

# Expected Insurance Coverage and Pharmaceutical Innovation: Evidence from China's National Drug Price Negotiation Policy\*

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## Abstract

How can developing countries promote pharmaceutical innovation when price negotiations threaten firms' incentives? China's National Drug Price Negotiation policy combines large price cuts with expanded insurance coverage for innovative drugs, increasing the effective market size. Using a difference-in-differences design that compares clinical trials of negotiated drugs (treated) with vaccines (unaffected) in each disease group, we find that the policy raises the number of trials by 0.56 per disease per year. Effects are stronger for more novel innovations and are similar for domestic and foreign firms. The policy also encourages entry by smaller R&D firms and increases inter-firm collaboration and outsourcing. *JEL Codes: I18, O31.*

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# 1 Introduction

Pharmaceutical innovation is essential to improving population health, yet high drug prices have become a major and growing concern for healthcare systems worldwide, straining public insurance budgets and limiting patient access to effective treatments. High prices largely reflect the economics of pharmaceutical R&D: drug development entails substantial fixed costs, high failure rates, and long development timelines, whereas successful drugs have negligible marginal production costs. Temporary market exclusivity and premium pricing during patent protection are therefore widely viewed as a key mechanism for firms to recoup R&D investments and finance future innovation (Garthwaite, 2025).

This linkage between prices and innovation makes drug price regulation inherently contentious. Policies that limit or negotiate drug prices can improve affordability and access for current patients, but may reduce firms' expected returns and weaken incentives for future R&D. These concerns have long shaped U.S. healthcare policy, including Medicare Part D's historical prohibition of direct government price negotiation. They have re-emerged with the Inflation Reduction Act, which authorizes Medicare to negotiate prices for selected high-expenditure Part D drugs beginning in 2026. Whether cost containment can be achieved without discouraging pharmaceutical innovation remains a central and unresolved question in health economics.

China's National Drug Price Negotiation (NDPN) policy provides a compelling institutional context to study this question. Since 2016, the Chinese government has conducted centralized price negotiations targeting exclusive drugs on the market. The policy functions through two primary mechanisms: first, the government bargains prices with firms for exclusive drugs; second, upon a successful outcome, the drug will be included in the National Reimbursement Drug List (NRDL) at the negotiated price and will become eligible for generous coverage under the basic public health insurance program. By combining large price reductions with expanded market access and increased demand, the policy reshapes firms' expected returns in a theoretically ambiguous manner, making it an ideal natural experiment for evaluating how drug price negotiation affects pharmaceutical innovation.

This paper first examines the impact of the negotiation policy on the sales of successfully negotiated drugs. Using sales data from more than 500 representative public hospitals across 20 cities between 2013 and 2021, we employ a staggered difference-in-differences (DID) design to quantify the policy's effects on retail prices, out-of-pocket prices, sales volumes, and revenues. We find that the policy substantially reduces drug prices. At the same time, the availability of public health insurance coverage results in an even greater reduction in patients' out-of-

pocket costs. We also find that the policy significantly broadens market access, resulting in a volume expansion that more than offsets price reductions, thereby driving a net increase in total drug revenues. These findings suggest that the policy increases firms' expected profitability of developing a new drug, providing a strong incentive for pharmaceutical R&D.

Next, we evaluate the policy's impact on pharmaceutical innovation. We measure firms' innovation activities using comprehensive clinical trial data from the Center for Drug Evaluation (CDE) under the National Medical Products Administration (NMPA) for the period from 2013 to 2023. We focus exclusively on clinical trials for new products that have not been marketed anywhere globally. These trials are more likely to represent true innovation in new drugs than research efforts to bring existing products to China's markets. We employ a difference-in-differences design to compare innovation activities in chemical drugs and therapeutic biologics—both eligible for price negotiation and insurance coverage—against preventive vaccines, which are not covered by China's public health insurance system by law and therefore unaffected by the policy. Vaccines serve as a natural control group because they share similar technological foundations and regulatory oversight with the treatment group, ensuring they are exposed to the same industry-wide shocks. We construct a disease-by-group-by-year panel, where a group is one of the following two categories: chemical drugs and therapeutic biologics, or preventive vaccines. We then examine changes in the incidence and number of clinical trials following the introduction of the negotiation policy in 2016.

We find that the negotiation policy increases both the incidence and the number of clinical trials. Specifically, the number of clinical trials increases by 0.56 per disease per year after the policy, a significant rise compared to the pre-policy mean of 0.18. We also find that this effect is driven primarily by trials for more innovative drugs.<sup>1</sup> In contrast, the effect is negligible among trials involving incremental changes to existing molecules. We conduct several robustness checks to validate the main findings. To ensure our results capture frontier innovation rather than mere market-entry strategy, we conduct subsample analyses on foreign and domestic firms. We find that policy's impact is markedly more pronounced among domestic firms for which China constitutes the primary market, and that these firms' clinical trials are more likely to represent true innovations. To address concerns regarding contemporaneous policy shocks, we narrow our treatment group to therapeutic biologics—vaccines' closest technological counterparts—and find consistent results. We further conduct firm-level analysis, comparing clinical trials conducted by pharmaceutical firms with those conducted by firms specializing in vaccines. We find not only

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<sup>1</sup>We measure drug novelty using the registration category in China, and we find the effects solely come from Type I drugs, which represent new molecules and enjoy longer patent protection.

a general increase in R&D across the pharmaceutical sector after the policy's implementation but also an idiosyncratic surge in clinical trials immediately following a firm's successful price negotiation.

Finally, we examine the policy's broader impact on industry dynamics. We find that the policy not only expands the scope of firms' R&D activities by increasing the number of research fields pursued by the average pharmaceutical firm, but also encourages entry into the pharmaceutical R&D market, particularly among small firms. In addition, collaboration and outsourcing among firms become more prevalent after the policy, while marketing authorization holders (MAHs) also strengthen their in-house innovation activities.

This paper contributes to the existing literature in several important ways. First, we contribute to the literature on the determinants of pharmaceutical innovation. Prior studies emphasize the roles of market size (Acemoglu and Linn, 2004; Blume-Kohout and Sood, 2013; Dubois et al., 2015; Agha, Kim and Li, 2022), intellectual property protection (Kyle and McGahan, 2012; Budish, Roin and Williams, 2015; Gaessler and Wagner, 2022; Budish et al., 2025; Dix and Lensman, 2025), and regulatory practices (Jia et al., 2023) in shaping innovation incentives in both developed and developing countries. In the context of China, prior studies find that insurance coverage increases pharmaceutical innovation (Zhang and Nie, 2021), while price controls reduce it (Geng and Shi, 2024). We contribute to the literature by examining the synergistic impact of price negotiation and expanded insurance coverage and highlighting the role of demand-side policies in shaping firms' R&D decisions.

Second, we contribute to the literature on the economics of pharmaceutical price regulation. Prior studies primarily examine competitive bidding and centralized procurement for generics (Cao, Yi and Yu, 2024; Liu, Lu and Yang, 2025) and medical equipment (Ding, Duggan and Starc, 2025). In this literature, Ji and Rogers (2024) document substantial long-run innovation losses following large, sustained Medicare price cuts in the medical device market, highlighting the potential dynamic costs of aggressive price regulation. Similarly, using a forward-looking framework, Vogel et al. (2024) assess the expected revenue exposure and innovation implications of Medicare drug price negotiation under the Inflation Reduction Act and find modest but highly heterogeneous effects.

We offer new insights into the regulation of prices for innovative drugs by studying a policy that combines price negotiation with expanded insurance coverage. The paper most closely related to ours is Barwick, Swanson and Xia (2025), who analyze the same policy but focus on bargaining design and static consumer welfare. We extend their analysis by shifting attention to

firms' long-run innovation responses. In contrast to the pessimistic predictions in prior work, we provide direct empirical evidence that price negotiation—when paired with market expansion—can mitigate innovation losses and meaningfully shape pharmaceutical R&D incentives.

The rest of the article is organized as follows. Section 2 describes the institutional background of China's NDPN policy and its effects on drug revenues. Section 3 presents the data, sample construction, and empirical strategy. Section 4 reports the baseline results, robustness checks, and the policy's impacts on industry dynamics. Section 5 concludes.

## 2 Institutional Background

### 2.1 Pharmaceutical Industry in China

China hosts one of the largest pharmaceutical markets in the world, yet domestic pharmaceutical firms historically invested little in innovative R&D and contributed minimally to global drug innovation (Friedman, 2010). As of the 2010s, China's pharmaceutical sector comprised more than 5,000 domestic manufacturers, yet large and medium-sized pharmaceutical firms spent less than 2% of sales on R&D by 2010, compared with a global average of around 8% and more than 15% in developed economies (Qiu et al., 2014; Li, 2016; Kanavos, Mills and Zhang, 2019). As a result, the pharmaceutical industry in China was dominated by generic production and incremental modifications, with relatively few innovative drugs developed domestically.

This lack of innovation is largely attributable to the demand-side constraints embedded in China's public health insurance system. Prioritizing cost containment, broad population coverage, and fiscal sustainability, the insurance system historically reimbursed essential drugs with affordable generic substitutes, while excluding many high-priced innovative drugs. The exclusion of such drugs from the NRDL resulted in high out-of-pocket payments for patients (Barwick, Swanson and Xia, 2025)<sup>2</sup>, which in turn suppressed effective demand and shrunk the potential market for innovative drugs. Consequently, firms' expected returns to R&D investment were diminished, weakening their incentives to invest in new drug development. Empirical studies support this mechanism: expansions in insurance coverage have been shown to increase pharmaceutical innovation in affected disease areas (Finkelstein, 2004; Blume-Kohout and Sood, 2013; Zhang and Nie, 2021; Agha, Kim and Li, 2022).

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<sup>2</sup>Before the negotiation policy was implemented, the NRDL had stagnated since 2009 update, leaving drugs launched between 2009 and 2016 uncovered by public health insurance and fully paid out of pocket by patients (Ministry of Human Resources and Social Security, 2017).

## 2.2 China's NDPN Policy

China began to launch NDPN in 2015. In February of that year, the State Council proposed a transparent, multi-shareholder negotiation mechanism specially targeting patented drugs and drugs with exclusive manufacturers. Following rigorous expert assessment, patented drugs characterized by high prices, significant disease burden, and significant clinical benefits for conditions such as hepatitis B, lung cancer, and multiple myeloma, were selected as candidates for the pilot price negotiation. In May 2016, the government completed its first pilot round, successfully negotiating price reductions for three out of five candidate drugs and publicly announcing the corresponding negotiated prices and procurement periods. Under this framework, public hospitals were required to procure these drugs at the negotiated prices, though no specific volume guarantees were required.

During 2017-2019, the negotiation process became institutionalized through annual cycles. Candidates were selected and voted on by clinical and pharmaceutical experts, while health insurance and pharmacoeconomic specialists assessed and determined the reference prices deemed appropriate for inclusion in the NRDL. If a pharmaceutical firm agreed to participate in the negotiation, the government bargained with the firm based on the assessed price. Upon successful negotiation, the drug was added to the NRDL at the negotiated price, either by the end of the same year or in the following year. Notably, the 2018 round focused exclusively on anticancer drugs.

A landmark shift occurred in 2020 when the process transitioned to a firm-initiated application system. Under this new paradigm, the National Healthcare Security Administration (NHSA) issues annual application guidelines specifying eligibility criteria for drugs seeking inclusion in the NRDL. In addition to being supplied by a single firm in China, eligible drugs must also satisfy at least one of several conditions, such as being a new molecular entity launched within the past five years, or having undergone a major change in approved indications within the past five years; notably, drugs launched within the past five years account for the majority of negotiated drugs. After firms submit applications within the designated period, NHSA conducts a preliminary formal review and publicly discloses the submitted materials. Eligible drugs are then identified through expert evaluation, followed by price negotiations between the government and pharmaceutical firms according to procedures similar to those used in previous rounds.

Figure 1 illustrates the 2016-2022 trends for exclusive drugs launched within the past five years (thus eligible for negotiation), drugs selected by the government or passing the formal

review after firm applications, and drugs successfully negotiated and listed. The number of eligible exclusive drugs increased steadily and substantially, rising from 125 in 2016 to 312 in 2022. At the same time, the number of applied or invited drugs rose sharply after 2020 and remained above 100 thereafter, reflecting firms’ increased participation under the firm-initiated application system. The number of successfully negotiated drugs increased steadily, from only a few in 2016 to 79 in 2022, highlighting the expanding scope and growing importance of China’s NDPN policy.

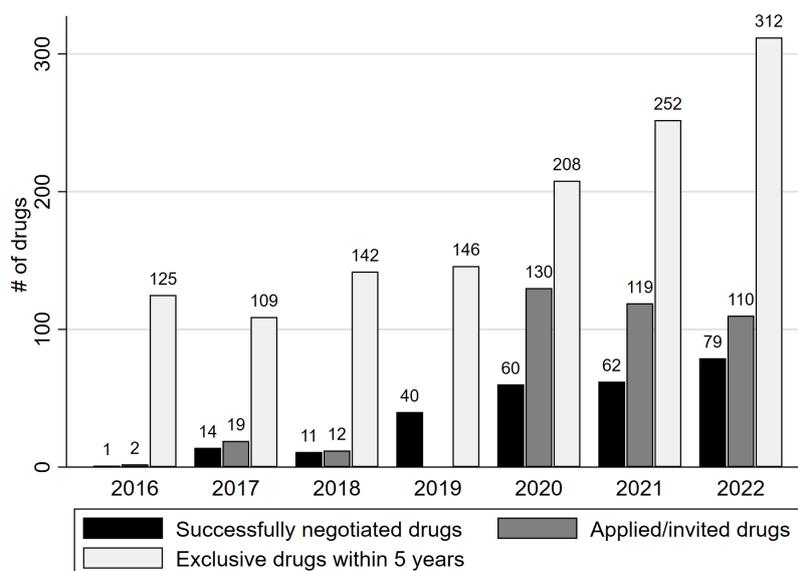


Figure 1: Trends in Drug Eligibility, Participation, and Success in China’s National Drug Price Negotiation

*Notes:* This figure shows the evolution of drugs related to China’s National Drug Price Negotiation from 2016 to 2022, including exclusive drugs launched within the past five years, drugs selected by the government or passing the formal review following firm applications, and drugs that were successfully negotiated and added to the NRDL.

