < \theta^P$ (i.e., $0.05 < p \leq 0.15$). The gap is small enough that reframing may bridge it.
- **Fail (F):** $\theta < \theta^F$ (i.e., $p > 0.15$). No credible reframing can close the gap.

Let ρ_P, ρ_M, ρ_F denote the ex-ante probabilities of each zone, with $\rho_P + \rho_M + \rho_F = 1$.

Firm Values. Let $V(\theta)$ be firm value from the trial result, with $V'(\theta) > 0$. Define V_P, V_M, V_F as the average values in each zone, where $V_P > V_M > V_F$.

Specification Search. When the firm holds an embargo, it can search across N primary endpoints at t_2. Additional endpoints increase the probability that at least one specification crosses a given significance threshold. When $N = 1$, the pre-registered endpoint is reported without modification. When the regulatory payoff jumps at extreme significance levels (Section 3), the firm has the strongest incentive to find the specification with the lowest p-value.

Narrative Spin. At t_4, the firm can reframe the abstract at cost $C_{ctrl} \geq 0$ (publication delay and editorial friction with the investigator). Spin does not alter θ—the p-value on ClinicalTrials.gov is fixed—but changes how the abstract presents the result. If successful (probability ρ_m), the abstract frames the trial as if it had met its primary outcome, yielding $V_{spin} > V_M$. If unsuccessful, the firm publishes honestly at V_M. The closer θ is to θ^P, the easier the gap is to bridge. θ^F is the point where the expected gain from spin equals its cost.

Embargo Cost. Including an embargo at t_0 costs $C_{rep} \geq 0$, reflecting reputational damage from reduced transparency and investigator resistance.[24] Once paid, C_{rep} is sunk.

Gatekeepers. We assume two types:

- **Sophisticated (H):** Top journal reviewers and FDA evaluators, who detect manipulation with probability $d_H > 0$.
- **Less sophisticated (L):** Lower-tier reviewers, physicians, and capital markets, with $d_L \approx 0$.

Let $V_H > V_L$ denote firm value from publication in each outlet type.

A.4 Firm Payoffs

With No Embargo:

$$\pi_{NE} = \rho_P V_P + \rho_M V_M + \rho_F V_F \tag{7}$$

With Embargo: The firm pays C_{rep} upfront and gains flexibility in disclosure—specification search at t_2 followed by narrative spin at t_4 if the reported result is Marginal.

$$\pi_E = -C_{rep} + \rho_P V_P + \rho_M E[\text{Manipulate}] + \rho_F V_F \tag{8}$$

The expected payoff from manipulation is:

$$E[\text{Manipulate}] = \rho_m(V_{spin} - L_{detect}) + (1 - \rho_m) V_M - C_{ctrl} \tag{9}$$

where V_{spin} is the expected value of a successfully spun publication, after accounting for gatekeeper detection (Section A.6).[25] L_{detect} is the expected penalty from attempted manipulation.[26] With probability $(1 - \rho_m)$, spin fails and the firm publishes honestly at V_M.[27]

Why the Embargo Option Is Exercised Only in the Marginal Zone. When results narrowly miss significance, the gap between the data and a favorable narrative is small

[24] The cost C_{rep} stems from the contracting environment: prestigious investigators may demand higher compensation for restricted autonomy, and co-sponsors resist reduced transparency. Expected downstream penalties from gatekeepers add to total cost, but the primary friction preventing universal adoption is this upfront contracting cost.

[25] $V_{spin} = (1 - d_H) V_H + d_H V_L$. If the gatekeeper detects spin, the paper sorts to a lower-tier outlet; V_{spin} is the probability-weighted average.

[26] $L_{detect} = \Pr(\text{detected}) \times \text{penalty}$, already probability-weighted to avoid double-counting. C_{rep} is borne at t_0 regardless of outcomes; L_{detect} is incurred only conditional on exercise and detection.

[27] For parsimony, equations (8)–(9) suppress the specification search channel, which operates across all zones at t_2 before the reported zone is determined. Specification search affects the *composition* of the zone populations (shifting some natural-Marginal trials into Pass), while ρ_m governs spin success conditional on a trial remaining in the Marginal zone after search. Prediction 2 tests the compositional effect; Prediction 3 tests the spin effect on the residual Marginal population.

enough that reframing can bridge it. Investigators spin Marginal results independently for publication purposes, but the embargo adds incremental intensity—the sponsor's commercial motive exceeds the investigator's publication motive, and the clause provides leverage to act on it. In Pass, the trial met its primary outcome, so spin is unnecessary; Pass serves as a placebo. In Fail, investigators may spin on their own (e.g., emphasizing safety), but the sponsor's option adds nothing—the gap to θ^P is too large for credible reframing.[28]

Numerical Example. Suppose $\rho_M = 0.20$, $\rho_m = 0.50$, $V_{spin} = \$500\text{M}$, $V_M = \$200\text{M}$, $L_{detect} = \$50\text{M}$, $C_{ctrl} = \$25\text{M}$. Then $E[\text{Manipulate}] = 0.50 \times (500 - 50) + 0.50 \times 200 - 25 = \$300\text{M}$, and the option value is $\Delta = 300 - 200 = \$100\text{M}$. Adoption requires $0.20 \times 100 = \$20\text{M} \geq C_{rep}$, so a firm adopts whenever the reputational cost is below \$20M.

A.5 Optimal Decisions

Ex-Post: Exercise the Option. At t_4, if the reported result falls in the Marginal zone, the firm decides whether to spin. Define:

$$\Delta(\theta) \equiv E[\text{Manipulate} \mid \theta] - V(\theta) \tag{10}$$

The firm exercises when $\Delta(\theta) > 0$, which holds only in the Marginal zone.[29]

Ex-Ante: Buy the Option. Treating adoption as a threshold-crossing condition and assuming firms are heterogeneous in C_{rep} (or equivalently, in trial-level commercial stakes), the firm includes an embargo when the expected option value exceeds its cost:

$$\rho_M \cdot E[\Delta(\theta) \mid \theta \in \text{Marginal}] \geq C_{rep} \tag{11}$$

Adoption rises with ρ_M and the gain from spin conditional on landing in Marginal, and falls with C_{rep}. The comparative statics below describe how the adoption margin shifts across firms with different C_{rep}.

Participation Constraint. The option is in-the-money when:

$$\rho_m(V_{spin} - L_{detect} - V_M) > C_{ctrl} \tag{12}$$

The probability-weighted gain from successful spin (net of detection penalties) must exceed the strike price of invoking the clause.

[28] This parallels optimal severance contracts, where mediocre performance receives strategic intervention but total failure does not (Van Wesep and Wang, 2014).

[29] Because specification search depletes the Marginal zone of its most manipulable trials—those with many endpoints that are successfully pushed to Pass at t_2—the spin estimate is identified on the residual population and represents a lower bound on the total editorial effect.

A.6 Stratified Sophistication

When a firm submits a spun manuscript, a sophisticated gatekeeper detects it with probability d_H and rejects it. The paper is then resubmitted to a less sophisticated outlet ($d_L \approx 0$):

$$V_{spin} = (1 - d_H)\, V_H + d_H\, V_L$$

As d_H rises, V_{spin} falls toward V_L—better detection erodes the value of spin but does not eliminate it. Manipulated trials are redirected to lower-tier journals, not eliminated from the published record. The FDA discounts highly significant results from embargoed trials; capital markets do not. Manipulation persists whenever $V_L > V_M$—a spun paper in a lower-tier journal is worth more than an honest account of a marginal trial.

A.7 Comparative Statics

Taking derivatives of the adoption condition (11):

- $\frac{\partial \Pr(\text{Embargo})}{\partial (V_{spin} - V_M)} > 0$: Embargo use rises when manipulation gains are larger (e.g., Phase 3 trials where approval hinges on the result).
- $\frac{\partial \Pr(\text{Embargo})}{\partial \rho_m} > 0$: Embargo use rises when manipulation is more feasible (e.g., larger trials permitting subgroup analysis, or more experienced sponsors).
- $\frac{\partial \Pr(\text{Embargo})}{\partial C_{rep}} < 0$: Embargo use falls when reputational costs are higher (e.g., more co-sponsors, increasing coordination frictions and transparency pressure).

A.8 Payoff Summary and Predictions

Table 1: Firm Payoffs by Outcome Zone and Embargo Status. All entries are conditional payoffs; the expected value in the Marginal zone is $\rho_m \cdot (V_{spin} - L_{detect}) + (1 - \rho_m) \cdot V_M - C_{ctrl}$.

