



An Event-Study of Biopharma Stock Returns

Using Lend-RX Technology News Dataset

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2024 June

Introduction

Abstract

The healthcare sector and especially the Nasdaq Biotech are highly volatile market segments, driven by binary events such as clinical trial outcomes, regulatory changes and drug registrations. Those events can lead to significant fluctuations in stock prices, presenting both opportunities and risks. Successful investments in biopharma stocks necessitates an in-depth comprehension of the clinical trial process, regulatory landscape, and potential market effects of new therapies and importance for investors to rely on robust data and evidence-based strategies.

This whitepaper aims to uncover potential alpha by studying Press Releases issued by Biotech and Pharma companies. We used the Lend-RxNews Dataset, a comprehensive point in time Company Press Releases topic and sentiment dataset to analyse stock market reactions to different type of events. The event-study methodology covers index relative stock prices performance, from 5 days before events to 30 days after, although our focus in this White Paper will be mostly centered on the intraday immediate market reaction to the event.

Review of the literature

Event studies have been a fundamental component of financial research for a long time, as they offer a reliable approach to analyzing the impact of specific events on stock prices. Brown and Warner's [2] approach for conducting event studies provides a statistical framework for identifying abnormal returns by comparing actual stock returns to normal returns, which are typically estimated using a market model. They emphasize the significance of selecting an appropriate time frame to fully convey the impact of an event in their seminal

work. This foundation facilitated a significant quantity of research in a variety of disciplines, including medicine. The study by Guo, Lev, and Zhou [4] emphasizes the substantial market responses to product development milestones in the biotechnology subdivision of the pharmaceutical industry. Biotechnology stock prices can even move in the right direction before results are publicly announced, as demonstrated by a 2000 event-study conducted on products undergoing phase-3 clinical trials and FDA Advisory Panel review [6]. Moreover, the pharmaceutical sector’s stock performance and investor sentiment are greatly influenced by the regulatory landscape, particularly the decisions made by the Food and Drug Administration (FDA). Bosch and Lee [1] investigated the wealth effects of FDA decisions, discovering that approvals typically generate positive abnormal returns, while rejections or requests for additional information produce negative market reactions. It is underscored by these results that regulatory milestones are crucial for stock performance. Kothari and Warner [5] further refined the econometric techniques for event studies, addressing concerns regarding the reliability and accuracy of the results. The robustness of event study findings is improved by the utilization of various models to estimate normal returns, as recommended by their comprehensive review.

More recently, several research articles focus on correlation of Clinical Trial Results with Trial sponsors stock prices. In a study undertaken at the MIT, reviewing several type of Events extracted from financial press outlined that drug development outcomes are pivotal determinants of stock valuation in the biopharmaceutical sector [3]. A more detailed analysis about Clinical Trial outcomes concluded that the clinical trial properties, ie condition, study design and timing cannot completely explain the average abnormal returns observed due to clinical trial outcomes.[7].

Data

We used [Lend-RxNews dataset](#) from Lend-Rx Technology which is a comprehensive dataset covering 1000 listed companies. In the dataset Daily Press Releases issued by companies are classified into 55 different topics including topics that are specific to the pharmaceutical industry such as drug registrations or clinical trial results. Each Press Release is also enriched with Entities extracted from the text such as name of Therapeutics, Clinical Trial Name, Clinical Trial Phase and entity linking to external datasets.

Methodology

For this analysis, we utilized the Lend-RxNews daily dataset, comprising 116,598 press releases issued from January 2019 to April 2024. During data preprocessing, for each news event associated with one of the 317 target companies, we calculated the company’s returns within a window spanning from 5 days before the event to 30 days after the event. These returns were then adjusted according to the relevant index: for early-stage biotechnology companies (defined as those with fewer than five drugs on the market), we used the iShares

Biotechnology ETF (IBB), while for large pharmaceutical companies (those with five or more drugs on the market), we used the Health Care Select Sector SPDR Fund (XLV). To compute the adjusted returns, we estimated the stock’s beta and alpha using a window of 60 trading days prior to the study, specifically employing the daily returns of the stock and its relevant index from 66 to 6 days before the event

Abnormal return by Event category

Companies frequently issue press releases to disclose market-sensitive information. These press releases cover various types of events, each of which can impact stock values to varying degrees. We conducted an analysis of the impact of press releases on stock price performance, categorized by event type as defined in the dataset. The tables below present the statistical summaries of adjusted intraday returns for the topics in [Lend-Rx’s dictionary](#) that trigger the highest and lowest performances. We applied a two-sided Student’s t-test to evaluate the significance of the adjusted returns and included the p-values in these summaries. A lower p-value indicates a more significant adjusted return, with a 5% threshold conventionally used in experimental sciences to denote statistical significance.