### 2.3 Stylized Facts: Changes in Revenues after Successful Negotiation

The policy’s impact on firms’ R&D activities depends crucially on how it alters firms’ expectations of future revenues. We therefore begin by documenting the policy impacts of successful drug negotiation on revenues. Since Kremer (2002) documents that marginal production costs are negligible relative to high R&D costs in drug development, revenue changes are a good proxy for profit changes—the unobserved variable of ultimate interest.<sup>3</sup> Our results complement those of Barwick, Swanson and Xia (2025), while employing different control groups.

<sup>3</sup>The argument is particular true for small molecule drugs. For biologics, the marginal production cost may not be negligible, thus the revenue change represents the upper bound for profit change.

**Data** To evaluate the effect of successful negotiation on revenues, we use a dataset on drug sales obtained from a consulting firm. The dataset records quarterly sales revenues and quantities, measured in the stock-keeping unit, for drug products produced by pharmaceutical firms across 20 cities from 2013 to 2021.<sup>4</sup> The dataset is collected from more than 500 representative public hospitals, so the ratio of sales revenue and quantity of a product represents the retail price before insurance reimbursement. We aggregate the raw sales data to the city-quarter level and restrict the analysis sample to exclusive drugs supplied by a single firm; therefore, each drug corresponds to one molecule.

We supplement the sales data with additional drug information obtained from government websites. Information on successfully negotiated drugs and the exact implementation dates of negotiated prices are collected from the official websites of the Ministry of Human Resources and Social Security (MOHRSS) and the NHTSA. Drugs eligible for negotiation are identified based on whether their molecules are supplied by a single firm (i.e., exclusive drugs) using drug registration records published by the National Medical Products Administration (NMPA). In addition, we obtain provincial coinsurance rates for the NRDL from the Provincial Healthcare and Security Administration.

**Empirical Strategy** We estimate the impact of successful price negotiation on revenues using a staggered DID design. The treatment group consists of drugs that were successfully negotiated and added to the insurance coverage. We construct two never-treated groups. In the baseline analysis, we use drugs launched in China within the past five years that are therefore eligible for negotiation but never successfully negotiated. We also construct an alternative group with drugs that applied for or were invited to negotiation but eventually failed and remained uninsured. Results are similar across both groups (see Appendix Table A3).

There are two potential concerns regarding the empirical design above. First, successfully negotiated drugs may generate spillover effects on other drugs treating similar conditions, because insurance coverage could shift demand away from unsuccessfully negotiated or non-negotiated substitutes. To address this concern, we follow Dubois and Lasio (2018) to use the Anatomical Therapeutic Chemical (ATC) classification to identify close substitutes and remove from the control group any drug sharing the same ATC-4 code as a treated drug.

Second, treatment and control drugs may not be comparable before the policy implementation. We compare baseline characteristics at each drug’s first appearance in our sample. We

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<sup>4</sup>The included cities are Beijing, Changchun, Changsha, Chengdu, Chongqing, Fuzhou, Guangzhou, Hangzhou, Harbin, Jinan, Nanjing, Shanghai, Shenyang, Shenzhen, Shijiazhuang, Taiyuan, Tianjin, Wuhan, Xi’an, and Zhengzhou.

find that the treated and never-treated drugs are similar in domestic manufacturing status, first-launch year, and quarterly revenues, suggesting that ex-ante balance on observables (see Appendix Table A1).

We use the staggered DID method to estimate the effects of the negotiation policy on drug prices, quantities, and revenues. To mitigate the bias of two-way fixed-effects estimators in staggered-adoption settings, we follow Cengiz et al. (2019) and Deshpande and Li (2019) to reconstruct the sample as follows. First, we split the full sample into six subsets: one for each of the five rounds of successfully negotiated drugs, and one for never-treated drugs. Second, for each negotiation round, we construct a subsample in which the treatment group consists of drugs successfully negotiated in that round and the control group consists of drugs not negotiated in that round but negotiated in later rounds and drugs that are never successfully negotiated. Third, for each subsample, we define the event quarters based on the implementation date of the negotiated price for the treatment drugs and restrict the observation window to periods before the control group becomes treated. Finally, we stack all subsamples to form the final analysis sample, which contains 215 drugs. We further restrict our main sample to three years before and two years after the negotiation, comprising a total of 11,819 drug–subsample–quarter observations.

We then estimate the following staggered DID specification:

$$\ln(y_{isq}) = \sum_{k \neq -1} \beta_k \text{treat}_{is} \times \mathbf{1}\{q - \tau_s = k\} + \delta_{is} + \mu_{sq} + \varepsilon_{isq}, \quad (1)$$

where the dependent variable,  $\ln(y_{isq})$ , represents the natural logarithm of the price, quantity, or revenue of drug  $i$  in subsample  $s$  and calendar quarter  $q$ .  $\text{treat}_{is}$  indicates whether drug  $i$  in subsample  $s$  is in the treatment group.  $\mathbf{1}\{q - \tau_s = k\}$  is an indicator that equals one if quarter  $q$  is  $k$  quarters after the event quarter  $\tau_s$  in which the negotiated price and insurance coverage take effect for subsample  $s$ . The coefficient  $\beta_k$  captures the dynamic treatment effect relative to the implementation quarter ( $k \neq -1$  is omitted).  $\delta_{is}$  and  $\mu_{sq}$  denote drug–subsample and quarter–subsample fixed effects, respectively. Standard errors are clustered at the drug level.

**Results** Figure 2 shows the result. Panel (a) jointly presents the estimated effects on retail prices and patients’ out-of-pocket prices. We find that successful negotiation results in a substantial 50.2% reduction in retail price, suggesting that the negotiation is quite aggressive.<sup>5</sup>

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<sup>5</sup>Percentage changes are calculated as  $(e^{\hat{\beta}} - 1) \times 100\%$ . Appendix Table A2 reports the regression estimates, while Appendix Table A3 presents robustness check results using invited and applied drugs during the negotiation.

Combining with city-specific coinsurance rates for covered drugs, this retail price cut translates into an 85.5% decline in patients' out-of-pocket payments, highlighting the substantial financial relief brought to patients through insurance coverage. Panel (b) shows that the policy also increases the quantity by 476.6%, suggesting that the price reduction, along with the insurance coverage, greatly expands the market size. Panel (c) shows that the combined effect on revenues is positive: revenues of successfully negotiated drugs increase by 187.2%, indicating a strong and persistent positive response.

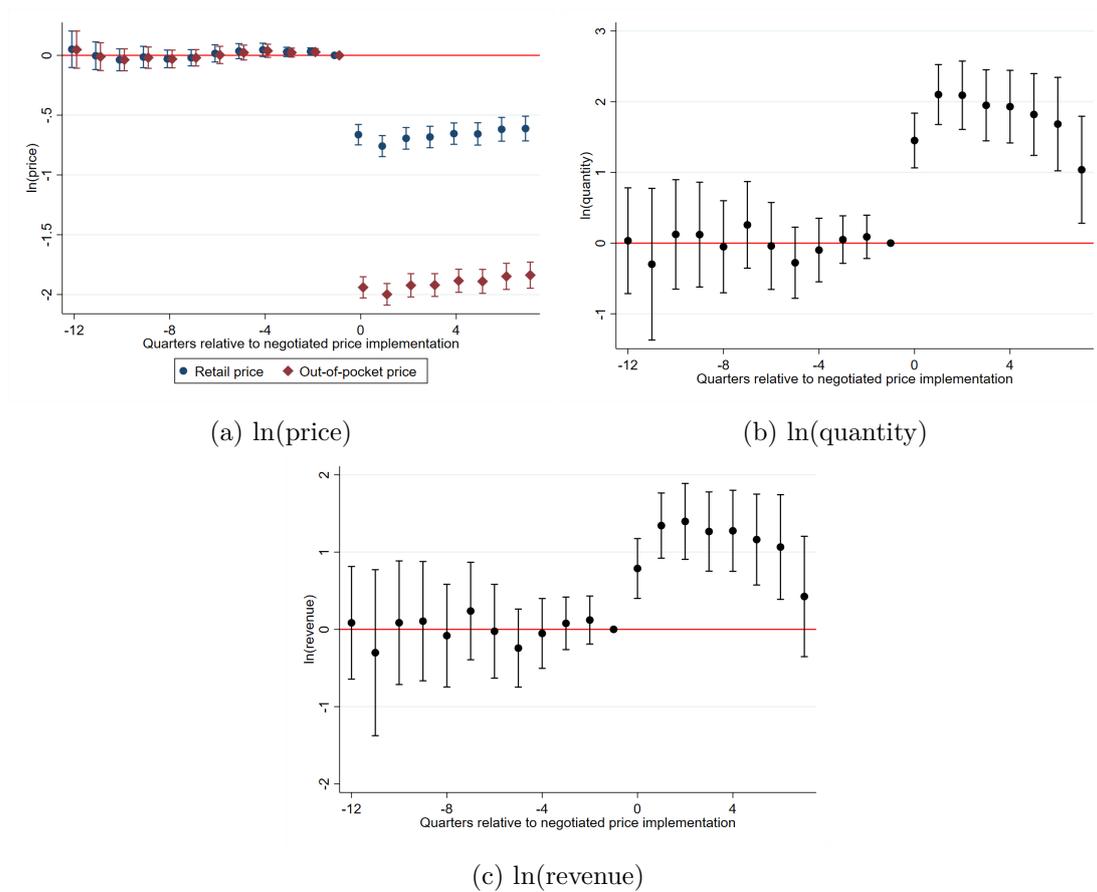


Figure 2: Impacts of Successful Negotiation on Price, Quantity, and Revenue

*Notes:* These figures plot the estimated coefficients of the successful negotiation's effects on the log of retail price, out-of-pocket price, quantity, and revenue of drugs, along with their 95% confidence intervals. Standard errors are clustered at the drug level.

### 3 Data and Empirical Strategy

Section 2.3 shows that the negotiation policy increases total revenues for the successfully negotiated drugs. Consequently, the expected return to drug development is increased, as firms now have an opportunity to expand their market size through insurance coverage. Indeed, con-

sulting and news reports document anecdotal evidence that both domestic and foreign firms are increasing their R&D of new drugs in response to the policy.<sup>6</sup> In this section, we systematically examine how the policy changes pharmaceutical firms’ innovation activities.

### 3.1 Data and Sample

**Clinical Trials Data** We use clinical trial data to gauge firms’ R&D activities. This measure has been used in similar contexts, including China (Jia et al., 2023; Geng and Shi, 2024; Gu, 2024). The initiation of a new clinical trial represents the final and most expensive stage of a drug candidate’s development (Finkelstein, 2004), and new clinical trials directly reflect firms’ investment decisions under current market conditions (Yin, 2008). In contrast, other measures are less suitable for our context. R&D expenditure measures innovative inputs rather than outputs (Griliches, 1990), and increases in spending do not necessarily translate into meaningful or high-quality innovation. Patent data also provide a noisy proxy for innovation: firms typically apply for patents well before clinical trials begin (Acemoglu and Linn, 2004), and patenting behavior often reflects strategic motives rather than genuine scientific progress (Budish, Roin and Williams, 2015). Likewise, using new drug approvals as an innovation measure is impractical in our sample period: given the decade-long development process from initial discovery to market approval (DiMasi, Hansen and Grabowski, 2003), any approval observed today mirrors R&D decisions made many years earlier and thus cannot capture firms’ immediate responses to policy changes.

The clinical trial data are obtained from the Center for Drug Evaluation (CDE) under the NMPA. This data source has been widely used in recent studies examining pharmaceutical innovation in China (Jia et al., 2023; Geng and Shi, 2024; Gu, 2024). Since 2013, all clinical trials conducted in China, including bioequivalence studies and Phase I-IV clinical trials, must be registered and disclosed on a public platform. We obtain detailed information on the active ingredient, dosage form, companies, registration category, indication, trial phase, date of first patient enrollment, and the first Institutional Review Board (IRB) approval date. We use the

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<sup>6</sup>China’s NDPN policy has reshaped firms’ expectations about commercializing innovative drugs and encourages greater investment in R&D. For example, Keyمند Biosciences, a domestic firm specializing in conducting clinical trials, reported having invested more than RMB 2 billion since its establishment and expected successful negotiations to generate a stable and sustained source of funding to support the development of over 50 products currently in its R&D pipeline (China Central Television News, 2025). Foreign pharmaceutical companies also have strong incentives to expand R&D activities in China, which is increasingly viewed as a strategically important and rapidly growing market supported by innovation-oriented policies (L.E.K. Consulting, 2023). For example, Roche Pharma China’s general manager noted that the successful price negotiation of bevacizumab signaled a more sustainable and predictable market environment, reinforcing Roche’s commitment to long-term investment in China’s innovation ecosystem (PharmaBoardroom, 2019), while AstraZeneca announced a USD 2.5 billion investment to establish a new global R&D center in Beijing (Li, 2025).

date of first patient enrollment as the clinical trial timestamp and conduct robustness checks using the first approval date of the IRB committee.

We implement the following data cleaning steps. First, we restrict our sample to clinical trials conducted since 2013, because earlier data are incomplete. Second, each clinical trial is assigned a registration category reflecting its marketing status in both domestic and international markets. We use this information to drop clinical trials for generic drugs (i.e., bioequivalence studies) and for diffuse products already marketed abroad but requiring local trials upon entry into China. We also exclude Phase IV clinical trials, as these studies are conducted after market approval and do not reflect pre-approval R&D activities. Thus, our sample comprises clinical trials of new drugs and vaccines that have not been marketed in any country at the time of trial application. Third, we drop COVID-19-related clinical trials. COVID-19 spurred research activity, but this shock was unforeseen and may interact with other policies. To ensure a clean identification, we exclude these trials from the sample.