Scenario	**Prob.**	**No Embargo**	**With Embargo**
Upfront cost	—	0	$-C_{rep}$
Pass zone ($\theta \geq \theta^P$)	ρ_P	V_P	V_P
Marginal zone ($\theta^F \leq \theta < \theta^P$)	ρ_M		
Spin succeeds	ρ_m	—	$V_{spin} - L_{detect}$
Spin fails	$1 - \rho_m$	—	V_M
Control cost	—	—	$-C_{ctrl}$
Publish honestly	—	V_M	—
Fail zone ($\theta < \theta^F$)	ρ_F	V_F	V_F

Table 2: Mapping from Framework to Empirics.

Parameter	Empirical Proxy	Mapping Rationale
$V_{spin} - V_M$	Phase indicator	Phase 3 trials carry larger commercial stakes; the gap between a spun success and an honest marginal result is largest when regulatory approval is at stake.
ρ_m	$N_{subjects}$; Sponsor experience	Larger samples permit subgroup analysis, increasing the probability that some reframing is credible. Experienced sponsors have more practice navigating editorial control.
C_{rep}	$N_{sponsors}$	More co-sponsors raise coordination costs and transparency pressure, increasing the upfront reputational cost of embedding an embargo.
d_H	Top journal publication; FDA action	Sophisticated gatekeepers (top reviewers, FDA) detect spin with higher probability; tested via differential publication rates and regulatory discounting.
N	$N_{outcomes}$	Number of pre-registered primary endpoints measures the specification search space available at t_2.

Prediction 1 (Buying the Option)**.** *Embargo clauses are more common when commercial stakes are higher (e.g., Phase 3 trials), manipulation is more feasible (e.g., larger samples, greater sponsor experience), and reputational costs are lower (e.g., fewer co-sponsors). This maps to Table 2.*

Prediction 2 (Specification Search)**.** *Embargoed trials with more primary endpoints exhibit excess concentration of p-values at extreme significance levels and reduced concentration just below conventional thresholds. This prediction is not conditional on outcome zone: specification search operates on the reported test statistic at t_2, upstream of zone classification. This maps to Table 3 and Figure 2.*

Prediction 3 (Narrative Spin — Conditional Exercise)**.** *Embargoed trials exhibit elevated abstract spin, but only when the reported primary outcome falls in the Marginal zone. The Pass zone serves as placebo: if embargo status proxied for firm-level spin propensity, the effect would appear regardless of outcome significance. The spin estimate is conservative because specification search at t_2 depletes the Marginal zone of its most manipulable trials. This maps to Tables 4–5.*

Prediction 4 (Sophisticated Gatekeepers Detect It)**.** *Top journal reviewers and FDA evaluators detect manipulation: embargoed trials with elevated spin are less likely to appear in top journals, and the FDA discounts highly significant results from embargoed trials. This maps to Tables 6–7.*

A.9 Notation Reference

Table 3: Summary of Notation.

Symbol	Description	Option Analogy	Real-World Referent
Outcome Zones			
θ = Reported outcome	$\theta\uparrow \iff$ p-value$\downarrow$	Underlying asset	p-value on CTgov
Pass ($\theta \geq \theta^P$)	Trial succeeded	OTM (unneeded)	$p \leq 0.05$
Marginal ($\theta^F \leq \theta < \theta^P$)	Narrowly missed	ITM (valuable)	$0.05 < p \leq 0.15$
Fail ($\theta < \theta^F$)	Clearly failed	OTM (worthless)	$p > 0.15$
Probabilities			
$\rho_P,\ \rho_M,\ \rho_F$	Zone probabilities	—	Ex-ante
ρ_m	Prob. manipulation succeeds	Prob. option pays off	PI agrees to framing
d_H	Detection probability	—	Gatekeeper catches spin
Values			
$V_P,\ V_M,\ V_F$	Firm value by zone	—	$V_P > V_M > V_F$
V_{spin}	Value if spin succeeds	Payoff if exercised	Gatekeeper-weighted pub. value
$V_H,\ V_L$	High / Low outlet value	—	Top vs. lower-tier journal
Costs			
C_{rep}	Upfront embargo cost	Option premium	PI resistance, transparency
C_{ctrl}	Cost of invoking embargo	Strike price	Delay, editorial friction
L_{detect}	Penalty if detected	—	FDA discount, journal rejection
Other			
N	Primary endpoints	—	Spec search degrees of freedom

Appendix B. Variable Definitions

Variable	Definition
Trial characteristics	
Embargo	An indicator that equals one if the clinical trial involves an embargo agreement between the sponsoring firm and the principal investigator, and zero otherwise.
N_sponsors	The number of sponsors for each trial.
N_subjects	The natural logarithm of the number of subjects enrolled in a trial.
Phase_2	An indicator that equals one if the trial is in phase 2, and zero otherwise.
Phase_3	An indicator that equals one if the trial is in phase 3, and zero otherwise.
Previous_trials	The number of trials the firm conducted before the focal trial started (reported in levels in Table 1; enters regressions as the natural logarithm).
N_outcomes	The number of primary outcomes reported by a trial on ClinicalTrials.gov.
Multi_outcomes	An indicator that equals one if the trial reports more than one primary outcome on ClinicalTrials.gov, and zero otherwise.
Primary outcome p-values	
Sig_0_0001	An indicator that equals one if the minimum (i.e., most significant) p-value reported across the trial's primary outcomes satisfies $p \leq 0.0001$, and zero otherwise.
Sig_04_05	An indicator that equals one if the minimum p-value reported across the trial's primary outcomes satisfies $0.04 < p \leq 0.05$, and zero otherwise.
Pass	An indicator that equals one if the minimum p-value reported across the trial's primary outcomes satisfies $p \leq 0.05$, and zero otherwise.
Marginal	An indicator that equals one if the minimum p-value reported across the trial's primary outcomes satisfies $0.05 < p \leq 0.15$, and zero otherwise.
Marginal_05_20	An indicator that equals one if the minimum p-value reported across the trial's primary outcomes satisfies $0.05 < p \leq 0.20$, and zero otherwise.
Tone and spin	
Spin	Measures the distortion in a publication abstract's tone, defined as *Tone_conclusion* − *Tone_results*.
Tone_results	The tone of the results section parsed from the publication abstract, calculated using the LIWC dictionary (Pennebaker et al., 2015).
Tone_conclusion	The tone of the conclusion section parsed from the publication abstract, calculated using the LIWC dictionary (Pennebaker et al., 2015).
Tone_abstract	The tone of the entire publication abstract, calculated using the LIWC dictionary (Pennebaker et al., 2015).

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Variable	Definition
V_Spin	A modified version of the LIWC-based *Spin* measure, which adjusts the list of positive and negative words following Vinkers et al. (2015).
Publication outcomes	
Top_pub	An indicator that equals one if the trial is associated with at least one publication in a top 10 medical journal, based on the ranking curated by the McGill University Department of Medicine.
Nontop_pub	An indicator that equals one if the trial is associated with at least one publication in a medical journal ranked outside the top 60.
FirstPub_top	An indicator that equals one if the first publication associated with the trial appeared in a top 10 medical journal.
FirstPub_nontop	An indicator that equals one if the first publication associated with the trial appeared in a medical journal ranked outside the top 60.
Capital market variables	
CAR	The cumulative abnormal return over the three-day window from the event date (day 0) through day +2, calculated as the sum of daily abnormal returns, where abnormal return equals the firm's raw daily return minus the CRSP value-weighted market return. Event dates are the result post date, first publication date, and first top 10 journal publication date.
Log(ME)	The natural logarithm of market capitalization, measured as of the event date.
BM	The book-to-market ratio, measured as of the event date.
FDA approval	
Approval_Pivotal	An indicator that equals one if the trial tests a drug that is approved by the FDA and the approval letter cites the trial as "pivotal" for clinical trial evidence, and zero otherwise.
Approval	An indicator that equals one if the trial tests a drug that is approved by the FDA, and zero otherwise.