Topic	Count	Mean (%)	STD (%)	P-value (%)
clinical_trial_toplevel_result_polarity_positive	210	12.45	51.81	0.06
clinical_trial_endpoint_polarity_positive	161	8.54	37.63	0.45
clinical_trial_endpoint_summary_polarity_positive	222	7.37	40.78	0.77
clinical_trial_hold_polarity_positive	31	5.85	19.59	10.70
registration_nda_grant	134	3.93	20.87	3.09
registration_fast_track	125	2.55	8.98	0.19
registration_ind	194	2.54	12.17	0.41
clinical_trial_interim_result_polarity_positive	111	2.33	19.54	21.20
registration_breakthrough	90	1.96	5.04	0.04
registration_approval_us	479	1.95	14.35	0.32

Table 1: Top 10 Topics Triggering the Best Performances

Topic	Count	Mean (%)	STD (%)	P-value (%)
clinical_trial_topline_result_polarity_negative	144	-13.73	36.11	0.00 ¹
clinical_trial_endpoint_summary_polarity_negative	103	-13.32	21.92	0.00
clinical_trial_hold_polarity_negative	32	-12.93	18.77	0.05
clinical_trial_endpoint_polarity_negative	48	-8.50	21.29	0.81
company_strategic_change	73	-2.79	15.15	12.00
company_market_change	46	-2.59	14.16	22.20
company_financing	1492	-0.99	13.75	0.53
company_alerts	180	-0.86	7.30	11.50
company_filing	75	-0.81	5.12	17.40
registration_committee_polarity_negative	103	-0.60	15.32	69.40

Table 2: Top 10 Topics Triggering the Worst Performances

¹ We have converted all numerical values to percentages and rounded the result to 2 digits for clarity, therefore a p-value of 0.00 % should be interpreted as $p < 0.005\%$, indicating a highly significant result.

It appears that the most significant events are generally clinical trial outcomes. Moreover, the losses triggered by negative results in clinical trials are more substantial than the surges caused by positive ones. This could be potentially explained by the investors positive anticipations before trial results announcement, meaning that positive outcomes are often already priced into the stock, while negative outcomes which are less frequent come as a surprise and lead to greater negative adjustments in the stock price.

Press Releases classified as Clinical Trial Results

In this section, we will take a deeper look at clinical trial results topics, providing insights into how the market responds to different domain-relevant topics, different clinical stages as well as the size of the company.

We have analysed how Clinical Trials outcomes sentiment produced by Lend-Rx covering topline, interim, and endpoint clinical trial results influence stock prices.

Clinical_Trial_Aggregate_Polarity	Count	Mean (%)	STD (%)	P-value (%)
negative	357	-6.22	26.94	0.00
positive	474	8.47	41.29	0.00

Table 3: Statistical Summary of Adjusted Returns by Clinical Trial Aggregate Polarity

Out of 831 instances, 357 with negative or neutral sentiment correlate with a mean adjusted return of -6.22 % and a standard deviation of 26.94 %. Conversely, the 474 positive sentiment come with a mean adjusted return of 8.47 % and with a standard deviation of 42.29 %. Those mean adjusted return are highly significant with a p-value below 0.005 %)

After this immediate market reaction of high magnitude, the adjusted stock price tends to move along with the index, which is visible in the event-study plot below. This highlights that the market is extremely quick to price Clinical Trial results.