We further classify the clinical trials into two types based on novelty, using the registration category in China. The classification is similar to the U.S. Food and Drug Administration new drug application classification: Type I clinical trials are for new drugs with novel chemical entities and well-defined structures, as well as new vaccines that embody substantial innovation, such as those featuring new antigen forms, new adjuvants or adjuvant systems, or new multivalent formulations incorporating new antigens. In contrast, Type II clinical trials are for new drugs or vaccines that are improved and refined versions of known active ingredients, such as modifications to their chemical structure, dosage form, formulation process, route of administration, or therapeutic indication. Therefore, Type I clinical trials are more novel, while Type II clinical trials are more incremental.

For each clinical trial, we map its indication listed in the application form to the National Clinical Version 2.0 of the Disease Coding System in China. This system is fully aligned with the ICD-10 framework while incorporating adjustments and refinements tailored to China’s clinical practice. We use the ICD-10 three-character category level, ensuring consistent and comparable disease classification.<sup>7</sup> We do not use the ATC system to classify drugs or vaccines because many trials lack ATC codes.

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<sup>7</sup>The ICD-10 adopts a hierarchical structure consisting of four levels: (1) chapters, which group diseases into 21 broad categories identified by letters (A–Z); (2) blocks, which organize related diagnostic conditions within each chapter; (3) three-character categories, the level used in our analysis, each represented by one letter followed by two digits (e.g., C50); and (4) four-character subcategories, which add a decimal digit to provide more detailed diagnostic information (e.g., C50.1).

**Firm Characteristics** Firm characteristics are obtained from Qichacha and the Orbis database. Qichacha is a leading Chinese business information platform that compiles all official registration records from the State Administration for Market Regulation and other government agencies. As of 2025, the platform covers more than 500 million enterprises, providing comprehensive data on company profiles, shareholder structure, historical operations, credit information, financial status, and change logs. Orbis, maintained by Bureau van Dijk, provides standardized firm-level data from official registries and financial disclosures. From these two sources, we extract key firm characteristics, including the year of establishment, year of deregistration (if applicable), firm size category, ownership type, and country or region of registration.

### 3.2 Research Design: Disease-Level Analysis

Because R&D incentives may respond to the initiation of the negotiation policy rather than to its successful outcome, we use a standard DID design—rather than a Staggered DID—to examine the policy’s impact on innovation. In principle, all new exclusive drugs, including chemical drugs and therapeutic biologics, are eligible for negotiation. Preventive vaccines, however, are not covered by the national health insurance program and are instead financed through separate public health funds.<sup>8</sup> Therefore, we treat new drug clinical trials as the treatment group and vaccine trials as the control group. Vaccines are an R&D-intensive sector that shares similar technologies and regulatory environments with new drugs, allowing us to difference out structural changes in the industry. For example, the 2015 regulatory reform cleared application backlogs and shortened administrative waiting times in the clinical trial application process for both drugs and vaccines. Similarly, in 2019, China implemented the MAH system for drugs and vaccines.<sup>9</sup> Furthermore, vaccines constitute a highly heterogeneous class covering dozens of distinct diseases. This inherent diversity provides enough variation to average out disease-specific shocks—such as the unique R&D surge during the COVID-19 pandemic—ensuring that the control group remains a stable benchmark for broader industry trends rather than a reflection of a single therapeutic breakthrough.

We construct a disease-by-group-by-year-level sample for analysis, where “group” refers to one of the two categories: drug/therapeutic biologics (treatment group) or vaccines (control group). The dependent variable is whether a clinical trial is conducted, or the number of

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<sup>8</sup>Article 8 of the Interim Measures for the Administration of Drugs under Basic Medical Insurance stipulates that preventive vaccines shall not be included in the NRDL.

<sup>9</sup>The revised Drug Administration Law came into effect in December 2019 (see <https://www.nhc.gov.cn/fzs/c100048/201909/3a86b1c3ae204640acf57080a6486240.shtml>), Similarly, the Vaccine Administration Law was also implemented in December 2019 (see [https://www.samr.gov.cn/zw/zfxxgk/fdzdgknr/fgs/art/2023/art\\_dde03480953841a5912c864dc29003d0.html](https://www.samr.gov.cn/zw/zfxxgk/fdzdgknr/fgs/art/2023/art_dde03480953841a5912c864dc29003d0.html)).

clinical trials conducted, in each year for each disease-group. If no clinical trial is conducted for a given disease group in a particular year, the value is recorded as 0. In total, our dataset includes 6,962 diseases. According to the WHO, a preventive vaccine functions solely to prevent infectious diseases. Thus, we restrict the vaccine sample to infectious diseases.<sup>10</sup> Summary statistics for the treatment and control groups are reported in Appendix Table A4. Appendix Figure A1 illustrates the raw pattern of the average number of clinical trials per disease. We find that before 2016, both groups followed a similar trend. However, after 2016, drug trials increased markedly.

We estimate the following model using two-way fixed effects:

$$y_{it} = \beta \text{treat}_i \times \text{post}_t + \zeta_i + \eta_t + \varepsilon_{it}, \quad (2)$$

where the subscript  $i$  denotes a disease-group, and  $t$  indexes year. The dependent variable  $y_{it}$  is either an indicator of any clinical trial, the total number of trials, or the corresponding measures for Type I and Type II trials.  $\text{treat}_i$  indicates the treatment group, and  $\text{post}_t$  equals one for years after 2016. The coefficient  $\beta$  measures the average change in clinical trial activity for drugs relative to vaccines after the implementation of the negotiation policy.  $\zeta_i$  and  $\eta_t$  denote disease-group and year fixed effects, respectively. Standard errors are clustered at the disease-group level.

We also estimate the following event study specification to examine the pre-trend and dynamics of the innovation response:

$$y_{it} = \sum_{k \neq -1} \beta_k \text{treat}_i \times \mathbf{1}\{t - \tau = k\} + \zeta_i + \eta_t + \varepsilon_{it}, \quad (3)$$

where  $\tau$  denotes the year in which the negotiation policy began (i.e., 2016). The coefficient  $\beta_k$  captures the dynamic effect relative to the implementation year ( $k \neq -1$  is omitted).

## 4 Results

### 4.1 Baseline Results

Table 1 presents the baseline DID estimates. Overall, the negotiation policy leads to an increase of 0.564 in the average number of drug clinical trials relative to vaccines, significant

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<sup>10</sup>The definition of infectious diseases follows WHO's Global Health Estimates, covering 207 ICD-10 categories. See <https://www.who.int/data/global-health-estimates>.

at the 1% level. We also find the results are mainly driven by Type I, i.e., more radical, innovations: after the negotiation policy, drugs exhibit a 1.9 percentage point increase in the likelihood of conducting Type I clinical trials and an average increase of 0.547 Type I trials (both are significant). In contrast, the policy has no significant effect on Type II clinical trials for drugs.

Table 1: Effect of the Negotiation Policy on Clinical Trials

	1(clinical trial)			# of clinical trials		
	(1)	(2)	(3)	(4)	(5)	(6)
	Any	Type I	Type II	All	Type I	Type II
treat $\times$ post	0.009	0.019**	-0.003	0.580***	0.547***	0.033
	(0.009)	(0.008)	(0.007)	(0.103)	(0.082)	(0.031)
Observations	40568	40568	40568	40568	40568	40568
Mean of Dep. Var.	0.070	0.055	0.038	0.650	0.510	0.140
SD of Dep. Var.	0.254	0.229	0.192	5.929	5.014	1.202
Adj. R <sup>2</sup>	0.642	0.631	0.538	0.667	0.613	0.624
Within R <sup>2</sup>	0.000	0.000	0.000	0.000	0.000	0.000

*Notes:* This table reports the baseline DID estimates of the price negotiation policy’s effects on the incidence of any new clinical trial. Columns (1)–(3) present the estimated effects on the incidence of any new trial, while columns (4)–(6) present the effects on the number of new trials. Standard errors are clustered at the disease-treatment level. \*  $p < 0.10$ , \*\*  $p < 0.05$ , \*\*\*  $p < 0.01$ .

Figure 3 presents the event study estimates of the policy impacts on the incidence of conducting any clinical trials (panel (a)) and separately for more novel Type I and less novel Type II trials (panel (b)). Both panels exhibit parallel pre-2016 trends and significant increases in the probability of initiating drug trials after 2021. The lagged extensive-margin response reflects the time required for basic research, target validation, and team assembly when entering a completely new disease area. In addition, the policy effect is shown to be more pronounced for Type I drugs, with a statistically significant increase of 2.57% in 2021.

Figure 4 presents the event study estimates of the negotiation policy’s effects on the number of clinical trials for all types (panel (a)) and separately for Type I and Type II clinical trials (panel (b)). Trial counts began to rise steadily in 2017 and stabilized at nearly one clinical trial per disease per year after 2021. This effect is solely driven by Type I trials, consistent with the observation that Type I new drugs often have higher clinical values and enjoy longer patent protection (i.e., are more likely to receive patent extension approval), which may amplify revenue gains from successful negotiation. Overall, these patterns indicate that the negotiation policy primarily stimulates more innovative drug development.

Further, we compute the number of Phase I-III clinical trials conducted for drugs and vaccines. When a trial simultaneously spans multiple phases (e.g., a combined Phase I/II study),

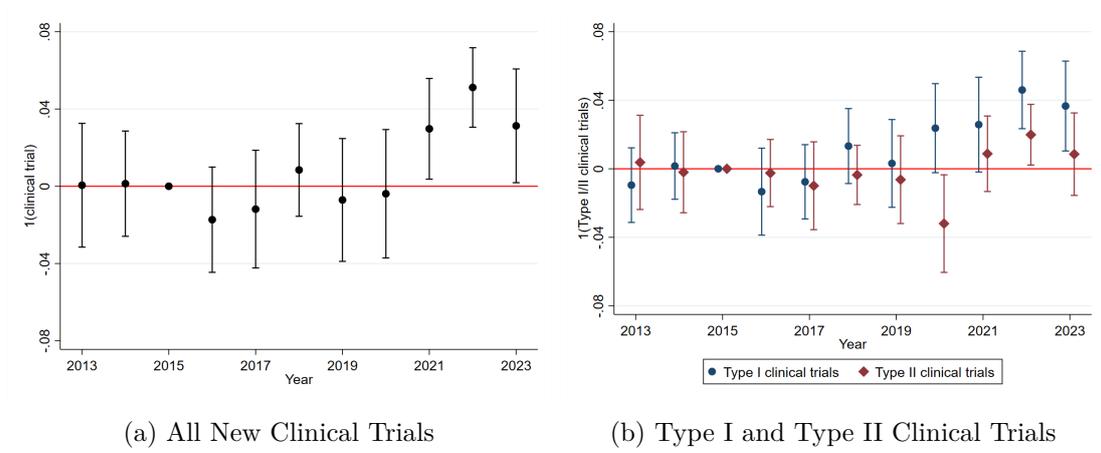


Figure 3: Event Study for the Incidence of Clinical Trials

*Notes:* This figure plots the estimated event study coefficients of the negotiation policy's effects on the incidence of new clinical trials (Panel a) and on the incidence of new Type I and Type II trials separately (Panel b), together with their 95% confidence intervals. Standard errors are clustered at the disease-group level.

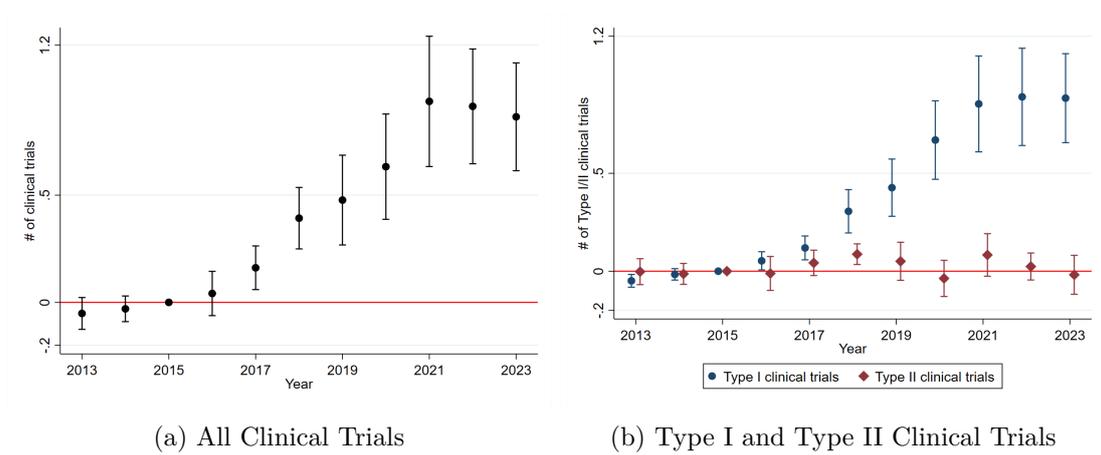


Figure 4: Event Study for the Number of Clinical Trials

*Notes:* This figure plots the estimated event study coefficients of the negotiation policy's effects on the number of new clinical trials (Panel a) and on the number of new Type I and Type II trials separately (Panel b), together with their 95% confidence intervals. Standard errors are clustered at the disease-treatment level.

we count it toward each phase total. Figure 5 presents the event study estimates by clinical phase. The results show lagged treatment effects across later-stage trials: the largest increase occurs in Phase I, followed by Phase II, whereas Phase III exhibits a comparatively modest response. This pattern is consistent with Blume-Kohout and Sood (2013), which documents similar phase-specific responses in pharmaceutical R&D to Medicare Part D.