Appendix C. Notable Trials with Restrictive Embargo Agreements

Sponsor	NCT ID	Drug (Brand) / Trial	N	Agreement Description	Post-Approval Adverse Events / Notes
Cardiovascular Mega-Trials					
Merck	NCT00526474	Vorapaxar (Zontivity) TRA 2°P–TIMI 50	26,449	PI may not publish or present interim results without prior written consent; must submit abstracts/ manuscripts 45 days before submission.	FDA boxed warning for bleeding incl. intracranial hemorrhage; stroke arm halted 2011. Source: *NEJM* 2012; FDA label.
AstraZeneca	NCT01991795	Ticagrelor (Brilinta) THEMIS	19,271	†	FDA boxed warning for bleeding and aspirin interaction; approved over objections of both primary FDA reviewers, statistical reviewer, and team leader; 2017 lot recall. Source: PubMed 22832506; FDA 2015.
Eli Lilly	NCT00097591	Prasugrel (Effient) TRITON–TIMI 38	13,619	†	FDA boxed warning for bleeding; contraindicated in prior stroke/TIA; REMS required; withdrawn from Canada 2020. Source: NCBI NBK557427; FDA label.
Bayer	NCT00501059	Aspirin (Bayer) ARRIVE	12,546	†	
Eli Lilly	NCT01687998	Evacetrapib ACCELERATE	12,092	†	Never approved. Trial stopped 2015 for futility—no CV benefit despite raising HDL.
Bayer	NCT02556203	Rivaroxaban (Xarelto) COMPASS-related	1,653	†	$775M settlement (Bayer + J&J) for 25,000+ bleeding lawsuits; no reversal agent until andexanet alfa (2018).
Daiichi Sankyo	NCT02072434	Edoxaban (Savaysa) ENSURE-AF	2,199	†	

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Sponsor	NCT ID	Drug (Brand) / Trial	N	Agreement Description	Post-Approval Adverse Events / Notes
Anticoagulants / VTE Prevention					
Boehringer Ingelheim	NCT00808067	Dabigatran (Pradaxa) RELY-ABLE	5,897	Publication must be consistent with BI publication policy; PI rights per separate investigator contract (not publicly disclosed).	$650M settlement for bleeding claims; 4,000+ lawsuits alleging inadequate warnings and lack of reversal agent. Source: ASH Clinical News.
Boehringer Ingelheim	NCT00152971	Dabigatran (Pradaxa) RE-MODEL	2,615	Same BI policy as above.	$650M settlement (Pradaxa class).
Boehringer Ingelheim	NCT00291330	Dabigatran (Pradaxa) RE-COVER	2,564	Same BI policy as above.	$650M settlement (Pradaxa class).
Alexion / Portola	NCT01583218	Betrixaban (Bevyxxa) APEX	7,513	Agreement terms vary across centers, studies, and countries; no specific provisions disclosed.	
GLP-1 Agonists / Obesity					
Eli Lilly	NCT01394952	Dulaglutide (Trulicity) REWIND	9,901	†	
Eli Lilly	NCT04184622	Tirzepatide (Mounjaro / Zepbound) SURMOUNT-1	2,539	†	Boxed warning for thyroid C-cell tumors; gastroparesis lawsuits ongoing; FDA evaluating suicidal ideation (GLP-1 class); label updated Dec. 2025. Source: PMC 12469573; drugwatch.com.
Eli Lilly	NCT03987919	Tirzepatide (Mounjaro) SURPASS-2	1,879	†	Same as above (tirzepatide).
Eli Lilly	NCT03730662	Tirzepatide (Mounjaro) SURPASS-4	2,002	†	Same as above (tirzepatide).
Novo Nordisk	NCT01272219	Liraglutide (Saxenda / Victoza) SCALE	3,731	Sponsor reserves right to release results (e.g., press release) without PI consultation; may withhold data until specified milestones (e.g., clinical trial report available).	

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Sponsor	NCT ID	Drug (Brand) / Trial	N	Agreement Description	Post-Approval Adverse Events / Notes
COVID-19 Therapeutics					
AstraZeneca	NCT04625725	Tixagevimab + Cilgavimab (Evusheld) PROVENT	5,254	†	EUA only; authorization later revoked as Omicron variants rendered it ineffective.
Eli Lilly	NCT04427501	Bamlanivimab + Etesevimab BLAZE-1‡	3,307	†	EUA only; revoked April 2022 due to ineffectiveness against Omicron variants.
Opioid Analgesics (Purdue Pharma)					
Purdue Pharma	NCT01358526	Oxycodone / Naloxone CR (Targiniq ER)	1,095	†	Product discontinued. Purdue bankruptcy 2019; $8.3B settlement. DOJ press release.
Purdue Pharma	NCT01400139	Hydrocodone bitartrate ER (Hysingla ER)	922	†	Purdue bankruptcy 2019; $8.3B settlement. DOJ.
Purdue Pharma	NCT00313846	Buprenorphine transdermal (Butrans)	529	†	Purdue bankruptcy 2019; $8.3B settlement. DOJ.
Respiratory (COPD)					
Boehringer Ingelheim	NCT00144339	Tiotropium (Spiriva) UPLIFT	5,993	Publication must be consistent with BI publication policy; PI rights per separate investigator contract (not publicly disclosed).	FDA safety warning 2008 for stroke/MI risk; retracted 2010 after UPLIFT showed no increase. Respimat formulation showed elevated mortality until TIOSPIR trial.

Notes: Twenty-two Phase 3 trials with restrictive embargo agreements, selected from 4,879 restrictive trials in our sample (`can_publish` = "no" or `restriction_type` = "GT60"). Selection requires: (i) Phase 3, (ii) a publicly traded sponsor with a verifiable FDA outcome, and (iii) corroboration via FDA records, court documents, or peer-reviewed publications. Post-approval events are descriptive and do not imply a causal link to embargo status. All trial data from ClinicalTrials.gov (AACT).

† Agreement text not disclosed; coded as >60-day embargo under AACT legacy format. ‡ Phase 2/3 trial.

Figure 1. Time trends in the use of embargo clauses

The y-axis shows the share of trials that have embargo clauses with external PIs. The x-axis indicates the year of trial completion (trials in our sample have registration and initiation dates between 2007 and 2023, and completion and results posting dates between 2008 and 2023).

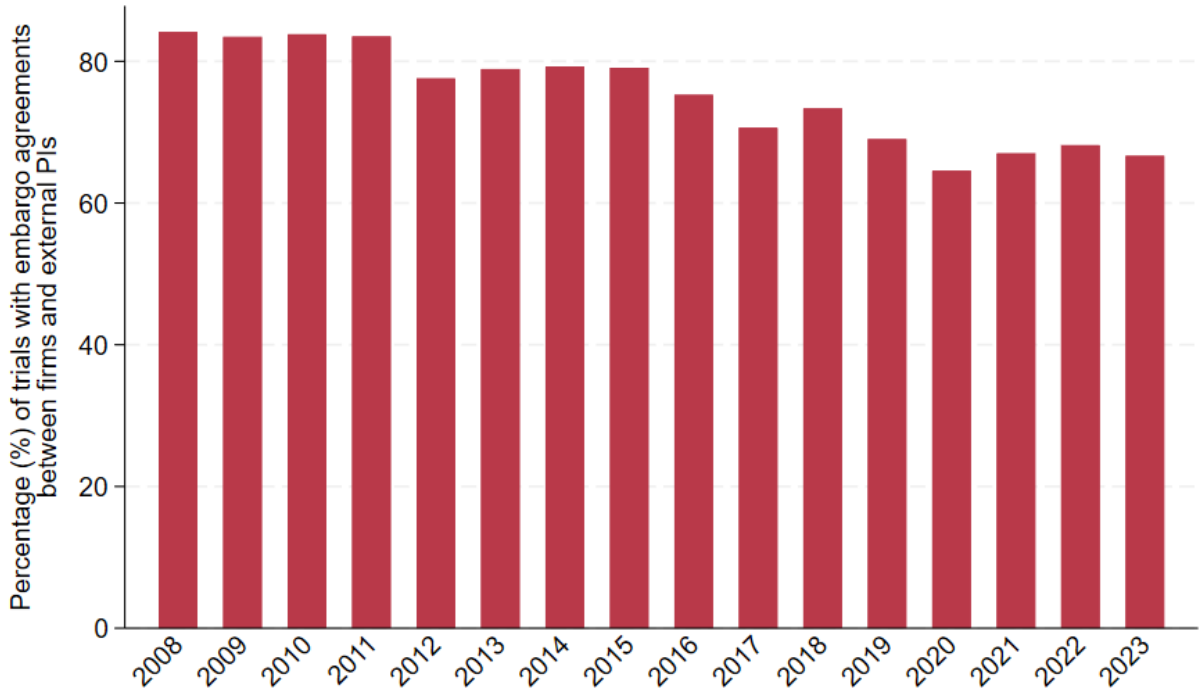


Figure 2. Distribution of the most significant p-value in each clinical trial for embargoed vs non-embargoed groups

This figure displays the full distribution of minimum reported p-values across trials in our sample, grouped into decile bins. Red bars (on the right) indicate an embargo agreement. Blue bars (on the left) indicate no embargo agreement. Test statistics are two-proportion z-tests with Bonferroni correction.