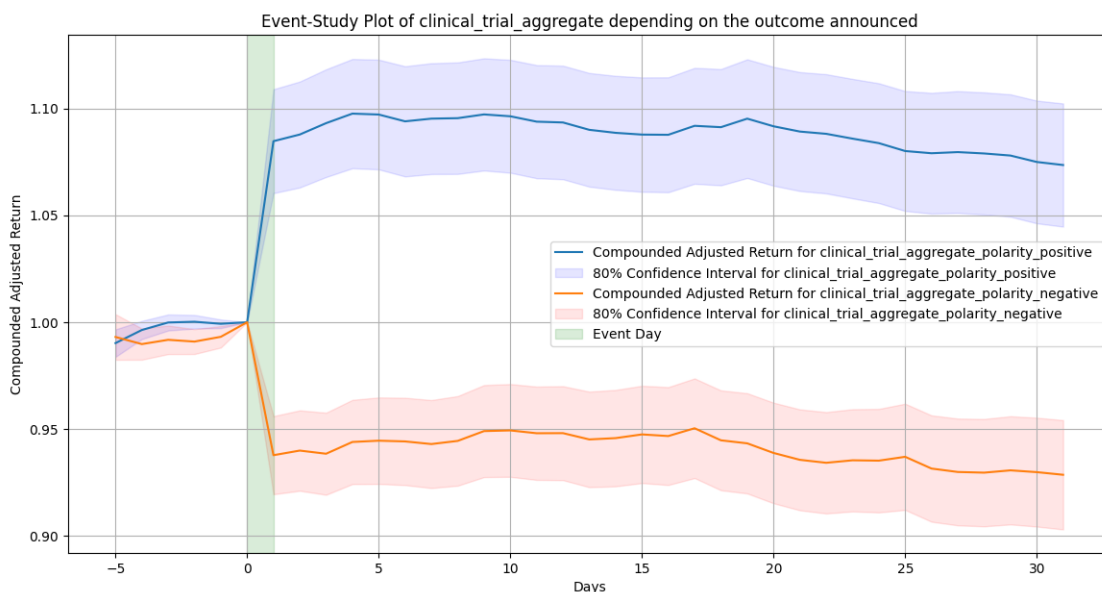


Figure. 1: Event-Study Plot of the Aggregate Clinical Trial Result Topic

Segmentation by Clinical Trial Phase

Clinical trials are generally divided into three phases, each of which represents a distinct stage of drug development, with escalating levels of investment, risk, and potential reward. The primary objective of phase 1 trials is to evaluate the safety and appropriate dosage of a drug, with a small number of participants. Early indications of the drug’s potential effectiveness are provided by phase 2 trials, which expand the focus to preliminary efficacy and adverse effects in a broader patient population. Phase 3 trials are the most conclusive and final stage prior to regulatory approval, evaluating the drug’s efficacy and safety on a significantly larger scale.

The Lend-RxNews dataset includes contextual information with the trial phase, either because it is mentioned in the press release or by inferring from the trial’s identifier. This

level of detail helps us to precisely segment the data, which improves the robustness and precision of our research. Lend-Rx’s ability to reliably retrieve this information improves the quality and depth of our analysis, resulting in a more complex understanding of market dynamics in the biopharmaceutical industry.

Based on a sufficiently large sample size we segmented the analysis by trial phase. This method offers a more precise and comprehensive comprehension of the impact of various stages of clinical trials on stock performance, thereby allowing investors to make more informed decisions based on the risks and opportunities associated with each phase.

Clinical_Trial_Aggregate_Polarity	Phase	Count	Mean	STD	P-value
Negative	Phase 2	133	-10.13 %	24.20 %	0.00
	Phase 3	104	-7.09 %	37.04 %	0.05
Positive	Phase 2	149	10.39 %	48.26 %	0.01
	Phase 3	205	7.76 %	37.86 %	0.00

Table 4: Statistical Summary of Adjusted Returns by Clinical Trial Aggregate Polarity and by Phase

Our findings highlight a more pronounced stock price change for Phase 2 studies, particularly those with negative results, that may generate larger market reactions than Phase 3 trials. The strong negative returns for Phase 2 negative results (-10.13%) show the importance of early proof-of-concept data, as disappointing results might have a significant influence on investor opinion. Positive results in Phase 2 resulted in significant stock price rises (10.39%), indicating the strong optimism surrounding early outcomes, despite the uncertainties. While the reactions in Phase 3 trials remain significant, they are less severe. Negative Phase 3 results cause significant underperformance (-7.09%), Positive Phase 3 results continue to fuel stock price gains (7.76%), highlighting the significance of these findings for regulatory approval and commercialization prospects.