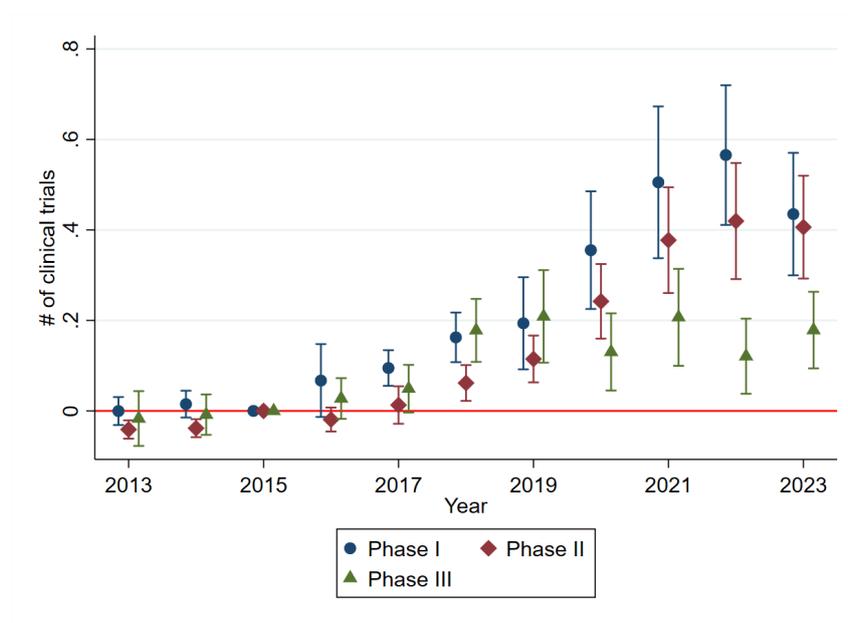


Figure 5: Event Study for the Number of Clinical Trials in Different Phases

*Notes:* This figure presents the estimated event study coefficients of the negotiation policy’s effects on the numbers of new Phase I, II, and III clinical trials separately, together with their 95% confidence intervals. Standard errors are clustered at the disease-treatment level.

## 4.2 Robustness Checks

We conduct a series of robustness checks. All results consistently confirm the robustness of our baseline findings.

**Chemical Drugs and Therapeutic Biologics** The key identification concern is whether vaccines are truly comparable to drugs. To address this concern, we split the treatment group into chemical drugs and therapeutic biologics. The latter group is even more similar to preventive vaccines with respect to R&D processes, manufacturing complexity, and clinical evaluation standards, making the comparison tighter and also not affected by other policy changes regarding the pharmaceutical market. For example, during this period, China gradually implemented bioequivalence evaluation, beginning with chemical generic drugs and subsequently extending the quality consistency requirements to therapeutic biologics and vaccines. In addition, China

implemented central procurement for selected generic drugs, which targeted only chemical products, leaving therapeutic biologic drugs and vaccines unaffected during the sample period. We find that the results are consistent with the baseline estimates: the policy impacts on therapeutic biologics are positive and significant, measured in both the probability of initiating clinical trials and the number of trials. Moreover, the policy effect is noticeably larger for therapeutic biologics than chemical drugs (see Appendix Figure A2 and Appendix Table A5 for the results.)

**Poisson Regression Model** We quantify the effect of the negotiation policy on the proportional change in clinical trials using a Poisson regression model. Specifically, we estimate the following DID specification:

$$y_{it} = \exp(\beta \text{treat}_i \times \text{post}_t + \zeta_i + \eta_t) + \xi_{it}, \quad (4)$$

where all variables are as defined in Equation (2). The coefficient  $\beta$  represents the proportional change in the outcome variable. Its magnitude can be interpreted as a percentage change, calculated as  $(e^\beta - 1) \times 100\%$ . We find that the number of overall new clinical trials for all drugs increases by 77.4%. In 2020, the number of Type I trials increase by 121.2% relative to baseline period. In contrast, the number of new Type II trials does not change significantly (see Appendix Table A6 and Appendix Figure A3). Overall, our findings remain robust when the model is estimated using a Poisson specification.

**Alternative Definitions of Clinical Trial Timing** We adopt an alternative definition of clinical trial timing that sets trial start dates equal to the IRB approval dates. In China, clinical trials must obtain approval from the IRB before investigators are allowed to begin participant recruitment. As a result, some trials in the data have received IRB approval but have not yet completed participant enrollment, which increases the number of trials captured under this alternative definition (8,549 trials, compared with 7,282 trials in the baseline specification). Appendix Table A7 and Appendix Figures A4 and A5 confirm that our findings are robust to this alternative timing definition.

**Alternative Measures of R&D Activity** We use alternative measures of R&D activity based on project-level counts, measuring innovation as the number of new or active clinical projects at the active ingredient-dosage form-firm level. A new clinical project is defined as one that starts a clinical trial in a given year. In addition, a clinical project is classified as active in a given year if the firm continues to develop the same drug or vaccine, even if no clinical

trial happens to be carried out in that specific year. The corresponding results are reported in Appendix Table A8 and Appendix Figures A6 and A7. The results remain robust, and the observed increase in innovation is primarily driven by Type I projects.

**Excluding the MAH Pilot Program** In November 2015, China implemented an MAH pilot program for ten provinces, which are Beijing, Fujian, Guangdong, Hebei, Jiangsu, Shandong, Shanghai, Sichuan, Tianjin, and Zhejiang, and vaccines are not eligible for this pilot. To rule out the confounding effects of the MAH pilot program on pharmaceutical innovation, we drop trials led by MAHs in these regions and restrict the sample period to 2013-2019, prior to the nationwide rollout in December 2019. The results are consistent with the baseline estimates (see Appendix Table A9 and Appendix Figure A8).

### 4.3 Firm-Level Analysis

We replicate the disease-level analysis using firm-level regressions to provide further insight into the potential mechanisms underlying the effects. The sample includes pharmaceutical and vaccine firms that conducted clinical trials in our baseline sample and were invited to or applied for the negotiation during 2016-2023. For each firm, we collect the information on its establishment and deregistration year (if applicable) and calculate the number of clinical trials conducted during this period. We impute zeros for years without trials. Following the baseline classification, firms that conducted only vaccine clinical trials during 2013-2023 serve as the control group, as they were not affected by the negotiation policy. All other firms engaged in drug R&D constitute the treatment group.<sup>11</sup> Appendix Table A10 reports summary statistics at the firm level, including characteristics of treatment and control firms and their R&D activities. In general, vaccine firms are more likely to be domestic, but are similar in size.

We distinguish the effects on firms that successfully negotiate from those on all pharmaceutical firms. All pharmaceutical firms are affected by the negotiation policy because of a change in expectations. Moreover, a subset of firms successfully negotiate contracts and experience substantial revenue increases. These firms may increase their research activities more than the other pharmaceutical firms if they form a different belief about the policy, or if they are financially constrained and benefit from immediate cash flow. To separately identify these two effects, we first estimate the overall effects on all pharmaceutical firms using a two-way fixed

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<sup>11</sup>1.36% of firms conducted both pharmaceutical and vaccine clinical trials in our sample. Our results are robust excluding these firms, as shown in Appendix Table A11 and Figure A10.

effects model and treating vaccine firms as the control group:

$$y_{ft} = \beta \text{treat}_f \times \text{post}_t + \theta_f + \lambda_t + \nu_{ft}, \quad (5)$$

where the subscript  $f$  denotes firm, and  $t$  indexes year. The dependent variable  $y_{ft}$  is either an indicator of any clinical trial, the total number of trials, or the corresponding measures separately for Type I and Type II trials.  $\text{treat}_f$  indicates whether firm  $f$  is in the treatment group.  $\text{post}_t$  equals one for years after 2016. The coefficient  $\beta$  captures the policy effect for all pharmaceutical firms.  $\theta_f$  and  $\lambda_t$  denote firm and year fixed effects, respectively. Standard errors are clustered at the firm level.

Table 2 reports the DID estimates of the negotiation policy’s effects for all pharmaceutical firms.<sup>12</sup> Relative to vaccine firms, pharmaceutical firms experience a significant increase in both the incidence and the number of Type I clinical trials following the implementation of the policy. In contrast, both the incidence and the number of Type II clinical trials decline significantly after the policy.

Table 2: Effects of the Negotiation Policy on Clinical Trials for All Firms

	1(clinical trial)			# of clinical trials		
	(1) Any	(2) Type I	(3) Type II	(4) All	(5) Type I	(6) Type II
treat × post	-0.046 (0.037)	0.063** (0.025)	-0.107*** (0.038)	0.199* (0.104)	0.348*** (0.061)	-0.149* (0.077)
Observations	18271	18271	18271	18271	18271	18271
Mean of Dep. Var.	0.246	0.195	0.076	0.581	0.443	0.138
SD of Dep. Var.	0.430	0.396	0.264	2.150	1.866	0.682
Adj. R <sup>2</sup>	0.251	0.281	0.265	0.553	0.540	0.402
Within R <sup>2</sup>	0.000	0.000	0.002	0.000	0.001	0.001

*Notes:* This table reports DID estimates of the price negotiation policy’s effects on the conduction of new clinical trials for all firms. Columns (1)-(3) present the estimated effects on the incidence of any new trial, while columns (4)-(6) present the effects on the number of new trials. Standard errors are clustered at the firm level. \*  $p < 0.10$ , \*\*  $p < 0.05$ , \*\*\*  $p < 0.01$ .

We then estimate the effects of successful negotiation using a staggered DID approach. After reconstructing the corresponding sample as in the way introduced in Section 2.3, we compare successfully negotiated firms with those that were invited or applied but did not secure a negotiated price. The estimation equation is specified as:

$$y_{fmt} = \gamma \text{treat}_{fm} \times \text{post}_t + \theta_{fm} + \lambda_{mt} + \nu_{fmt}, \quad (6)$$

<sup>12</sup>Appendix Figure A9 presents the event study results.

where  $f$  indexes firm,  $m$  denotes the subsample, and  $t$  indexes year.  $treat_{fm}$  equals one if firm  $f$  in subsample  $m$  successfully negotiated during the sample period, and  $\tau_m$  denotes the year in which the negotiated price became effective for subsample  $m$ . The coefficient  $\gamma$  captures the effect of successful negotiation. Firm-by-subsample fixed effects  $\theta_{fm}$  and subsample-by-year fixed effects  $\lambda_{mt}$  are included, and standard errors are clustered at the firm level.

Table 3 reports the staggered DID estimates of the successful negotiation’s effects.<sup>13</sup> Compared with firms that did not successfully negotiate, firms that successfully entered the NRDL exhibit a statistically significant increase in the number of new clinical trials, yet no significant rise in the likelihood of starting any new trial. A plausible interpretation is that the substantial revenue gains from successful negotiation provide the corresponding firms with greater financial resources to accelerate their existing R&D pipeline, while the lag from discovery-to-clinical prevents an extensive margin from responding in the short run. Decomposing by trial type, successfully negotiated firms experience significant gains in both the incidence and the number of new Type I trials, but for Type II trials, the count increases significantly but the incidence rises little.

Table 3: Effects of Successful Negotiation Policy on Clinical Trials per Firm

	1(clinical trial)			# of clinical trials		
	(1)	(2)	(3)	(4)	(5)	(6)
	Any	Type I	Type II	All	Type I	Type II
$treat \times post$	0.049 (0.038)	0.072** (0.033)	0.067* (0.034)	1.427*** (0.494)	1.117** (0.454)	0.311*** (0.110)
Observations	13006	13006	13006	13006	13006	13006
Mean of Dep. Var.	0.265	0.191	0.128	1.027	0.735	0.292
SD of Dep. Var.	0.441	0.393	0.334	3.782	3.271	1.122
Adj. R <sup>2</sup>	0.481	0.493	0.397	0.614	0.592	0.537
Within R <sup>2</sup>	0.001	0.004	0.004	0.022	0.017	0.010

*Notes:* This table reports staggered DID estimates of the price negotiation policy’s effects on the conduction of new clinical trials for firms involved in negotiation. Columns (1)-(3) present the estimated effects on the incidence of any new trial, while columns (4)-(6) present the effects on the number of new trials. Standard errors are clustered at the firm level. \*  $p < 0.10$ , \*\*  $p < 0.05$ , \*\*\*  $p < 0.01$ .

#### 4.4 Impacts on Industry Dynamics

Understanding how the negotiation policy reshapes industry dynamics is crucial for interpreting its broader economic consequences (Lenox, Rockart and Lewin, 2007). Beyond influencing firms’ incentives to undertake innovation activities, the policy may also alter the competitive

<sup>13</sup>Appendix Figure A11 reports the event study results

environment (Acemoglu and Linn, 2004), affect firm entry and exit (Parker, 2025), and reorganize the division of labor and inter-firm collaboration (Cunningham and Gök, 2016). Moreover, its impacts are likely to vary across different types of firms, for example, by firm size (Acemoglu and Linn, 2004) or by ownership structure (Geng and Shi, 2024). These structural adjustments shape not only the aggregate level of innovation but also the long-run configuration of the pharmaceutical industry.

Hence, in this section, we examine how the negotiation policy shapes the evolution of industry structure along the above key dimensions. We begin by analyzing its effects on firm behavior, including the number of firms operating within each market, defined as a disease-by-group cell, as well as patterns of entry and firms' innovation activities. We then turn to the division of labor and inter-firm collaboration, and finally investigate the heterogeneity of policy impacts across domestic and foreign firms.

#### 4.4.1 Firm Entry

Our baseline results indicate that the negotiation policy increases the number of new clinical trials per disease per year. We decompose the increase into the intensive and extensive margins. On the intensive margin, we find that both pharmaceutical and vaccine firms conduct a similar number of clinical trials each year within each disease in which they already operate (see Appendix Figure A12). In contrast, on the extensive margin, we find that there are more firms conducting clinical trials per disease. Table 4 reports the DID results at the disease level.<sup>14</sup> To be specific, after the negotiation policy, more firms conduct Type I clinical trials for drugs relative to vaccines per disease, whereas no significant effect is observed for Type II trials. Overall, these results indicate that the policy impact is primarily driven by the extensive margin, with the number of active firms rising and the market becoming more competitive.