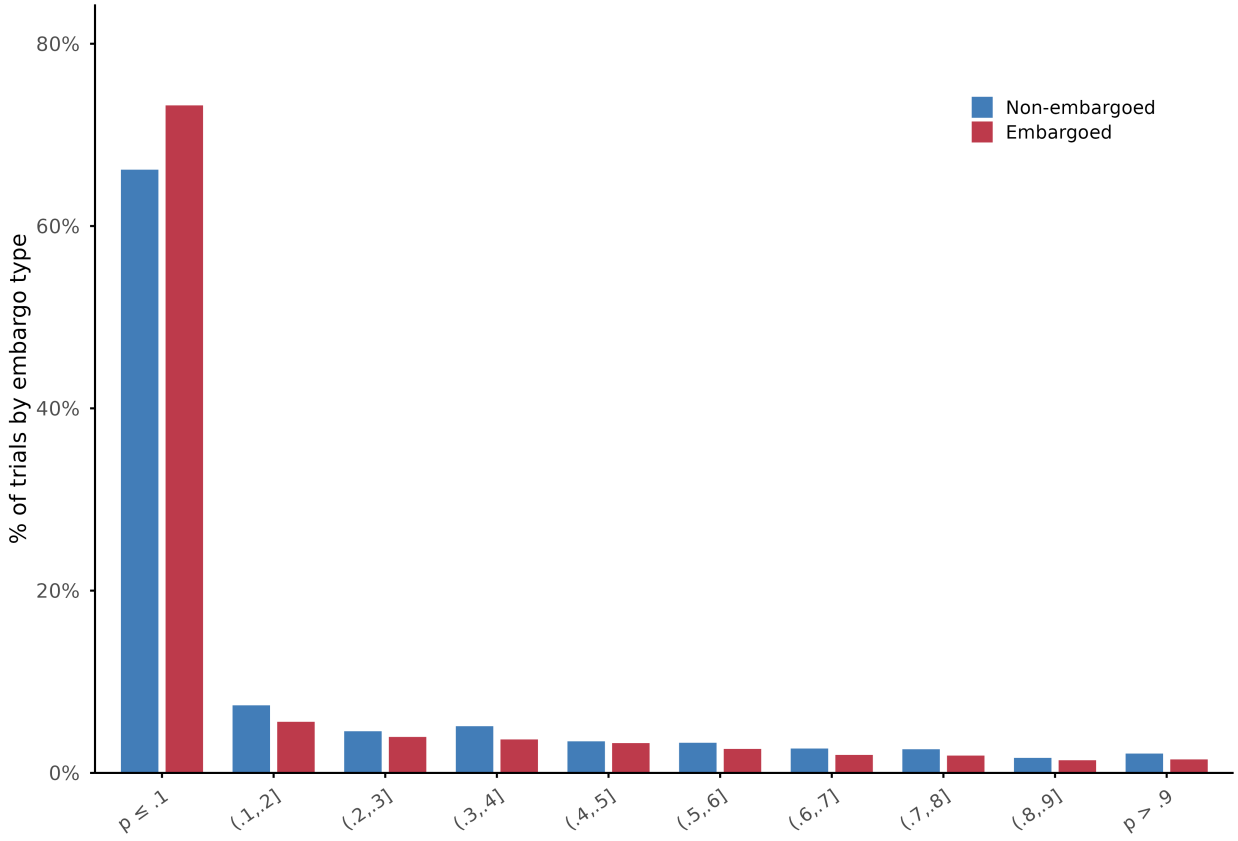


Figure 3. Distribution of the most significant p-value in each clinical trial around key thresholds for embargoed vs non-embargoed groups

The left panel examines the "statistically very persuasive" threshold ($p < 0.0001$) used by the FDA for single-study drug approval (Sasinowski and Butler, 2020). The right panel examines the conventional statistical significance threshold ($p \leq 0.05$). Red bars (on the right) indicate an embargo agreement. Blue bars (on the left) indicate no embargo agreement. Hatched bars denote inequality-reported p-values (e.g., "$p < 0.0001$") rather than exact values. Both panels in Figure 3 share a common y-axis. Test statistics are two-proportion z-tests with Bonferroni correction.

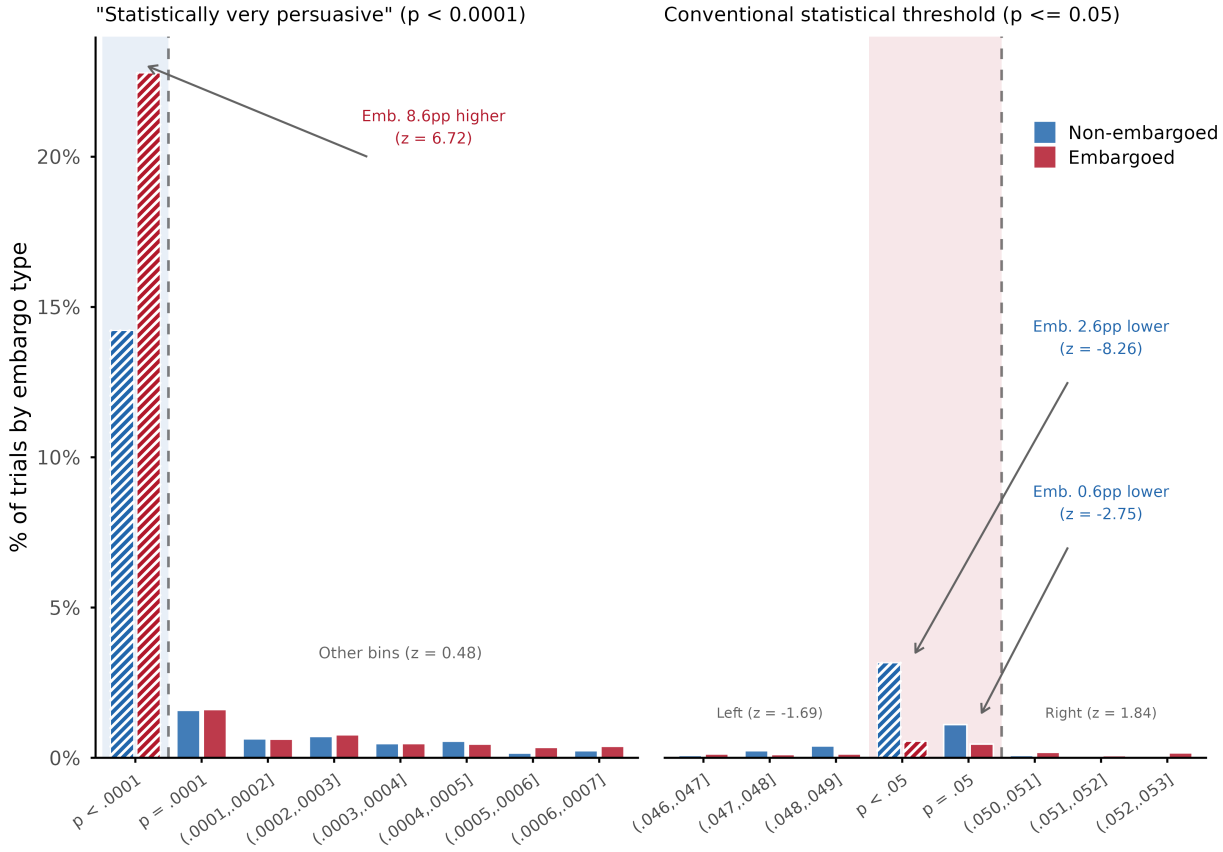


Table 1. Descriptive statistics

This table reports summary statistics for the variables used in the main analyses. All variables are defined in Appendix B.