From a financial perspective, the results are surprising since the Net Present Value (NPV) of a Phase 3 compound, with its higher likelihood of approval and shorter time to market, should have a stronger impact stock prices. We had hypothesized that the high uncertainty and low probability of early-phase drugs reaching the market would lead to muted market reactions, as investors view early-phase results as preliminary. In contrast, Phase 3 trials, with their higher stakes and greater likelihood of regulatory approval and market entry, should have substantially impacted companies’ market value, especially with positive results driving significant stock price increases.

A possible explanation for the higher market reaction to Phase 2 results compared to Phase 3 results, particularly for negative outcomes, lies in the critical nature of Phase 2 trials. These trials provide early indicators of a drug’s efficacy and safety, and investors have

high expectations at this stage. Negative Phase 2 results can be particularly disheartening, ending the drug’s development and commercialization prospects, leading to significant stock underperformance. In contrast, Phase 3 trials are more publicized and anticipated, with investor expectations already adjusted, leading to less dramatic market reactions. Positive Phase 2 results can boost investor enthusiasm as they signal progression to the final Phase 3 trials, driving significant stock price gains. However, Phase 3 results may yield less pronounced reactions since investors already expect favorable outcomes based on earlier trial performance.

These hypotheses must be balanced with the frequency of press releases by phase, influenced by the size and number of companies. Indeed smaller companies with higher stock price volatility report Phase 2 events more frequently than larger companies.

Segmentation of Clinical Trial results Events by Phase and by Company Maturity

Considering the previous results, we enhance our analysis by incorporating a second layer of splitting based on company maturity. We have defined company maturity as a binary variable: Early Biotech for firms with fewer than five drugs on the market and Large Pharma for firms with five or more drugs on the market. This cross-segmentation enables us to examine the combined impact of company maturity and the trial phase on market reactions, thereby acquiring a more comprehensive comprehension of the behavior of stock performances upon trial results announcements.

The rationale for this approach comes from the unique ways in which clinical trial outcomes influence companies at varying levels of maturity:

- Early-stage biotechnology companies, which are characterized by a limited number of products on the market, are more reliant on clinical trial results for their valuation. This dependence leads to significant volatility in their stock prices, as successful trial results can be transformative, while failures can be fatal.
- In contrast, mature pharmaceutical companies, which have established market presences and more diversified product portfolios, typically experience less pronounced stock price reactions, particularly during the early stages of clinical trials.

With this cross-segmentation, we can gain a more comprehensive understanding of the responses of various categories of companies to clinical trial results. This method enables us to identify patterns and relationships that may have been overlooked in a more comprehensive analysis. In particular, it enables us to compare the responses of early-stage companies to trial outcomes with those of more mature companies, providing more practical insights for investors and stakeholders.

Company Maturity	Clinical_Trial_Aggregate_Polarity	Phase	Count	Mean (%)	STD (%)	P-value (%)
Early Biotech	Negative	Phase 2	123	-10.92	25.01	0.00
		Phase 3	80	-8.95	42.05	6.07
	Positive	Phase 2	135	11.42	50.60	0.97
		Phase 3	119	12.69	48.96	0.55
Large Pharma	Negative	Phase 2	10	-0.45	1.69	41.80
		Phase 3	24	-0.89	4.36	32.87
	Positive	Phase 2	14	0.36	0.98	18.72
		Phase 3	86	0.94	5.52	11.84

Table 5: Statistical Summary of Adjusted Returns by Clinical Trial Aggregate Polarity, by Phase and by Company Maturity

The cross-segmentation of clinical trial aggregate results by both trial phase and company maturity gives useful information on the market’s reaction to clinical trial findings. Data from early-stage biotechnology companies reveal significant volatility in reaction to clinical trial outcomes.

Negative outcomes in Phase 2 trigger significant stock price declines with a mean adjusted return of -10.92% (p-value = 0.00 %), indicating a strong negative market reaction. Positive Phase 2 results for these companies show a significant mean adjusted return of 11.42 % (p-value = 0.97 %), reflecting strong investor optimism despite the high variability (standard deviation of 50.60 %). In Phase 3, early biotech companies also experience considerable market reactions, with negative outcomes resulting in a mean adjusted return of -8.95 % (p-value = 6.07 %) and positive outcomes leading to a mean adjusted return of 12.69 % (p-value = 0.55 %).