We find that the extensive margin changes come from two sources. We define a disease-by-group as a research field in which a firm engages in R&D activity. First, we examine the effects of the policy on the number of research fields in which pharmaceutical firms operate, compared with vaccine firms, from their respective years of establishment. Table 5 shows the DID regression results. Following the negotiation policy, pharmaceutical firms enter 0.838 additional research fields on average relative to vaccine firms, concentrating on Type I trials.<sup>15</sup> Second, there is also substantial new firm entry. Figure 6 presents the number of firms that conduct Phase I clinical trials for the first time in each year. Before 2016, the number of first-

<sup>14</sup>Appendix Figure A13 shows the event study estimates.

<sup>15</sup>Appendix Figure A14 reports the event study estimates

Table 4: Policy Effects on the Number of Firms Conducting Clinical Trials Per Disease

	(1)	(2)	(3)
	All	Type I	Type II
treat $\times$ post	0.388*** (0.076)	0.393*** (0.059)	0.003 (0.030)
Observations	40568	40568	40568
Mean of Dep. Var.	0.496	0.389	0.115
SD of Dep. Var.	3.859	3.293	0.860
Adj. R <sup>2</sup>	0.659	0.614	0.635
Within R <sup>2</sup>	0.000	0.000	0.000

*Notes:* The table shows the disease-group-year level DID results. The dependent variable is the number of firms conducting clinical trials in each disease, group, and year. Standard errors are clustered at the disease-treatment level. \*  $p < 0.10$ , \*\*  $p < 0.05$ , \*\*\*  $p < 0.01$ .

time entrants into clinical trials of drugs or vaccines remained relatively stable. After 2016, however, the number of new pharmaceutical firm entries increased markedly, especially among small firms, while the number of new vaccine firms stayed stable.<sup>16</sup>

Table 5: Effects on the Number of Research Fields Each Firm Conducting Clinical Trials

	(1)	(2)	(3)
	All	Type I	Type II
treat $\times$ post	0.838*** (0.127)	0.873*** (0.091)	-0.008 (0.077)
Observations	18271	18271	18271
Mean of Dep. Var.	1.213	0.944	0.294
SD of Dep. Var.	4.077	3.570	1.681
Adj. R <sup>2</sup>	0.599	0.578	0.552
Within R <sup>2</sup>	0.001	0.001	0.000

*Notes:* This table reports DID estimates of the price negotiation policy's effects on the number of research fields in which a firm is actively engaged in clinical trials. Standard errors are clustered at the firm level. \*  $p < 0.10$ , \*\*  $p < 0.05$ , \*\*\*  $p < 0.01$ .

#### 4.4.2 Clinical-Trial Collaboration Modes

We also observe changes in how firms collaborate in R&D after the negotiation policy. There are two main types of firms involved in the R&D of drugs and vaccines. An MAH is a firm or research institution that has obtained marketing authorization for a drug. The MAH bears primary responsibility for the entire product life cycle, including clinical trials, manufacturing and commercialization, post-marketing studies, and the monitoring, reporting,

<sup>16</sup>Firm size is classified according to the *Standards for the Classification of Large, Medium, Small, and Micro Enterprises* issued by the National Bureau of Statistics of China in 2017. We map the Orbis categories to the same four size groups to ensure consistency with domestic classification.

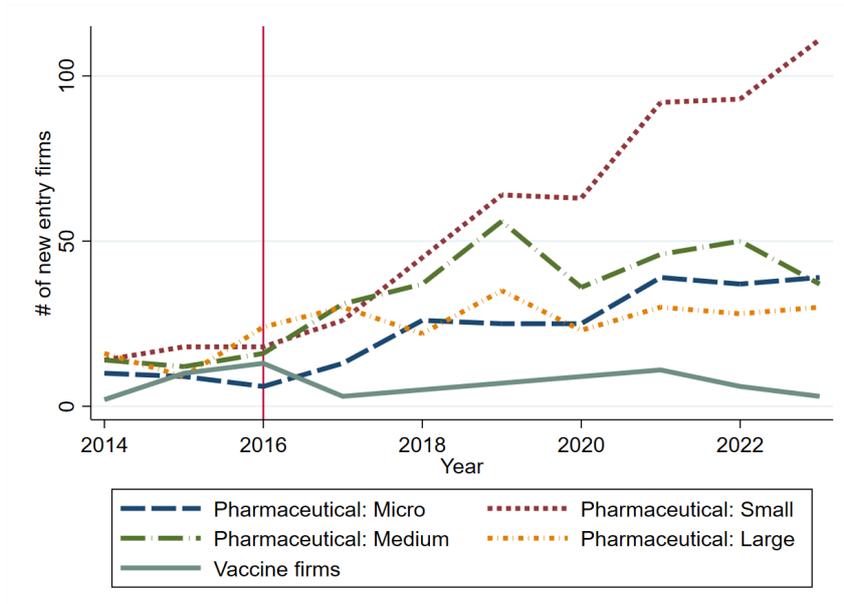


Figure 6: Number of New Firm Entries

*Notes:* This figure shows the time-series pattern of the number of firms that start conducting Phase I clinical trials for drugs or vaccines.

and management of adverse drug reactions. In addition, there are firms that specialize in the operational execution of clinical development, providing services such as trial management, site coordination, and manufacturing-related support. In our dataset, MAH firms are the entities that apply for clinical trials and obtain market approval for the corresponding product, and there is a separate variable indicating which firms actually conduct clinical trials.

We classify all clinical trials into three categories. In-house trials are conducted by a single firm; collaborative trials are jointly conducted by the MAH and non-MAH firms; and outsourced trials are carried out solely by non-MAH firms without the MAH’s direct involvement. MAHs can reduce development costs by outsourcing clinical activities to other specialized service providers (Steadman, 2018). Outsourcing allows firms to avoid the heavy fixed costs of maintaining in-house clinical operations, including dedicated personnel, clinical infrastructure, and quality-management systems. Moreover, non-MAH firms enhance efficiency and data quality by supplying scalable clinical labor, accelerating trial timelines, providing independent monitoring, standardizing multi-center processes, and ensuring regulatory-compliant data collection (Roberts, Kantarjian and Steensma, 2016).

Figure 7 presents the results. We find that both the likelihood and the total number of collaborated and outsourced clinical trials increase steadily following the negotiation policy, and the magnitude is similar for the two types. In contrast, the in-house trials experience

some lag in the change: the increase in both the incidence and trial counts show up after 2021. The delayed surge in MAH’s internal innovation efforts reflects the economics of internal R&D. Building or expanding internal trial capacity requires upfront investments in staff, facilities and regulatory systems; these investments may take time to build on, and the fixed costs are justified only after several rounds of successful negotiations signal that the policy is durable and profitable. Consequently, MAHs front-load collaboration to shorten time-to-market, then scale up in-house activity once financial resources are sufficiently large and policy commitment is fully credible.

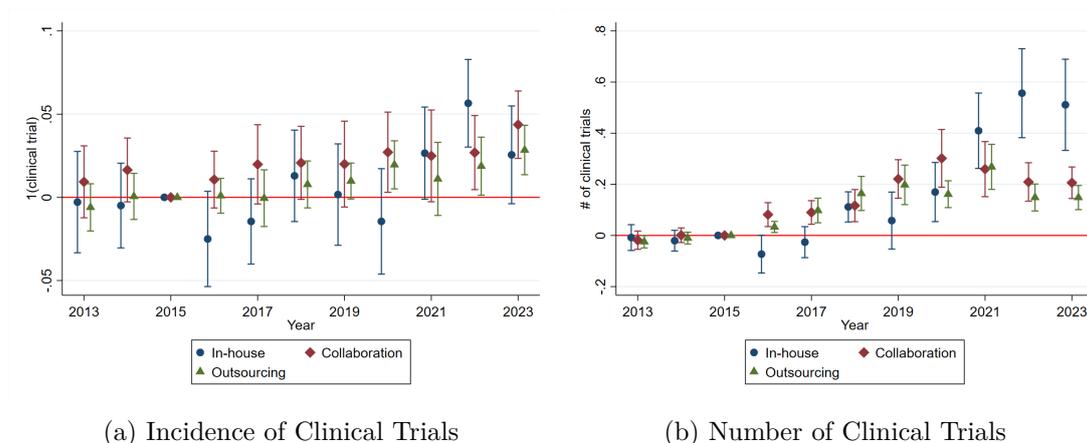


Figure 7: Event Study by Clinical-Trial Collaboration Modes

*Notes:* This figure plots the estimated event study coefficients of the negotiation policy’s effects on the incidence of any new clinical trial (Panel a) and the number of new trials (Panel b), separately for in-house, collaboration, and outsourcing modes, along with their 95% confidence intervals. Standard errors are clustered at the disease-group level.

#### 4.4.3 Firm Origin

To examine how the negotiation policy affects firms’ R&D behavior, we conduct separate analyses for domestic and foreign pharmaceutical firms. Although we exclude diffused drugs from the sample, clinical trials conducted by foreign firms may still primarily reflect efforts to enter the Chinese market rather than genuinely new innovations developed exclusively for China. These trials are typically components of global development programs conducted across multiple regions, where China is rarely the primary or initial target; consequently, their presence in our data may represent a localized expansion of existing global R&D rather than a direct response to China-specific policy incentives. In contrast, innovation by domestic firms is more likely to be directly driven by the negotiation policy, given that China constitutes their primary market. These considerations motivate us to separately examine the average number of clinical

trials conducted by domestic and foreign firms at the disease level. Based on the country in which the firm is located and whether the drug under development is domestically developed or imported, we classify firms as domestic or foreign.

Table 6 reports the DID regression results of the policy’s effects on the number of Type I and Type II clinical trials conducted by domestic and foreign firms, relative to vaccine trials per disease.<sup>17</sup> Following the implementation of the negotiation policy, Type I drug innovation activities increase for both domestic and foreign firms, with domestic firms exhibiting a markedly larger rise. For Type II clinical trials, the policy has no statistically significant effect on domestic firms but significantly promotes innovation by foreign firms. These heterogeneous effects may be explained by differences in R&D capabilities and strategic responses across firm types and innovation categories. Domestic firms, which have historically focused on building original innovation capacity, may therefore react more strongly to the negotiation policy by increasing Type I clinical trial activities. In contrast, Type II innovation, often involving incremental modifications of existing drugs, entails relatively lower R&D risk and technological uncertainty. Foreign firms, which possess extensive global pipelines and accumulated experience in incremental development, may be better positioned to rapidly adapt existing products or indications to the Chinese market in response to improved reimbursement prospects. As a result, the policy significantly stimulates Type II clinical trials among foreign firms, while domestic firms exhibit no comparable response.

Table 6: Effects of Negotiation Policy on the Number of Clinical Trials by Firm Origin

	Type I		Type II	
	(1)	(2)	(3)	(4)
	Domestic	Foreign	Domestic	Foreign
treat $\times$ post	0.494*** (0.075)	0.062*** (0.008)	-0.042 (0.027)	0.077*** (0.012)
Observations	40568	40568	40568	40568
Mean of Dep. Var.	0.510	0.510	0.140	0.140
SD of Dep. Var.	5.014	5.014	1.202	1.202
Adj. R <sup>2</sup>	0.620	0.389	0.441	0.574
Within R <sup>2</sup>	0.000	0.000	0.000	0.000

*Notes:* This table reports DID estimates of the price negotiation policy’s effects on the number of new clinical trials by different firm origins. Columns (1)-(2) present the estimated effects on the number of new Type I clinical trial, while columns (3)-(4) present the effects on the number of new Type II clinical trials. Standard errors are clustered at the disease-group level. \*  $p < 0.10$ , \*\*  $p < 0.05$ , \*\*\*  $p < 0.01$ .

<sup>17</sup>Appendix Figure A15 reports the event study estimates.

## 5 Conclusion

This study provides novel empirical evidence on the effects of China’s NDPN policy on pharmaceutical innovation in a developing-country context. Using drug sales data, we show that the negotiation policy significantly reduces drug prices while expanding market size and increasing drug revenues, thereby improving firms’ expected returns from innovation. Leveraging detailed clinical trial data, we further document that the policy substantially stimulates pharmaceutical R&D relative to vaccine development, with particularly pronounced effects on more innovative Type I drugs and on early-stage clinical trials. These increases are observed among both domestic and foreign firms conducting R&D in China, suggesting that the policy reshapes innovation incentives across a broad set of market participants.

We also show that the expansion in innovation is driven primarily by firm entry and the reallocation of R&D efforts. In particular, small and micro firms play an important role in driving innovation, and pharmaceutical firms expand their R&D scope into new research fields. At the same time, firms respond to the policy by adjusting their organizational strategies, increasing collaboration and outsourcing, and strengthening their internal R&D activities. Further research is needed to elucidate the underlying drivers of these structural changes in the industry.

In the context of a developing country, China’s NDPN policy combines price reductions with expanded insurance coverage, thereby increasing consumer surplus and fostering incentives for innovation. Our findings provide empirical evidence for other countries considering the adoption of similar drug price negotiation policies. One limitation of this study is that we do not conduct a full welfare evaluation: the policy’s cost is the resulting increase in government expenditure. Future research is needed to evaluate the program’s overall welfare effects.