	N	Mean	P25	Median	P75	Std. Dev.
Panel A: Trial characteristics						
Embargo	58,144	0.750	0	1	1	0.433
N_sponsors	58,144	1.319	1	1	2	0.596
N_subjects	58,144	4.791	3.761	4.852	5.858	1.460
Phase_2	58,144	0.459	0	0	1	0.498
Phase_3	58,144	0.425	0	0	1	0.494
Previous_trials	58,144	135.523	3	31	178	211.029
Panel B: Primary outcome variables						
Sig_0_0001	21,528	0.233	0	0	0	0.423
Sig_04_05	21,528	0.031	0	0	0	0.173
N_outcomes	21,721	1.313	1	1	1	0.814
Multi_outcomes	21,721	0.194	0	0	0	0.395
Pass	21,528	0.667	0	1	1	0.471
Marginal	21,528	0.081	0	0	0	0.272
Marginal_05_20	21,528	0.109	0	0	0	0.312
Panel C: Tone and spin						
Spin	17,032	0.270	0	0.152	0.642	0.402
Tone_conclusion	18,087	0.575	0.258	0.687	0.953	0.371
Tone_results	19,417	0.305	0.090	0.258	0.455	0.260
Tone_abstract	23,231	0.330	0.165	0.307	0.464	0.208
Panel D: Publication outcomes						
Nontop_pub	54,225	0.401	0	0	1	0.490
Top_pub	54,225	0.058	0	0	0	0.234
FirstPub_top	54,225	0.054	0	0	0	0.226
FirstPub_nontop	54,225	0.367	0	0	1	0.482
Panel E: Capital market variables						
CAR_result	23,399	0	−0.013	−0.001	0.012	0.033
CAR_Fpub	10,295	0.001	−0.013	−0.001	0.013	0.029
CAR_Ftop10	2,193	0.001	−0.016	−0.001	0.014	0.039
Panel F: FDA approval						
Approval_Pivotal	925	0.210	0	0	0	0.407
Approval	21,528	0.301	0	0	1	0.459

Table 2. Determinants of embargo adoption

Panel A reports univariate comparisons of trial characteristics between non-embargoed (*Embargo* = 0) and embargoed (*Embargo* = 1) trials. Panel B presents results from OLS regressions examining the determinants of embargo agreements. The dependent variable is *Embargo*, an indicator that equals one if the clinical trial involves an embargo agreement between the sponsoring firm and the principal investigator, and zero otherwise. All variables are defined in Appendix B. Standard errors are clustered at the firm level; *t*-statistics are reported in parentheses. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively (two-tailed).

Panel A: Univariate tests

	Mean (*Embargo*=0)	Mean (*Embargo*=1)	Diff (0 − 1) (*t*-stat)
N_sponsors	1.380	1.299	0.081***
			(14.18)
N_subjects	4.251	4.970	−0.720***
			(−52.69)
Phase_2	0.547	0.430	0.118***
			(24.76)
Phase_3	0.314	0.462	−0.148***
			(−31.52)
Previous_trials	2.481	3.613	−1.132***
			(−57.81)
N	14,537	43,607	58,144

Panel B: Multivariate tests

	Dependent variable: *Embargo*				
	(1)	(2)	(3)	(4)	(5)
N_sponsors	−0.046***	−0.035***	−0.032***	−0.043***	−0.042***
	(−4.131)	(−3.294)	(−3.069)	(−4.139)	(−4.151)
N_subjects	0.054***	0.051***	0.055***	0.044***	0.045***
	(10.363)	(9.912)	(11.094)	(8.130)	(8.340)
Phase_2	0.051**	0.083***	0.085***	0.092***	0.095***
	(2.320)	(3.652)	(3.840)	(3.855)	(4.156)
Phase_3	0.075***	0.101***	0.090***	0.101***	0.097***
	(3.223)	(4.328)	(3.969)	(4.065)	(4.061)
Previous_trials	0.043***	0.049***	0.048***	0.006	0.006
	(8.049)	(9.603)	(10.193)	(1.376)	(1.243)
Year FE	No	Yes	Yes	Yes	Yes
Indication FE	No	No	Yes	No	Yes
Firm FE	No	No	No	Yes	Yes
Observations	58,144	58,128	56,427	57,836	56,218
Adjusted R^2	0.096	0.123	0.142	0.464	0.474

Table 3. Number of primary outcomes and p-value significance

Panel A presents results from OLS regressions testing the association between embargo clauses and the statistical significance of primary outcomes reported by the trial. Panel B tests whether this association varies with the number of primary outcomes. *Embargo* is an indicator that equals one if the clinical trial involves an embargo agreement between the sponsoring firm and the principal investigator, and zero otherwise. *Sig_0_0001* is an indicator that equals one if the minimum (i.e., most significant) p-value reported across the trial's primary outcomes satisfies $p \leq 0.0001$. *Sig_04_05* is an indicator that equals one if the minimum p-value reported across the trial's primary outcomes satisfies $0.04 < p \leq 0.05$. *N_outcomes* is the number of primary outcomes reported by a trial on ClinicalTrials.gov. *Multi_outcomes* is an indicator that equals one if the trial has more than one primary outcome reported on ClinicalTrials.gov. All other variables are defined in Appendix B. Standard errors are clustered at the firm level; t-statistics are reported in parentheses. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively (two-tailed).

Panel A: Multivariate tests

	(1) *Sig_0_0001*	(2) *Sig_04_05*
Embargo	**0.071*** **	**−0.036*** **
	(2.854)	**(−3.086)**
N_sponsors	0.059***	−0.007
	(2.939)	(−1.448)
N_subjects	0.013**	−0.010***
	(2.023)	(−3.316)
Phase_2	−0.025	−0.021*
	(−1.077)	(−1.939)
Phase_3	0.111***	−0.021**
	(4.270)	(−2.464)
Previous_trials	0.013**	−0.006**
	(2.208)	(−2.146)
Year FE	Yes	Yes
Indication FE	Yes	Yes
Firm FE	Yes	Yes
Observations	20,832	20,832
Adjusted R^2	0.273	0.252

Table 3 (Continued)

Panel B: Interaction with outcome multiplicity

	(1) *Sig_0_0001*	(2) *Sig_04_05*	(3) *Sig_0_0001*	(4) *Sig_04_05*
Embargo	0.007	−0.014	0.054**	−0.029**
	(0.204)	(−0.695)	(2.144)	(−2.409)
N_sponsors	0.057***	−0.008	0.056***	−0.008
	(2.824)	(−1.564)	(2.803)	(−1.511)
N_subjects	0.011*	−0.009***	0.010	−0.010***
	(1.668)	(−3.328)	(1.575)	(−3.424)
Phase_2	−0.024	−0.020*	−0.026	−0.020*
	(−1.035)	(−1.907)	(−1.121)	(−1.912)
Phase_3	0.112***	−0.021**	0.107***	−0.021**
	(4.269)	(−2.411)	(4.136)	(−2.390)
Previous_trials	0.014**	−0.006**	0.013**	−0.006**
	(2.271)	(−2.199)	(2.192)	(−2.198)
N_outcomes	−0.006	0.016		
	(−0.711)	(0.946)		
Embargo* × *N_outcomes	**0.051*** **	**−0.016**		
	(4.001)	**(−1.014)**		
Multi_outcomes			0.005	0.043
			(0.185)	(1.330)
Embargo* × *Multi_outcomes			**0.093*** **	**−0.039**
			(3.161)	**(−1.206)**
Year FE	Yes	Yes	Yes	Yes
Indication FE	Yes	Yes	Yes	Yes
Firm FE	Yes	Yes	Yes	Yes
Observations	20,832	20,832	20,832	20,832
Adjusted R^2	0.278	0.253	0.279	0.253

Table 4. Embargo adoption and publication tone

Panel A compares tone and spin metrics between non-embargoed (*Embargo* = 0) and embargoed (*Embargo* = 1) trials. Panel B presents results from OLS regressions testing the association between embargo clauses and the tone of publications associated with each trial. The sample includes all trials linked to at least one publication. *Embargo* is an indicator that equals one if the clinical trial involves an embargo agreement between the sponsoring firm and the principal investigator, and zero otherwise. *Spin* measures the distortion in a publication abstract's tone and is defined as *Tone_conclusion* − *Tone_results*. *Tone_results* (*Tone_conclusion*) measures the extent of positive tone in the results (conclusion) section of the publication abstract, where tone is calculated using the LIWC dictionary. *Tone_abstract* is the tone of the whole abstract. All other variables are defined in Appendix B. Standard errors are clustered at the firm level; *t*-statistics are reported in parentheses. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively (two-tailed).