These findings indicate that early-stage companies are extremely sensitive to both positive and negative clinical trial results, highlighting their reliance on favorable trial outcomes for valuation. The stronger underperformance reported in Phase 2 negative results (-10.92 %) compared to Phase 3 (-8.95 %, with p-value 6.07 %) can be understood in line with what we previously suggested regarding Phase 2 results being less anticipated than Phase 3 results.

For large pharmaceutical companies, the reactions are much more muted, and none achieve statistical significance. Negative Phase 2 outcomes result in a negligible mean adjusted return of -0.45 %, and Phase 3 negative outcomes trigger only a slight decline with a mean adjusted return of -0.89 %. Positive results also lead to modest gains, with Phase 2 showing a mean adjusted return of 0.36% and Phase 3 showing 0.94%. This stability highlights the resilience of large pharma companies due to their diversified product portfolios and established market presence. The pattern of Phase 2 results triggering more significant market reactions than Phase 3, observed before segmenting by company maturity, does not hold for large pharma companies. This disparity can be due to the distinct natures of these organizations. Large

pharmaceutical companies have more resources and a larger drug pipeline, allowing them to better withstand the impact of early-stage trial results. Late-stage trials (Phase 3) are more important for these companies since they are closer to commercialization and regulatory approval, and so their market reactions are slightly more influenced by the results of these trials, but still even they do not have much of an influence on these companies' valuation.

In conclusion, our findings imply that trial phase and firm maturity have a considerable impact on market reactions to clinical trial results. Early-stage biotechnology firms experience greater volatility due to their reliance on trial findings, whereas large pharmaceutical corporations are more robust to single-trial outcomes.

Focus on Clinical Trial Topline Results

Topline results in clinical trials are the preliminary, high-level findings of a study that are, in general, disclosed to the public or stakeholders. These results frequently encompass a summary of whether the trial's primary objectives or endpoints, including efficacy and safety metrics, were accomplished. Topline results are frequently released before the entire dataset is evaluated and detailed conclusions are published in scientific publications. They provide an early indicator of the trial's success or failure and are critical in educating investors, regulators, and the scientific community about the potential of a new medication. Topline results are highly likely being the first results published for a given study, making them crucial for the initial assessment and decision-making processes related to the drug's development.

The Lend-RxNews dataset provides a classification of Clinical Trials results under different topics corresponding to the type of Outcomes disclosure.

- Interim results are disclosed during the trial and may suggest preliminary efficacy or safety trends; however, they are not conclusive.
- Topline results are the primary findings obtained after the trial has been completed but prior to a more thorough analysis.
- Endpoint results are the ultimate outcomes that are assessed at the conclusion of the trial, which serve as an indicator of whether the trial's objectives were achieved.

We have focused our analysis on 354 instances of topline results. Of these topline results, 144 are negative with a mean adjusted return of -13.73 % and a standard deviation of 36.11 %. Conversely, the 210 positive topline results come with a mean adjusted return of 12.45 % and with a standard deviation of 51.81 %. As already seen, after the immediate market reaction of high magnitude, the adjusted stock price tends to move along with the index,

which is visible in the event-study plot below. This highlights that the market is extremely quick to price topline results.