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## Appendix A. Supplementary Analysis

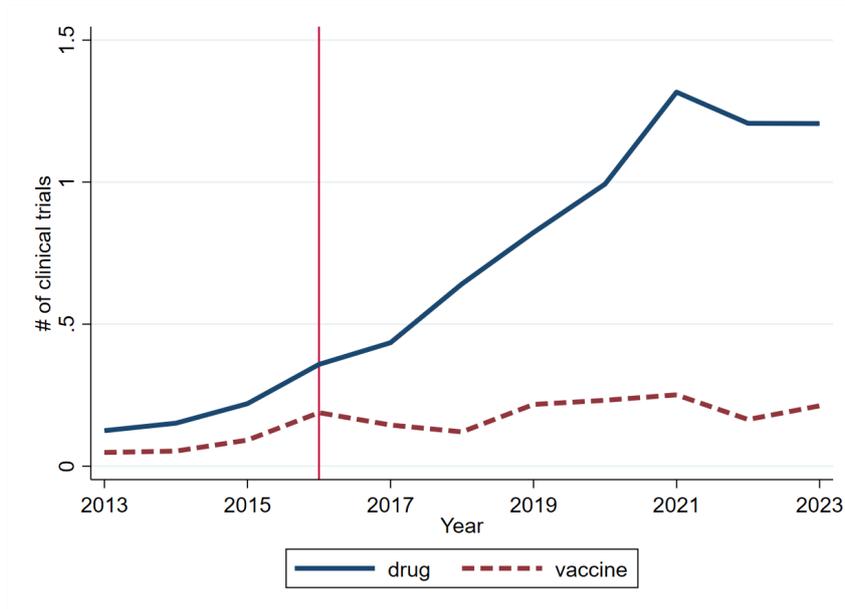


Figure A1: Raw Pattern of the Average Number of Clinical Trials per Disease

*Notes:* This figure shows the time-series pattern of the average number of drug or vaccine clinical trials, measured at the disease level.

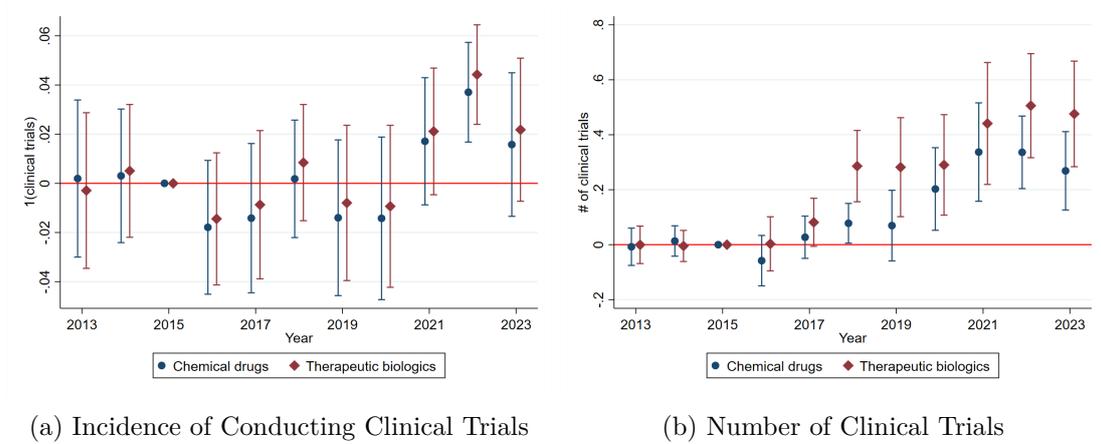


Figure A2: Event Study: Chemical Drugs and Therapeutic Biologics

*Notes:* This figure plots the estimated event study coefficients of the negotiation policy's effects on the incidence of new clinical trials (Panel a) and on the number of trials (Panel b), splitting the treatment group into chemical drugs and therapeutic biologics, together with their 95% confidence intervals. Standard errors are clustered at the disease-treatment level.

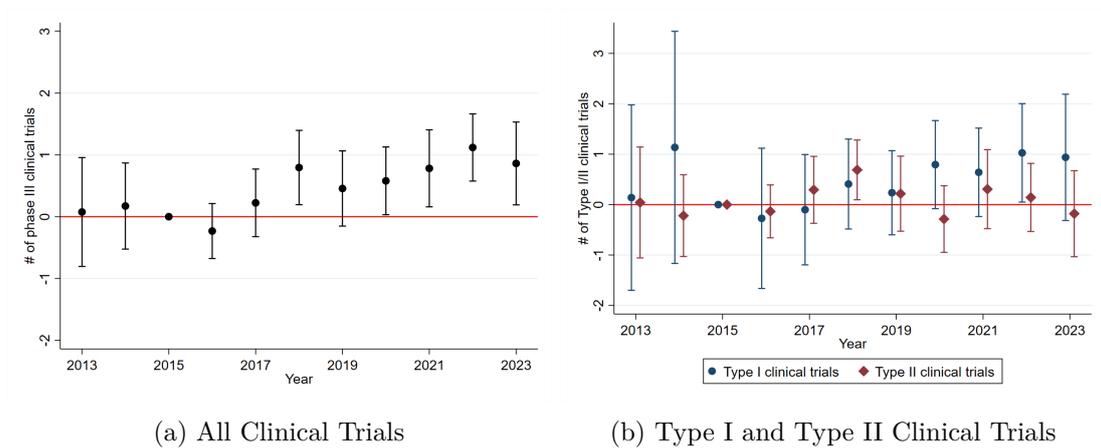


Figure A3: Robustness Event Study: Poisson Regression Model

*Notes:* This figure plot the estimated event study coefficients of the negotiation's effects policy on the number of new clinical trials (Panel a) and on the numbers of new Type I and Type II trials separately (Panel b), using Poisson regression model, together with their 95% confidence intervals. Standard errors are clustered at the disease-group level.

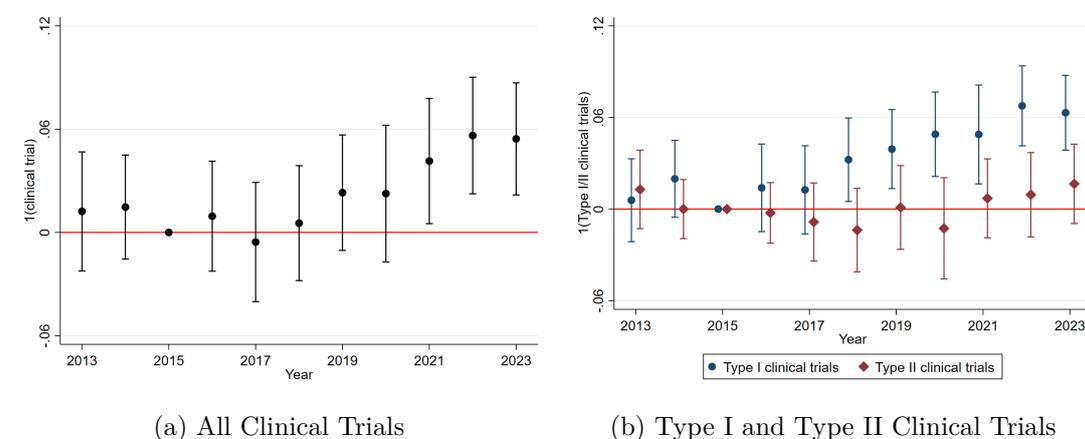


Figure A4: Robustness Event Study for the Incidence of Clinical Trials: Alternative Definition of Clinical Trial Start Date

*Notes:* This figure plots the robustness estimates of event study coefficients of the negotiation policy's effects on the incidence of new clinical trials (Panel a) and on the incidences of new Type I and Type II trials separately (Panel b), using an alternative definition of clinical trial start —IRB approval dates, together with their 95% confidence intervals. Standard errors are clustered at the disease-group level.

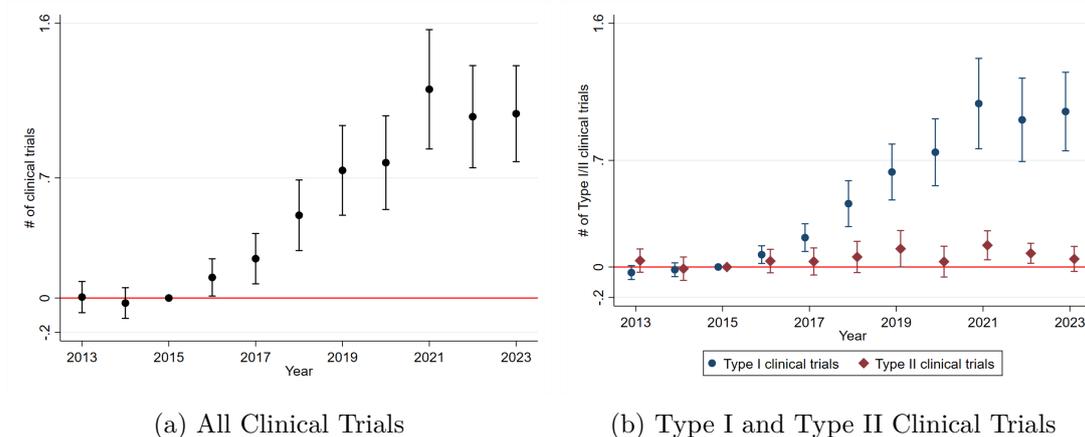


Figure A5: Robustness Event Study for the Number of New Clinical Trials: Alternative Definition of Clinical Trial Start Date

*Notes:* This figure plots the robustness estimates of event study coefficients of the negotiation policy's effects on the number of new clinical trials (Panel a) and on the numbers of new Type I and Type II trials separately (Panel b), using an alternative definition of clinical trial start date, together with their 95% confidence intervals. Standard errors are clustered at the disease-group level.

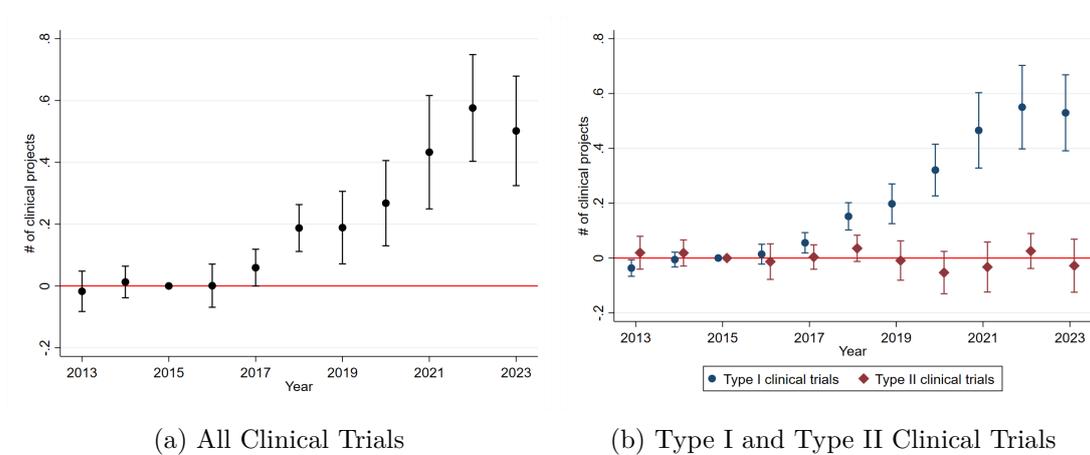


Figure A6: Robustness Event Study for the Number of New Clinical Projects

*Notes:* This figure plots the estimated event study coefficients of the negotiation policy’s effects on the number of new clinical projects (Panel a) and on the numbers of new Type I and Type II projects separately (Panel b), together with their 95% confidence intervals. Standard errors are clustered at the disease-group level.

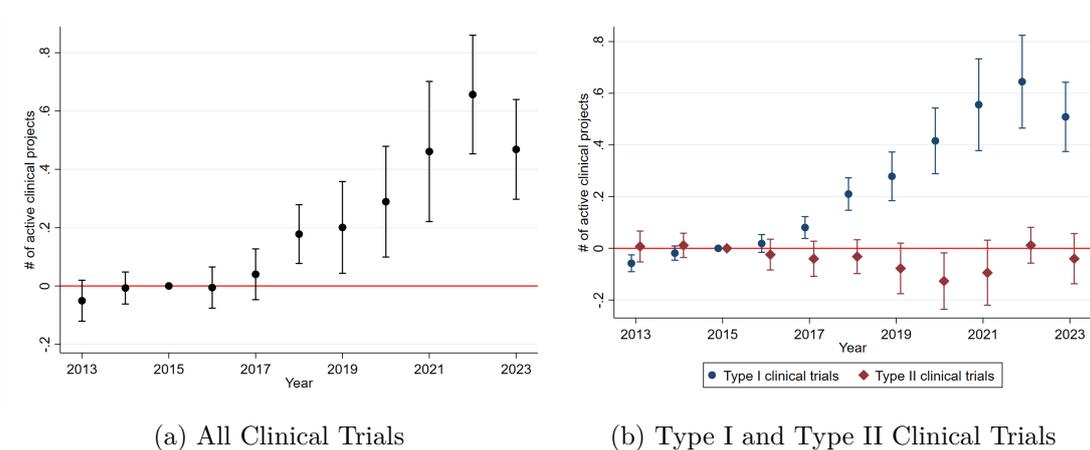


Figure A7: Robustness Event Study for the Number of Active Clinical Projects

*Notes:* This figure plots the estimated event study coefficients of the negotiation policy’s effects on the number of active clinical projects (Panel a) and on the numbers of active Type I and Type II projects separately (Panel b), together with their 95% confidence intervals. Standard errors are clustered at the disease-group level.