Panel A: Univariate tests

	Mean (*Embargo*=0)	Mean (*Embargo*=1)	Diff (0 − 1) (*t*-stat)
Spin	0.208	0.284	−0.076***
			(−9.71)
Tone_results	0.312	0.303	0.009*
			(1.82)
Tone_conclusion	0.529	0.586	−0.057***
			(−8.13)
Tone_abstract	0.319	0.332	−0.013***
			(−3.81)

Panel B: Multivariate tests

	(1) *Spin*	(2) *Tone_results*	(3) *Tone_conclusion*	(4) *Tone_abstract*
Embargo	**0.069*** **	**−0.027** **	**0.046** **	**0.010**
	(2.713)	**(−2.031)**	**(2.425)**	**(1.098)**
N_sponsors	0.038**	−0.033***	−0.006	−0.013**
	(2.288)	(−3.858)	(−0.423)	(−2.065)
N_subjects	−0.008	−0.003	−0.007	−0.005*
	(−1.178)	(−0.775)	(−1.240)	(−1.713)
Phase_2	0.052**	−0.025**	0.043*	0.016
	(2.515)	(−1.990)	(1.678)	(1.424)
Phase_3	0.040**	−0.009	0.042*	0.025**
	(2.321)	(−0.625)	(1.703)	(2.175)
Previous_trials	0.003	0.002	0.000	0.001
	(0.464)	(0.513)	(0.074)	(0.669)
Pub. Year FE	Yes	Yes	Yes	Yes
Indication FE	Yes	Yes	Yes	Yes
Firm FE	Yes	Yes	Yes	Yes
Journal FE	Yes	Yes	Yes	Yes
Observations	16,283	18,588	17,306	22,312
Adjusted R^2	0.402	0.394	0.418	0.405

Table 5. Embargo adoption, publication tone, and outcome insignificance

This table presents results from OLS regressions testing the association between embargo clauses and publication spin in the presence of outcome insignificance. Panel A reports the main specification. Panel B presents robustness tests using an alternative marginal zone definition (column 2). *Embargo* is an indicator that equals one if the clinical trial involves an embargo agreement between the sponsoring firm and the principal investigator, and zero otherwise. *Spin* measures the distortion in a publication abstract's tone using the LIWC dictionary and is defined as $Tone_conclusion - Tone_results$. *V_Spin* is a variant of *Spin* adjusted with the list of positive and negative words summarized by Vinkers et al. (2015). *Pass* is an indicator that equals one if the minimum p-value reported across the trial's primary outcomes satisfies $p \leq 0.05$. *Marginal* (*Marginal_05_20*) is an indicator that equals one if the minimum p-value reported across the trial's primary outcomes satisfies $0.05 < p \leq 0.15$ ($0.05 < p \leq 0.20$). All other variables are defined in Appendix B. Standard errors are clustered at the firm level; t-statistics are reported in parentheses. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively (two-tailed).

Panel A: Main specification

	(1) *Spin*
Embargo	−0.004
	(−0.062)
Pass	−0.148***
	(−2.745)
Embargo × *Pass*	0.097
	(1.446)
Marginal	−0.407***
	(−4.224)
Embargo* × *Marginal	**0.336*** **
	(3.054)
Control variables	Yes
Pub. Year FE	Yes
Indication FE	Yes
Firm FE	Yes
Journal FE	Yes
Observations	7,907
Adjusted R^2	0.457

Panel B: Alternate specifications

	(1) *Spin* Alt. zone	(2) *V_Spin* Alt. tone
Embargo	0.000	−0.013
	(0.002)	(−0.295)
Pass	−0.148***	−0.113***
	(−2.869)	(−2.808)
Embargo × *Pass*	0.093	0.091*
	(1.449)	(1.846)
Marginal_05_20	−0.264***	
	(−3.334)	
Embargo* × *Marginal_05_20	**0.201** **	
	(2.182)	
Marginal		−0.266***
		(−3.118)
Embargo* × *Marginal		**0.255*** **
		(2.771)
Control variables	Yes	Yes
Pub. Year FE	Yes	Yes
Indication FE	Yes	Yes
Firm FE	Yes	Yes
Journal FE	Yes	Yes
Observations	7,907	9,071
Adjusted R^2	0.455	0.436

Table 6. Embargoes and top journal publications

Panel A presents results from OLS regressions testing the association between embargo clauses and the likelihood of publications associated with a trial. Panel B presents results from OLS regressions testing the association between embargo clauses and the likelihood that the first publication appears in a top, or non-top medical journal, in the presence of tone spin. *Embargo* is an indicator that equals one if the clinical trial involves an embargo agreement between the sponsoring firm and the principal investigator, and zero otherwise. *Top_pub* (*Nontop_pub*) is an indicator that equals one if at least one publication associated with the trial appeared in a medical journal ranked among the top 10 (ranked outside the top 60), based on the ranking curated by the McGill University Department of Medicine. *FirstPub_top* (*FirstPub_nontop*) is an indicator that equals one if the first publication associated with the trial appeared in a medical journal ranked among the top 10 (outside the top 60). *Spin* measures the distortion in a publication abstract's tone and is defined as *Tone_conclusion* − *Tone_results* using the LIWC dictionary (Pennebaker et al., 2015). All other variables are defined in Appendix B. Standard errors are clustered at the firm level; *t*-statistics are reported in parentheses. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively (two-tailed).

Panel A: Publication likelihood

	(1) *Top_pub*	(2) *Nontop_pub*
Embargo	**−0.018***** **(−3.250)**	**0.001** **(0.106)**
N_sponsors	0.008 (1.431)	0.027*** (3.004)
N_subjects	0.039*** (14.646)	0.107*** (32.783)
Phase_2	0.009 (1.234)	0.057*** (3.110)
Phase_3	0.032*** (5.027)	0.094*** (4.873)
Previous_trials	−0.001 (−0.339)	0.002 (0.473)
Year FE	Yes	Yes
Indication FE	Yes	Yes
Firm FE	Yes	Yes
Observations	52,355	52,355
Adjusted R^2	0.190	0.280

Table 6 (Continued)

Panel B: First publication venue and spin

	(1) *FirstPub_top*	(2) *FirstPub_nontop*
Embargo	−0.008	0.026
	(−0.463)	(1.405)
Spin	0.061*	−0.105***
	(1.786)	(−2.629)
Embargo* × *Spin	**−0.115*** **	**0.138*** **
	(−2.950)	**(3.143)**
N_sponsors	0.025*	−0.016
	(1.774)	(−1.089)
N_subjects	0.059***	−0.065***
	(8.821)	(−9.968)
Phase_2	0.013	−0.035**
	(0.873)	(−2.240)
Phase_3	0.014	−0.017
	(1.165)	(−1.340)
Previous_trials	−0.006	0.007
	(−0.883)	(0.964)
Year FE	Yes	Yes
Indication FE	Yes	Yes
Firm FE	Yes	Yes
Observations	16,429	16,429
Adjusted R^2	0.311	0.310

Table 7. Embargo and FDA approval of drugs

Panel A compares FDA approval rates for drugs associated with non-embargoed (*Embargo* = 0) and embargoed (*Embargo* = 1) trials. Panel B presents results from OLS regressions testing the association between embargo clauses and the approval of drugs associated with the trial. *Embargo* is an indicator that equals one if the clinical trial involves an embargo agreement between the sponsoring firm and the principal investigator, and zero otherwise. *Approval_Pivotal* is an indicator that equals one if the trial-related drug receives approval from the FDA and the approval letter cites the trial as "pivotal" for clinical trial evidence. *Approval* is an indicator that equals one if the trial tests a drug that is approved by the FDA. *Sig_0_0001* is an indicator that equals one if the minimum (i.e., most significant) p-value reported across the trial's primary outcomes satisfies $p \leq 0.0001$. All other variables are defined in Appendix B. Standard errors are clustered at the firm level; t-statistics are reported in parentheses. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively (two-tailed).

Panel A: Univariate tests

	Mean (*Embargo*=0)	Mean (*Embargo*=1)	Diff (0 − 1) (t-stat)
Approval_Pivotal	0.157	0.225	−0.068**
			(−2.10)
Approval	0.239	0.315	−0.077***
			(−9.58)

Panel B: Multivariate tests

	(1) *Approval_Pivotal*	(2) *Approval*
Embargo	0.084**	0.037*
	(2.085)	(1.714)
Sig_0_0001	0.647***	0.087**
	(8.140)	(2.137)
Embargo* × *Sig_0_0001	**−0.227****	**−0.081***
	(−2.547)	**(−1.868)**
N_sponsors	0.015	0.016
	(0.466)	(1.009)
N_subjects	0.089***	0.003
	(3.387)	(0.495)
Phase_2	−0.033	−0.085***
	(−0.973)	(−4.954)
Previous_trials	0.011	−0.001
	(0.864)	(−0.114)
Year FE	Yes	Yes
Indication FE	Yes	Yes
Firm FE	Yes	Yes
Observations	855	20,832
Adjusted R^2	0.361	0.295

Table 8. Embargoes and capital market reaction to disclosure events

This table presents the association between embargo clauses and capital market reactions to key disclosure events. These events include the posting of clinical trial results on ClinicalTrials.gov (column 1), the first publication date (column 2), and the date of the first publication in a top 10 medical journal (column 3). *Embargo* is an indicator that equals one if the clinical trial involves an embargo agreement between the sponsoring firm and the principal investigator, and zero otherwise. *CAR* is the cumulative abnormal return over the three-day window from the event date (day 0) through day +2, calculated as the sum of daily abnormal returns, where abnormal return equals the firm's raw daily return minus the CRSP value-weighted market return. *Log(ME)* and *BM* are the natural logarithm of market capitalization and book-to-market ratio, both measured as of the event date. All other variables are defined in Appendix B. Standard errors are clustered at the firm level; *t*-statistics are reported in parentheses. *, **, and *** indicate statistical significance at the 10%, 5%, and 1% levels, respectively (two-tailed).