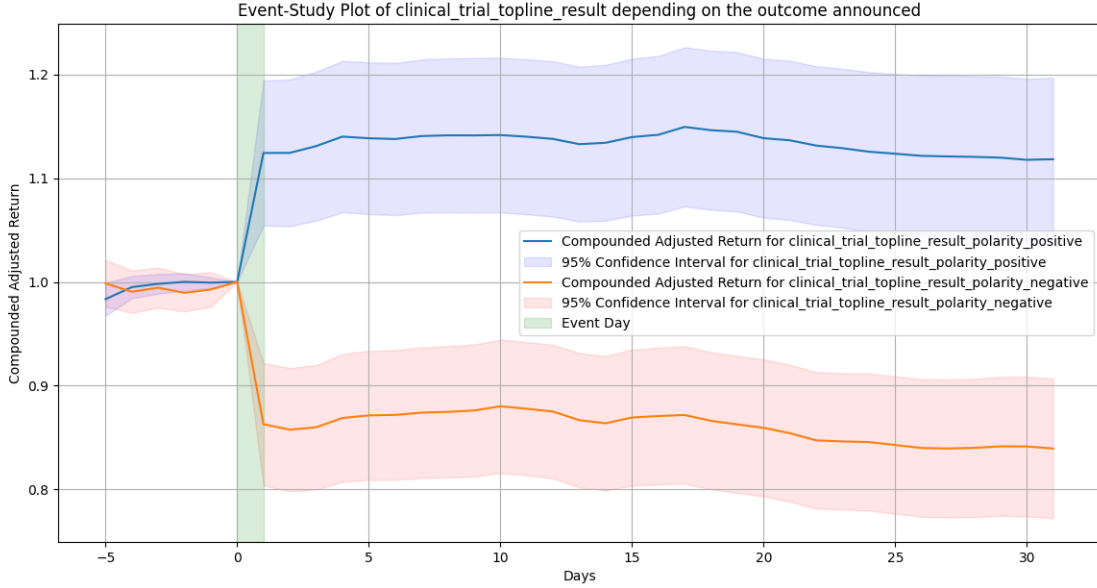


Figure. 2: Event-Study Plot of Clinical Trial Topline Result

Segmentation of Top Line Results by Trial Phase

It is valuable to segment the event-study by trial phase in order to accurately capture and interpret market reactions.

Clinical_Trial_Topline_Result	Phase	Count	Mean (%)	STD (%)	P-value (%)
Negative	Phase 2	55	-21.14	26.3	0.00
	Phase 3	58	-10.62	48.62	10.18
Positive	Phase 2	73	12.90	56.87	5.64
	Phase 3	98	11.25	52.29	3.58

Table 6: Statistical Summary of Adjusted Returns by Clinical Trial Topline Result Polarity and by Phase

Our segmentation study by trial phase yields key insights into how the market reacts to clinical trial topline results. For negative topline results, Phase 2 trials trigger a mean adjusted return of -21.14%, indicating considerable underperformance, whilst Phase 3 trials show a mean adjusted return of -10.62%. This finding shows that bad outcomes in Phase 2 elicit higher investor reaction than those in Phase 3. Similarly, for positive topline the

results, Phase 2 studies have a mean adjusted return of 12.90 %, whereas Phase 3 trials have a somewhat lower mean adjusted return of 11.25%, although because of the higher standard deviation of adjusted returns (56.87 % against 52.29 %) and lower sample size (73 against 98), positive Phase 2 results fail to achieve statistical significance (p-value = 5.64 %) even though positive Phase 3 results do reach the 5% significance threshold (p-value = 3.58 %). These findings are similar to those seen in the previous section. The high standard deviations seen in almost all subdivisions indicate large heterogeneity in market reactions, implying that interpretations of results vary greatly.

The sample size also decrease the statistical power of this part of the study, however segmenting the analysis by trial phase remains almost as relevant for topline results individually than for previously pooled Clinical Trial Outcomes.

Anticipation of Events : Registration Committee Results study

In this section, we aimed to investigate whether certain topics are priced in by the market before they actually occur. To do this, we extended the beginning of the event window to 20 trading days prior to the event and recomputed the adjusted returns. This analysis revealed interesting patterns for the topic of `registration_committee`, which are probably due to the public availability of deliberation documents two weeks before the registration committee makes its final decision during a public hearing.