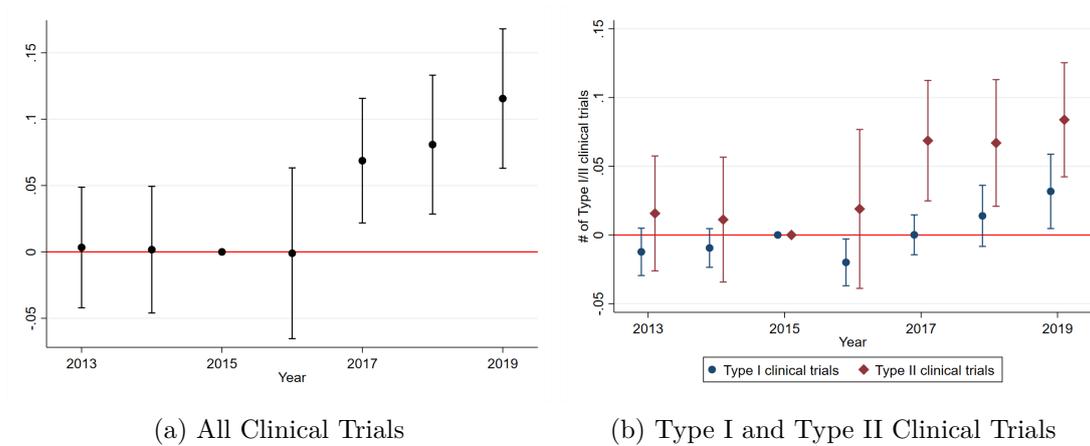


Figure A8: Robustness Event Study for the Number of Clinical Trials Excluding MAH Pilot Provinces

*Notes:* This figure plots the robustness estimates of event study coefficients of the negotiation policy's effects on the number of new clinical trials (Panel a) and on the numbers of new Type I and Type II trials separately (Panel b), excluding MAH pilot provinces, together with their 95% confidence intervals. Standard errors are clustered at the disease-group level.

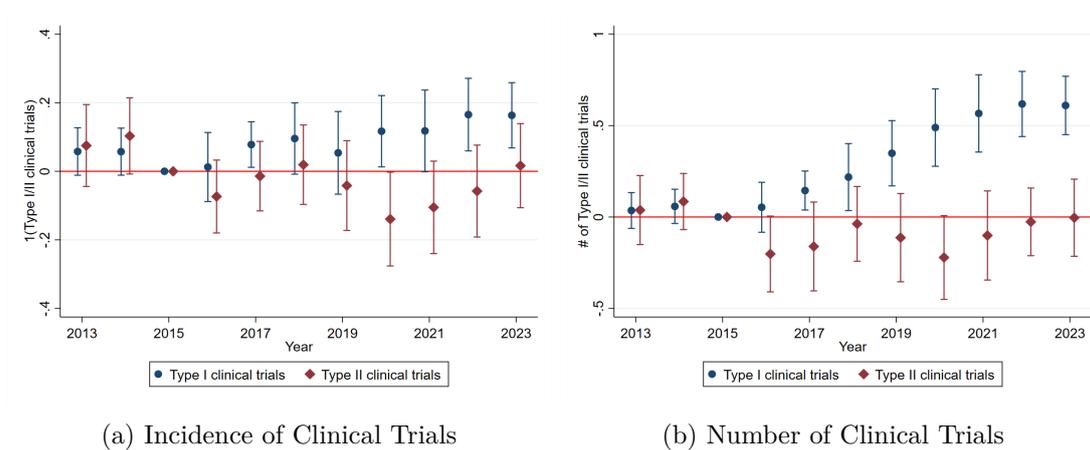


Figure A9: Event Study: Effects of the Negotiation Policy on Clinical Trials for All Firms

*Notes:* This figure plots the estimated event study coefficients of the expectation effect of the negotiation policy on a firm's initiation of any new Type I and Type II clinical trial separately (Panel a) and on a firm's numbers of new Type I and Type II trials separately (Panel b), together with their 95% confidence intervals. Standard errors are clustered at the firm level.

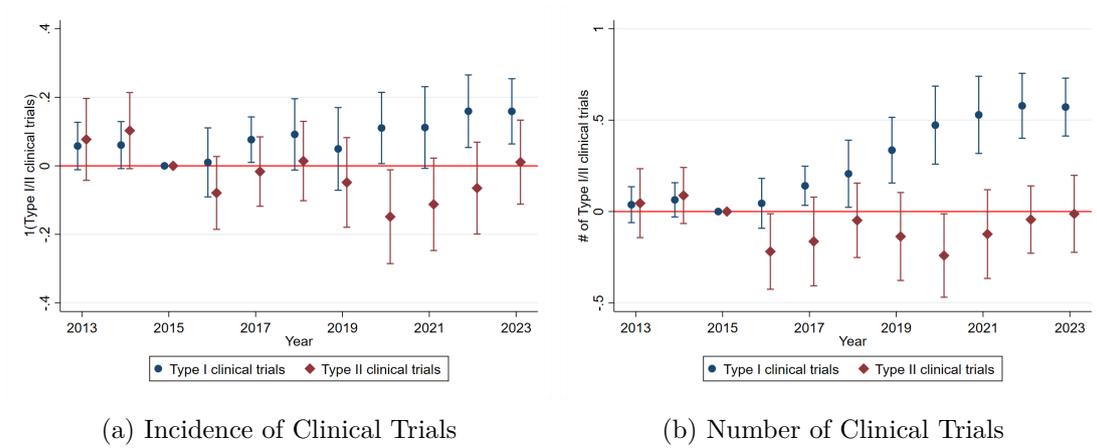


Figure A10: Robustness Event Study: Effects of the Negotiation Policy on Clinical Trials for All Firms

*Notes:* This figure plots the estimated event study coefficients of the negotiation policy's effects on a firm's initiation of any new Type I and Type II clinical trial separately (Panel a) and on a firm's numbers of new Type I and Type II trials separately (Panel b), together with their 95% confidence intervals. Firms having developed both drugs and vaccines are excluded from the sample. Standard errors are clustered at the firm level.

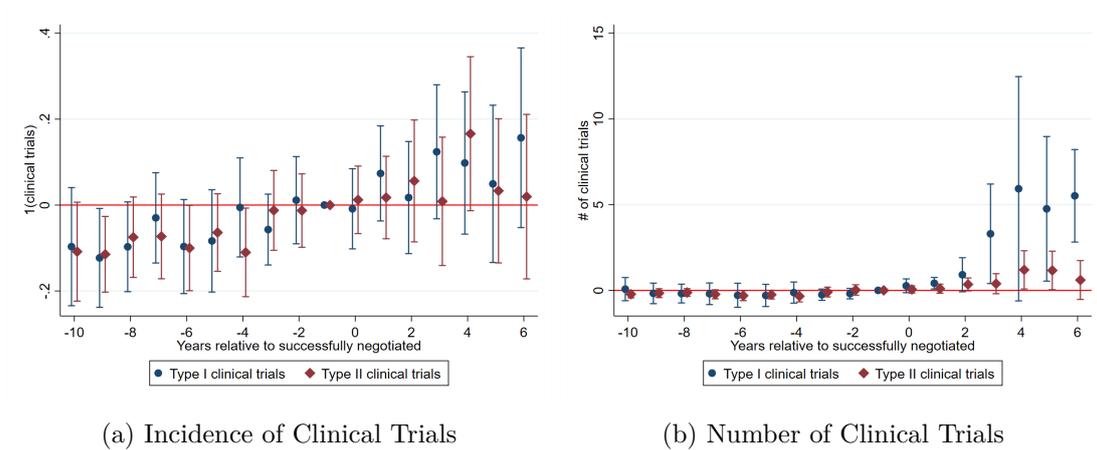


Figure A11: Event Study: Effects of Successful Negotiation on Clinical Trials per Firm

*Notes:* This figure plots the estimated event study coefficients of the revenue shock effects of the successful negotiation on the corresponding firm's initiation of any new Type I and Type II clinical trial separately (Panel a) and on the corresponding firm's numbers of new Type I and Type II trials separately (Panel b), together with their 95% confidence intervals. Standard errors are clustered at the firm level.

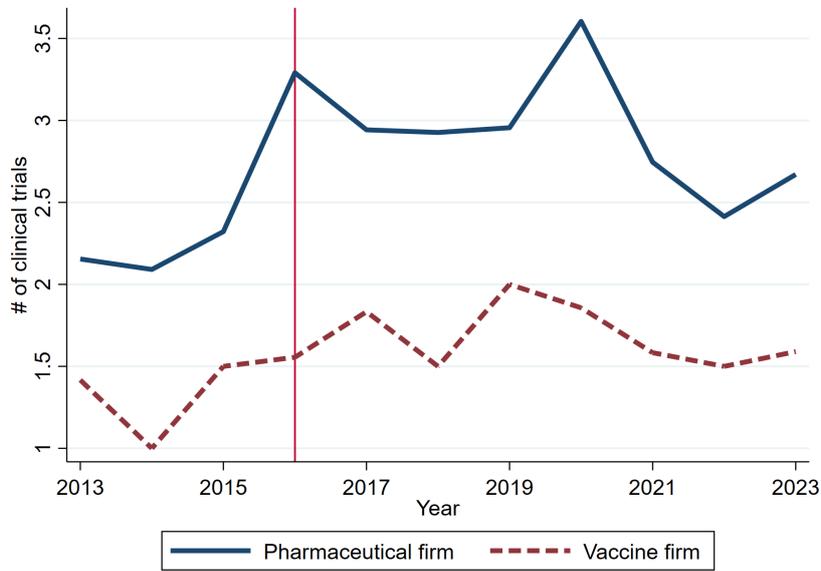


Figure A12: Raw Pattern of the Average Number of Clinical Trials per Research Field per Firm

Notes: This figure shows the time-series pattern of the average number of clinical trials a firm conducts within each research fields it already operates in.

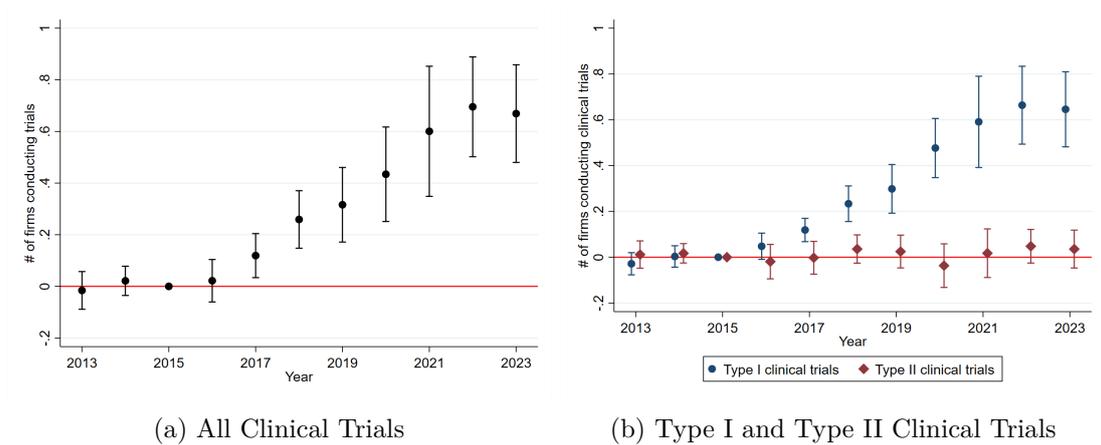


Figure A13: Event Study for Number of Firms Conducting Clinical Trials per Disease

Notes: This figure presents the estimated event study coefficients of the negotiation policy' effects on the number of firms conducting clinical trials per disease, together with their 95% confidence intervals. Standard errors are clustered at the disease-group level.

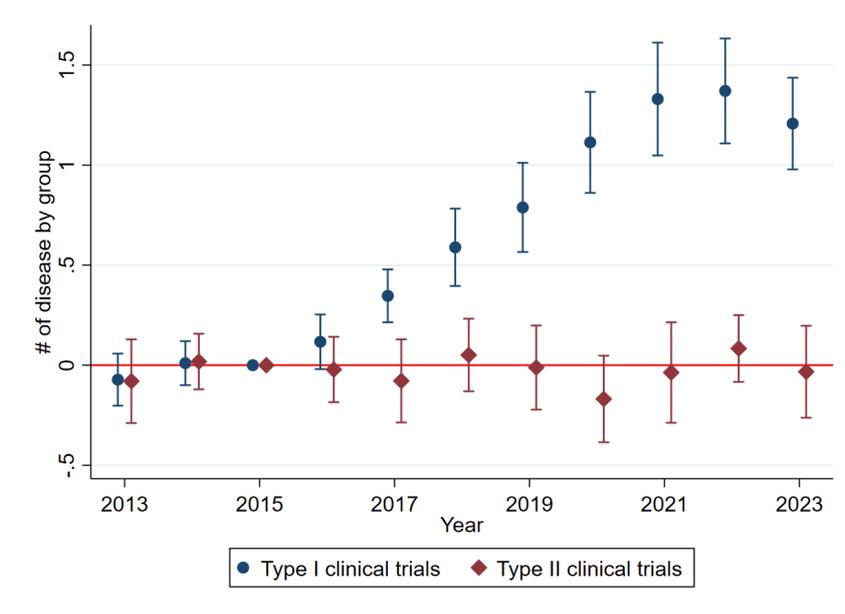
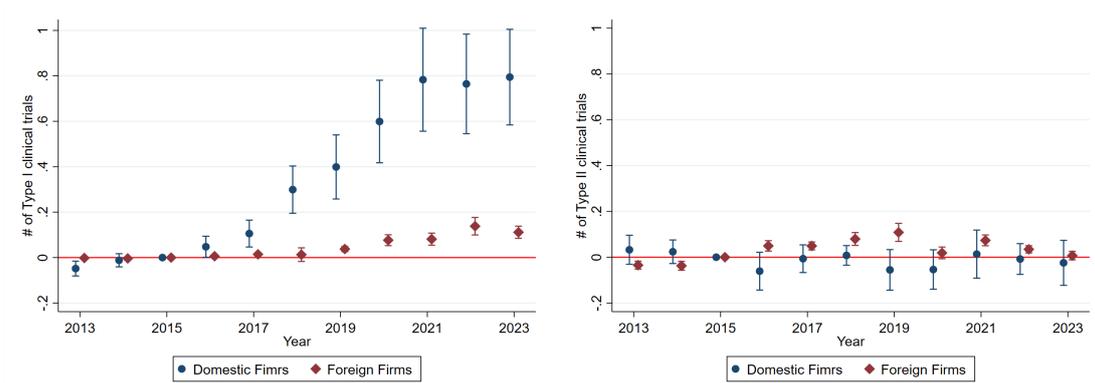


Figure A14: Event Study for Number of Research Fields per Firm

*Notes:* This figure plots the estimated event study coefficients of the negotiation policy’s effects on the number of research fields per firm, together with their 95% confidence intervals. Standard errors are clustered at the firm level.