	(1) *CAR* Result	(2) *CAR* First pub	(3) *CAR* First top pub
Embargo	−0.002	−0.001	0.004
	(−1.355)	(−0.338)	(0.736)
Log(ME)	−0.001	−0.001	−0.009
	(−0.569)	(−1.204)	(−1.576)
BM	−0.002	−0.003	0.009
	(−0.514)	(−0.831)	(0.831)
N_sponsors	−0.000	−0.000	−0.002
	(−0.179)	(−0.127)	(−0.661)
N_subjects	0.001***	0.000	0.002
	(3.308)	(0.810)	(1.188)
Phase_2	−0.000	0.005***	−0.009*
	(−0.049)	(2.711)	(−1.852)
Phase_3	−0.000	0.000	−0.005
	(−0.037)	(0.165)	(−1.188)
Previous_trials	0.000	−0.001	−0.000
	(0.209)	(−1.040)	(−0.241)
Year FE	Yes	Yes	Yes
Indication FE	Yes	Yes	Yes
Firm FE	Yes	Yes	Yes
Observations	22,400	7,339	2,055
Adjusted R^2	0.189	0.268	0.391

References

Adner, R. and Levinthal, D. A. (2004). What is not a real option: Considering boundaries for the application of real options to business strategy. *Academy of Management Review*, 29(1):74–85.

Ahn, R., Woodbridge, A., Abraham, A., Saba, S., Korenstein, D., Madden, E., Boscardin, W. J., and Keyhani, S. (2017). Financial ties of principal investigators and randomized controlled trial outcomes: cross sectional study. *BMJ*, 356:i6770.

Barry, H. C., Ebell, M. H., Shaughnessy, A. F., Slawson, D. C., and Nietzke, F. (2001). Family physicians' use of medical abstracts to guide decision making: Style or substance? *Journal of the American Board of Family Practice*, 14(6):437–442.

Barth, M. E. and Gee, K. H. (2024). Accounting and innovation: Paths forward for research. *Journal of Accounting and Economics*, 78(2–3):101733.

Baruffaldi, S., Simeth, M., and Wehrheim, D. (2024). Asymmetric information and R&D disclosure: Evidence from scientific publications. *Management Science*, 70:1052–1069.

Beyer, A., Cohen, D. A., Lys, T. Z., and Walther, B. R. (2010). The financial reporting environment: Review of the recent literature. *Journal of Accounting and Economics*, 50:296–343.

Blankespoor, E., deHaan, E., and Marinovic, I. (2020). Disclosure processing costs, investors' information choice, and firm disclosure. *Journal of Accounting and Economics*, 70(1):101344.

Boutron, I., Dutton, S., Ravaud, P., and Altman, D. G. (2010). Reporting and Interpretation of Randomized Controlled Trials With Statistically Nonsignificant Results for Primary Outcomes. *JAMA*, 303(20):2058–2064.

Boutron, I., Dutton, S., Ravaud, P., and Altman, D. G. (2014). Impact of spin in the abstracts of articles reporting results of randomized controlled trials in the field of cancer: the SPIN trial. *Journal of Clinical Oncology*, 32(36):4120–4126.

Bradley, D., Gokkaya, S., and Liu, X. (2017). Before an analyst becomes an analyst: Does industry experience matter? *The Journal of Finance*, 72(2):751–792.

Brodeur, A., Cook, N., and Heyes, A. (2020). Methods matter: p-hacking and publication bias in causal analysis in economics. *American Economic Review*, 110(11):3634–3660.

Brodeur, A., Lé, M., Sangnier, M., and Zylberberg, Y. (2016). Star wars: The empirics strike back. *American Economic Journal: Applied Economics*, 8(1):1–32.

Chabner, B. (2012). Approval of New Agents after Phase II Trials. *American Society of Clinical Oncology Educational Book*, (32):e1–e3.

Chan, A.-W., Song, F., Vickers, A., Jefferson, T., Dickersin, K., Gøtzsche, P. C., Krumholz, H. M., Ghersi, D., van der Worp, H. B., et al. (2014). Increasing value and reducing waste: addressing inaccessible research. *The Lancet*, 383:257–266.

Davis, A. K., Piger, J. M., and Sedor, L. M. (2012). Beyond the numbers: Measuring the information content of earnings press release language. *Contemporary Accounting Research*, 29:845–868.

DeAngelis, C. D. and Fontanarosa, P. B. (2008). Impugning the Integrity of Medical Science: The Adverse Effects of Industry Influence. *JAMA*, 299(15):1833–1835.

DiMasi, J. A., Grabowski, H. G., and Hansen, R. W. (2016). Innovation in the pharmaceutical industry: New estimates of R&D costs. *Journal of Health Economics*, 47:20–33.

Dranove, D., Kessler, D., McClellan, M., and Satterthwaite, M. (2003). Is more information better? the effects of "report cards" on health care providers. *Journal of Political Economy*, 111(3):555–588.

Dwan, K., Altman, D. G., Arnaiz, J. A., Bloom, J., Chan, A.-W., Cronin, E., Decullier, E., Easterbrook, P. J., Von Elm, E., Gamble, C., Ghersi, D., Ioannidis, J. P. A., Simes, J., and Williamson, P. R. (2008). Systematic review of the empirical evidence of study publication bias and outcome reporting bias. *PLoS ONE*, 3(8):e3081.

Eisfeldt, A. L. and Papanikolaou, D. (2013). Organization capital and the cross-section of expected returns. *Journal of Finance*, 68(4):1365–1406.

Elliott, G., Kudrin, N., and Wüthrich, K. (2022). Detecting p-hacking. *Econometrica*, 90(2):887–906.

Erkens, D. H. (2011). Do firms use time-vested stock-based pay to keep research and development investments secret? *Journal of Accounting Research*, 49(4):861–894.

Fontanarosa, P. and Bauchner, H. (2017). Conflict of Interest and Medical Journals. *JAMA*, 317(17):1768–1771.

Galkina Cleary, E., Jackson, M. J., Zhou, E. W., and Ledley, F. D. (2023). Comparison of research spending on new drug approvals by the national institutes of health vs the pharmaceutical industry, 2010–2019. *JAMA Health Forum*, 4:e230511.

Gigerenzer, G., Gaissmaier, W., Kurz-Milcke, E., Schwartz, L. M., and Woloshin, S. (2008). Helping doctors and patients make sense of health statistics. *Psychological Science in the Public Interest*, 9(2):53–96.

Glaeser, S. and Lang, M. (2024). Measuring innovation and navigating its unique information issues: A review of the accounting literature on innovation. *Journal of Accounting and Economics*, 78:101720.

Glaeser, S. A. and Landsman, W. R. (2021). Deterrent disclosure. *The Accounting Review*, 96:291–315.

Grossman, S. J. and Hart, O. D. (1986). The costs and benefits of ownership: A theory of vertical and lateral integration. *Journal of Political Economy*, 94(4):691–719.

Gøtzsche, P. C., Hróbjartsson, A., Johansen, H. K., Haahr, M. T., Altman, D. G., and Chan, A.-W. (2006). Constraints on publication rights in industry-initiated clinical trials. *JAMA*, 295(14):1645–1646.

Hart, O. D. and Moore, J. (1990). Property rights and the nature of the firm. *Journal of Political Economy*, 98(6):1119–1158.

Hauch, V., Blandón-Gitlin, I., Masip, J., and Sporer, S. L. (2015). Are Computers Effective Lie Detectors? A Meta-Analysis of Linguistic Cues to Deception. *Personality and Social Psychology Review*, 19(4):307–342.

Heflin, F., Subramanyam, K. R., and Zhang, Y. (2003). Regulation FD and the financial information environment: Early evidence. *The Accounting Review*, 78:1–37.

Hirshleifer, D. and Teoh, S. H. (2003). Limited attention, information disclosure, and financial reporting. *Journal of accounting and economics*, 36(1-3):337–386.

Huang, K., Li, M., and Markov, S. (2020). What do employees know? evidence from a social media platform. *The Accounting Review*, 95:199–226.

Huang, X., Teoh, S. H., and Zhang, Y. (2014). Tone management. *The Accounting Review*, 89:1083–1113.

Jaffe, A. B. (1989). Real effects of academic research. *American Economic Review*, 79:957–970.

Jiang, J. X., Stanford, M. H., and Xie, Y. (2012). Does it matter who pays for bond ratings? historical evidence. *Journal of Financial Economics*, 105(3):607–621.

Keller, M. B., Ryan, N. D., Strober, M., Klein, R. G., Kutcher, S. P., Birmaher, B., Hagino, O. R., Koplewicz, H., Carlson, G. A., Clarke, G. N., Emslie, G. J., Feinberg, D., Geller, B., Kusumakar, V., Papatheodorou, G., Sack, W. H., Sweeney, M., Wagner, K. D., Weller, E. B., Winters, N. C., Oakes, R., and McCafferty, J. P. (2001). Efficacy of paroxetine in the treatment of adolescent major depression: A randomized, controlled trial. *Journal of the American Academy of Child & Adolescent Psychiatry*, 40(7):762–772.

Kim, J. and Valentine, K. (2021). The innovation consequences of mandatory patent disclosures. *Journal of Accounting and Economics*, 71(2):101381.

Kirk, M. P. and Markov, S. (2016). Come on over: Analyst/investor days as a disclosure medium. *The Accounting Review*, 91:1725–1750.

Kothari, S. P., Shu, S., and Wysocki, P. D. (2009). Do managers withhold bad news? *Journal of Accounting Research*, 47:241–276.

Le Noury, J., Nardo, J. M., Healy, D., Jureidini, J., Raven, M., Tufanaru, C., and Abi-Jaoude, E. (2015). Restoring Study 329: Efficacy and harms of paroxetine and imipramine in treatment of major depression in adolescence. *BMJ*, 351:h4320.

Leuz, C. and Wysocki, P. D. (2016). The economics of disclosure and financial reporting regulation: Evidence and suggestions for future research. *Journal of Accounting Research*, 54(2):525–622.

Lexchin, J., Bero, L. A., Djulbegovic, B., and Clark, O. (2003). Pharmaceutical industry sponsorship and research outcome and quality: systematic review. *BMJ*, 326(7400):1167–1170.

Li, F. (2008). Annual report readability, current earnings, and earnings persistence. *Journal of Accounting and Economics*, 45:221–247.

Li, S. X., Nagar, V., and Radhakrishnan, S. (2024). Do commercial ties influence ESG ratings? Evidence from Moody's and S&P. *Journal of Accounting Research*, 62(5):1853–1894.

Lin, H.-w. and McNichols, M. F. (1998). Underwriting relationships, analysts' earnings forecasts and investment recommendations. *Journal of Accounting and Economics*, 25(1):101–127.

Lundh, A., Lexchin, J., Mintzes, B., Schroll, J. B., and Bero, L. (2018). Industry sponsorship and research outcome: systematic review with meta-analysis. *Intensive Care Medicine*, 44(10):1603–1612.

McGrath, R. G. and Nerkar, A. (2004). Real options reasoning and a new look at the R&D investment strategies of pharmaceutical firms. *Strategic Management Journal*, 25(1):1–21.

Mello, M. M., Clarridge, B. R., and Studdert, D. M. (2005). Academic medical centers' standards for clinical-trial agreements with industry. *New England Journal of Medicine*, 352(21):2202–2210.

Moore, T. J., Zhang, H., Anderson, G., and Alexander, G. C. (2018). Estimated Costs of Pivotal Trials for Novel Therapeutic Agents Approved by the US Food and Drug Administration, 2015-2016. *JAMA Internal Medicine*, 178(11):1451–1457.

Moynihan, R., Bero, L., Hill, S., Johansson, M., Lexchin, J., Macdonald, H., Mintzes, B., Pearson, C., Rodwin, M. A., Stavdal, A., Stegenga, J., Thombs, B. D., Thornton, H., Vandvik, P. O., Wieseler, B., and Godlee, F. (2019). Pathways to independence: towards producing and using trustworthy evidence. *BMJ*, 367:l6576.

Nascimento, D. P., Ostelo, R. W. J. G., van Tulder, M. W., Gonzalez, G. Z., Araujo, A. C., Vanin, A. A., and Costa, L. O. P. (2021). Do not make clinical decisions based on abstracts of healthcare research: A systematic review. *Journal of Clinical Epidemiology*, 135:136–157.

Pan, J., Sul, E., and Wang, S. (2026). Firm-specific information processing and the delayed discovery of macroeconomic news: Evidence from earnings announcement returns. *Review of Accounting Studies, Forthcoming*.

Pennebaker, J. W., Booth, R. J., Boyd, R. L., and Francis, M. E. (2015). *Linguistic Inquiry and Word Count: LIWC2015*. Pennebaker Conglomerates, Austin, TX. `http://www.liwc.net`.

Prasad, V. and Makary, M. A. (2026). One pivotal trial, the new default option for FDA approval—Ending the two-trial dogma. *New England Journal of Medicine*, 394(8):815–817.

Rathee, C., Malik, S., and Salandra, R. (2025). Timing, modifications, and tenor of firms mandatory R&D disclosures: The role of competition. *Research Policy*, 54:105112.

Reuer, J. J. and Tong, T. W. (2005). Real options in international joint ventures. *Journal of Management*, 31(3):403–423.

Rotolo, D., Camerani, R., Grassano, N., and Martin, B. R. (2022). Why do firms publish? a systematic literature review and a conceptual framework. *Research Policy*, 51:104606.

Sackett, D. L., Rosenberg, W. M. C., Gray, J. A. M., Haynes, R. B., and Richardson, W. S. (1996). Evidence based medicine: what it is and what it isn't. *BMJ*, 312(7023):71–72.

Sasinowski, F. J. and Butler, M. L. (2020). Single-study approvals: Quantum of evidence required. *Therapeutic Innovation & Regulatory Science*, 54(3):687–692.

Schulman, K. A., Seils, D. M., Timbie, J. W., Sugarman, J., Dame, L. A., Weinfurt, K. P., Mark, D. B., and Califf, R. M. (2002). A National Survey of Provisions in Clinical-Trial Agreements between Medical Schools and Industry Sponsors. *New England Journal of Medicine*, 347(17):1335–1341. _eprint: https://www.nejm.org/doi/pdf/10.1056/NEJMsa020349.

Singh, M., Rocafort, R., Cai, C., Siah, K. W., and Lo, A. W. (2022). The reaction of sponsor stock prices to clinical trial outcomes: An event study analysis. *PLOS ONE*, 17:e0272851.

Sinopoulou, V., Gordon, M., Dovey, T. M., and Akobeng, A. K. (2024). Prepublication abstract-only reports compared with full-text manuscripts for randomised controlled trials in inflammatory bowel disease: A systematic review. *BMJ Open Gastroenterology*, 11(1):e001372.

Tausczik, Y. R. and Pennebaker, J. W. (2010). The Psychological Meaning of Words: LIWC and Computerized Text Analysis Methods. *Journal of Language and Social Psychology*, 29(1):24–54.

Teoh, S. H. (1992). Auditor independence, dismissal threats, and the market reaction to auditor switches. *Journal of Accounting Research*, 30(1):1–23.

U.S. Food and Drug Administration (1998). Guidance for industry: Providing clinical evidence of effectiveness for human drug and biological products. Technical report.

U.S. Food and Drug Administration (2026). Demonstrating substantial evidence of effectiveness for human drug and biological products. Draft guidance for industry, U.S. Food and Drug Administration. Revision 1. Draft, not for implementation.

Valentine, K., Zhang, J. L., and Zheng, Y. (2025). Strategic Scientific Disclosure: Evidence from the Leahy–Smith America Invents Act. *Journal of Accounting Research*, 63(4):1723–1755.

Van Wesep, E. D. and Wang, S. (2014). The prevention of excess managerial risk taking. *Journal of Corporate Finance*, 29:579–593.

Verrecchia, R. E. (1983). Discretionary disclosure. *Journal of Accounting and Economics*, 5:179–194.

Vinkers, C. H., Tijdink, J. K., and Otte, W. M. (2015). Use of positive and negative words

in scientific PubMed abstracts between 1974 and 2014: retrospective analysis. *BMJ*, 351:h6467.

Wong, C. H., Siah, K. W., and Lo, A. W. (2019). Estimation of clinical trial success rates and related parameters. *Biostatistics*, 20(2):273–286.

Zhang, Y. (2024). Corporate R&D investments following competitors voluntary disclosures: Evidence from the drug development process. *Journal of Accounting Research*, 62:335–373.