(a) Type I Clinical Trials

(b) Type II Clinical Trials

Figure A15: Event Study for Number of Clinical Trials by Firm Origin

*Notes:* This figure plots the estimated event study coefficients of the negotiation policy’s effects on the numbers of Type I (Panel a) and Type II (Panel b) clinical trials conducted by domestic and foreign firms separately per disease, together with their 95% confidence intervals. Standard errors are clustered at the disease-group level.

Table A1: Comparison between Successfully Negotiated and Control drugs

	Treatment group		Control group		Robustness check	
	(1)	(2)	(3)	(4)	(5)	
	Negotiated drugs	Exclusive drugs	Difference	Invited/applied drugs	Difference	
ln(revenue)	10.751 (2.019)	10.467 (2.358)	0.285 (0.30)	11.549 (2.404)	-0.798* (0.44)	
First launch year	2017.257 (2.144)	2014.609 (3.285)	2.648*** (0.38)	2016.892 (3.332)	0.365 (0.59)	
1(Domestic drug)	0.352 (0.480)	0.382 (0.488)	-0.029 (0.07)	0.351 (0.484)	0.001 (0.09)	
N	105	110	215	37	142	

*Notes:* This table reports the summary statistics of key characteristics for the treatment group (successfully negotiated drugs) and two control groups (exclusive drugs and invited/applied drugs), as well as the mean differences between each control group and the treatment group in the first observed quarter of the sample. Reported values are sample means, with standard deviations in parentheses. \*  $p < 0.10$ , \*\*  $p < 0.05$ , \*\*\*  $p < 0.01$ .

Table A2: Effects of Successful Negotiation on Price, Quantity, and Revenue

	(1)	(2)	(3)	(4)
	ln(retail price)	ln(OOP price)	ln(quantity)	ln(revenue)
treat $\times$ post	-0.697*** (0.049)	-1.934*** (0.052)	1.752*** (0.264)	1.055*** (0.264)
Observations	11819	11819	11819	11819
Mean of Dep. Var.	4.696	4.529	8.914	13.610
SD of Dep. Var.	2.730	2.763	3.418	2.592
Adj. R <sup>2</sup>	0.992	0.992	0.895	0.831
Within R <sup>2</sup>	0.148	0.564	0.050	0.020

*Notes:* This table reports DID estimates of successful price negotiation on drugs' quarterly retail price, out-of-pocket price, quantity, and revenue. Standard errors are clustered at the drug level. \*  $p < 0.10$ , \*\*  $p < 0.05$ , \*\*\*  $p < 0.01$ .

Table A3: Robustness Results: Effects of Successful Negotiation on Price, Quantity, and Revenue

	(1)	(2)	(3)	(4)
	ln(retail price)	ln(OOP price)	ln(quantity)	ln(revenue)
treat $\times$ post	-0.770*** (0.053)	-2.006*** (0.053)	1.870*** (0.258)	1.100*** (0.257)
Observations	6859	6859	6859	6859
Mean of Dep. Var.	5.334	5.045	8.809	14.143
SD of Dep. Var.	2.904	3.016	3.782	2.767
Adj. R <sup>2</sup>	0.997	0.997	0.919	0.848
Within R <sup>2</sup>	0.417	0.808	0.074	0.027

*Notes:* This table reports DID estimates of successful price negotiation on drugs' quarterly retail price, out-of-pocket price, quantity, and revenue using invited and applied drugs during the negotiation as control group. Standard errors are clustered at the drug level. \*  $p < 0.10$ , \*\*  $p < 0.05$ , \*\*\*  $p < 0.01$ .

Table A4: Disease-Level Summary Statistics

	Drug		Vaccine	
	(1)	(2)	(3)	(4)
	2013-2015	2016-2023	2013-2015	2016-2023
<b>1</b> (clinical trial)	0.045	0.080	0.039	0.063
	(0.208)	(0.271)	(0.193)	(0.244)
<b>1</b> (Type I clinical trial)	0.030	0.067	0.010	0.028
	(0.171)	(0.251)	(0.098)	(0.166)
<b>1</b> (Type II clinical trial)	0.027	0.042	0.029	0.047
	(0.162)	(0.202)	(0.168)	(0.212)
# of clinical trials	0.165	0.873	0.064	0.191
	(1.237)	(7.101)	(0.371)	(0.985)
# of Type I clinical trials	0.109	0.699	0.011	0.054
	(0.886)	(6.017)	(0.120)	(0.396)
# of Type II clinical trials	0.057	0.174	0.053	0.137
	(0.487)	(1.406)	(0.353)	(0.758)
# of Phase I clinical trials	0.070	0.427	0.018	0.082
	(0.564)	(3.444)	(0.144)	(0.486)
# of Phase II clinical trials	0.060	0.310	0.005	0.026
	(0.533)	(2.882)	(0.069)	(0.187)
# of Phase III clinical trials	0.039	0.230	0.042	0.086
	(0.411)	(2.082)	(0.287)	(0.551)
N	10,443	27,848	621	1,656

*Notes:* This table shows the summary statistics of characteristics for drugs and vaccines separately. Reported values are sample means, with standard deviations in parentheses.

Table A5: Robustness Results: Chemical Drugs and Therapeutic Biologics

	<b>1</b> (clinical trial)		# of clinical trials	
	(1)	(2)	(3)	(4)
	Chemical Drugs	Biologics	Chemical Drugs	Biologics
treat $\times$ post	-0.000	0.006	0.156***	0.297***
	(0.009)	(0.009)	(0.052)	(0.078)
Observations	40568	40568	40568	40568
Mean of Dep. Var.	0.057	0.037	0.326	0.333
SD of Dep. Var.	0.233	0.188	2.546	3.729
Adj. R <sup>2</sup>	0.639	0.581	0.670	0.621
Within R <sup>2</sup>	0.000	0.000	0.000	0.000

*Notes:* This table reports the baseline DID estimates of the negotiation policy's effects on the conduction of new clinical trials, comparing chemical drugs and therapeutic biologics with vaccines separately. Columns (1)-(2) present the estimated effects on the incidence of any new trial, while columns (3)-(4) present the effects on the number of new trials. Standard errors are clustered at the disease-treatment level. \*  $p < 0.10$ , \*\*  $p < 0.05$ , \*\*\*  $p < 0.01$ .

Table A6: Robustness Results: Poisson Regression Model

	(1)	(2)	(3)
	All	Type I	Type II
treat $\times$ post	0.573***	0.289	0.169
	(0.149)	(0.414)	(0.146)
Observations	5863	4653	4015
Mean of Dep. Var.	4.500	4.447	1.418
SD of Dep. Var.	15.031	14.204	3.578

*Notes:* This table reports the Poisson regression estimates of the price negotiation policy effects on the number of new clinical trials. Standard errors are clustered at the disease-treatment level. \*  $p < 0.10$ , \*\*  $p < 0.05$ , \*\*\*  $p < 0.01$ .

Table A7: Robustness Results: Alternative Definition of Clinical Trial Start Date

	1(clinical trial)			# of clinical trials		
	(1)	(2)	(3)	(4)	(5)	(6)
	Any	Type I	Type II	All	Type I	Type II
treat $\times$ post	0.017*	0.032***	-0.005	0.722***	0.659***	0.062**
	(0.010)	(0.008)	(0.009)	(0.119)	(0.096)	(0.031)
Observations	40568	40568	40568	40568	40568	40568
Mean of Dep. Var.	0.074	0.059	0.042	0.757	0.600	0.157
SD of Dep. Var.	0.262	0.235	0.200	6.885	5.850	1.313
Adj. R <sup>2</sup>	0.651	0.644	0.548	0.665	0.630	0.598
Within R <sup>2</sup>	0.000	0.001	0.000	0.000	0.000	0.000

*Notes:* This table reports robustness DID estimates of the price negotiation policy's effects on the conduction of new clinical trials, using an alternative definition of the trial start—IRB approval dates. Columns (1)-(3) present the estimated effects on the incidence of any new trial, while columns (4)-(6) present the effects on the number of new trials. Standard errors are clustered at the disease-group level. \*  $p < 0.10$ , \*\*  $p < 0.05$ , \*\*\*  $p < 0.01$ .

Table A8: Robustness Results: Effect of the Negotiation Policy on the Number of Clinical Projects

	# of clinical projects			# of active clinical projects		
	(1)	(2)	(3)	(4)	(5)	(6)
	All	Type I	Type II	All	Type I	Type II
treat $\times$ post	0.278***	0.300***	-0.022	0.305***	0.365***	-0.059
	(0.057)	(0.045)	(0.022)	(0.077)	(0.056)	(0.036)
Observations	40568	40568	40568	40568	40568	40568
Mean of Dep. Var.	0.367	0.294	0.073	0.444	0.354	0.090
SD of Dep. Var.	3.134	2.759	0.507	3.763	3.302	0.608
Adj. R <sup>2</sup>	0.637	0.589	0.663	0.661	0.617	0.711
Within R <sup>2</sup>	0.000	0.000	0.000	0.000	0.000	0.000

*Notes:* This table reports robustness DID estimates of the price negotiation policy's effects on the number of new clinical projects and the number of active clinical projects, respectively. Standard errors are clustered at the disease-group level. \*  $p < 0.10$ , \*\*  $p < 0.05$ , \*\*\*  $p < 0.01$ .

Table A9: Robustness Results: Exclusion of MAH Pilot Provinces

	(1)	(2)	(3)
	All	Type I	Type II
treat $\times$ post	0.064*** (0.020)	0.014* (0.008)	0.051*** (0.016)
Observations	25816	25816	25816
Mean of Dep. Var.	0.082	0.022	0.060
SD of Dep. Var.	0.799	0.258	0.653
Adj. R <sup>2</sup>	0.547	0.410	0.512
Within R <sup>2</sup>	0.000	0.000	0.000

*Notes:* This table reports robustness DID estimates of the price negotiation policy's effects on the number of new clinical trials, excluding trials whose MAHs were located in the MAH pilot provinces before 2019. Standard errors are clustered at the disease-group level. \*  $p < 0.10$ , \*\*  $p < 0.05$ , \*\*\*  $p < 0.01$ .

Table A10: Firm-Level Summary Statistics

	Pharmaceutical firm		Vaccine firm	
	(1)	(2)	(3)	(4)
	2013-2015	2016-2023	2013-2015	2016-2023
<b>1</b> (domestic firm)	0.837 (0.370)	0.789 (0.408)	0.964 (0.187)	0.960 (0.195)
<b>1</b> (MAH)	0.668 (0.471)	0.661 (0.474)	0.802 (0.399)	0.771 (0.420)
<b>1</b> (clinical trial)	0.111 (0.314)	0.278 (0.448)	0.126 (0.333)	0.333 (0.472)
<b>1</b> (Type I clinical trial)	0.072 (0.259)	0.230 (0.421)	0.024 (0.153)	0.133 (0.340)
<b>1</b> (Type II clinical trial)	0.044 (0.206)	0.077 (0.267)	0.108 (0.311)	0.238 (0.426)
# of clinical trials	0.199 (0.802)	0.683 (2.397)	0.180 (0.518)	0.533 (0.971)
# of Type I clinical trials	0.128 (0.641)	0.537 (2.090)	0.030 (0.203)	0.169 (0.469)
# of Type II clinical trials	0.072 (0.429)	0.146 (0.726)	0.150 (0.474)	0.364 (0.811)
<b>1</b> (Micro firm)	0.134 (0.340)	0.155 (0.362)	0.120 (0.326)	0.130 (0.336)
<b>1</b> (Small firm)	0.350 (0.477)	0.377 (0.485)	0.311 (0.464)	0.326 (0.469)
<b>1</b> (Medium firm)	0.284 (0.451)	0.264 (0.441)	0.299 (0.459)	0.299 (0.458)
<b>1</b> (Large firm)	0.232 (0.422)	0.203 (0.403)	0.269 (0.445)	0.245 (0.431)
N	3,505	14,082	167	555

*Notes:* This table shows the summary statistics of characteristics for treatment and control groups of firms separately. Reported values are sample means, with standard deviations in parentheses.

Table A11: Robustness Results: Excluding Firms Developing Both Drugs and Vaccines

	1(clinical trial)			# of clinical trials		
	(1)	(2)	(3)	(4)	(5)	(6)
	Any	Type I	Type II	All	Type I	Type II
treat $\times$ post	-0.051 (0.037)	0.057** (0.025)	-0.114*** (0.038)	0.157 (0.104)	0.325*** (0.061)	-0.168** (0.077)
Observations	17969	17969	17969	17969	17969	17969
Mean of Dep. Var.	0.240	0.191	0.070	0.551	0.429	0.122
SD of Dep. Var.	0.427	0.393	0.255	2.110	1.856	0.631
Adj. R <sup>2</sup>	0.242	0.277	0.240	0.557	0.544	0.402
Within R <sup>2</sup>	0.000	0.000	0.002	0.000	0.000	0.001

*Notes:* This table reports DID estimates of the price negotiation policy's effects on the conduction of new clinical trials for all firms. Firms engaged in both drug and vaccine R&D are excluded from the sample. Columns (1)-(3) present the estimated effects on the incidence of any new trial, while columns (4)-(6) present the effects on the number of new trials. Standard errors are clustered at the firm level. \*  $p < 0.10$ , \*\*  $p < 0.05$ , \*\*\*  $p < 0.01$ .