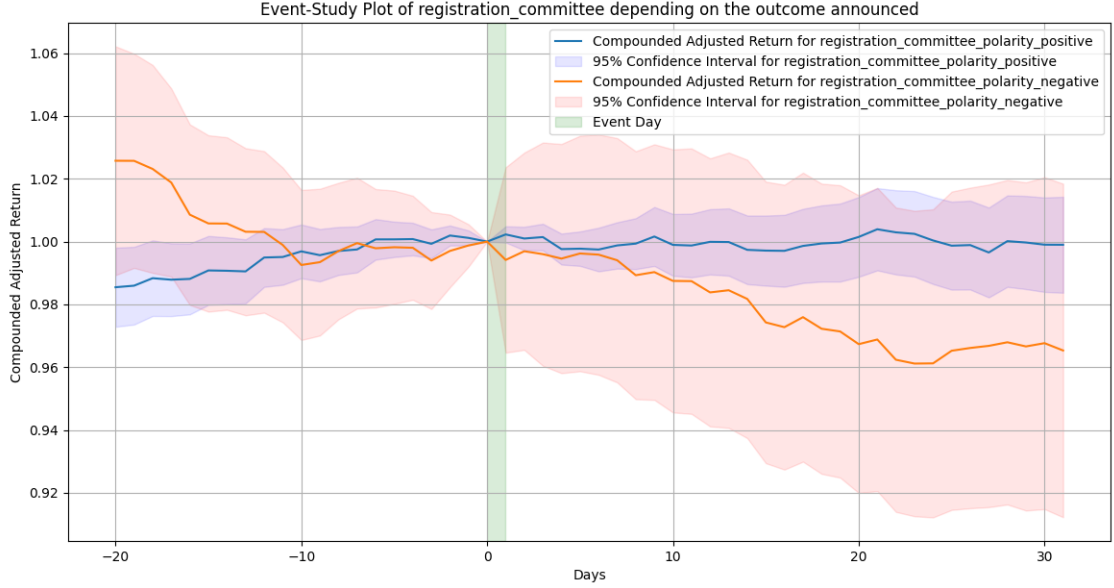


Figure. 3: Event-Study Plot of Registration Committee

We observe on the event-study plot of Registration Committee 3 that for negative outcomes the bearish trend starts already at the beginning of the event window 20 trading days before the event, and conversely there is somewhat a bullish trend, in this time-frame, for positive outcomes. In order to confirm this intuition, we computed, for every occurrence of a registration_committee event, the cumulative adjusted returns (CAR) over different time frames, specifically for a number of trading days before the event $t_1 = -5, -10, -15,$ and -20 :

$$CAR(t_1, -1) = \sum_{t=t_1}^{-1} AR_t$$

For each polarity (positive or negative) of the registration_committee event, we averaged the corresponding CARs and computed their empirical standard deviations. We then conducted a Student's T-Test to determine if the mean CARs are significantly positive or negative, indicating outperformance or underperformance respectively, before the event takes place. As we were interested in detecting directionally correct anticipations, we ran the test with different alternative hypotheses depending on the outcome of the registration_committee event: the alternative hypothesis was **less** for the negative polarity to test if the mean CAR is significantly negative, and the alternative hypothesis was **greater** for the positive polarity to test if the mean CAR is significantly positive.

Registration_Committee_Polarity	Count	Hypothesis	Time Frame (Days)	Mean (%)	STD (%)	P-value (%)
Negative	103	less	5	-1.96	12.17	5.27
			10	-3.28	14.85	1.36
			15	-2.71	17.91	6.38
			20	-2.53	21.84	12.13
Positive	278	greater	5	0.54	6.30	7.63
			10	1.15	11.54	4.83
			15	1.54	12.97	2.45
			20	1.47	13.14	3.18

Table 7: Statistical Summary of Cumulative Adjusted Returns on Different Time Frames Before Registration Committee Depending on the Outcome

The results of our anticipation study reveal that market participants indeed react to the registration committee’s forthcoming decisions, with discernible patterns emerging as early as 20 trading days before the event. For negative outcomes, we see a significant negative mean CAR of -3.28% over the 10 trading days prior to the event (p-value = 1.36%), indicating that the market begins to price in the likelihood of an adverse decision shortly before the announcement. This trend continues, albeit with slightly less magnitude, over longer time frames (15 and 20 trading days before the event), with mean CARs of -2.71% (p-value = 6.38%) and -2.53% (p-value = 12.13%), respectively. These findings suggest that while there is a significant underperformance as the event approaches, the market starts reacting even earlier, reflecting anticipatory behavior possibly due to the public availability of deliberation documents about two weeks before the registration committee announces its decision. For positive outcomes, the mean CARs are consistently positive and statistically significant across all time frames studied except the 5 trading days time frame. Specifically, the 15-day window shows a significant mean CAR of 1.54% with a p-value of 2.45%, and the 20-day window shows a mean CAR of 1.47% with a p-value of 3.18%. These results indicate that the market anticipates favorable decisions and adjusts stock prices accordingly once the data is public. Overall, the CARs’ anticipation effects are directly related to the data being available around two weeks before the registration committee’s decision. This explains the market’s first response to both positive and negative outcomes, as investors alter their holdings based on the information available. This research emphasizes the need of monitoring public disclosures connected to registration committee deliberations, which provide early indicators of prospective market changes. Investors and stakeholders can use this information to make more informed judgments, taking advantage of the market’s anticipatory behavior in response to upcoming events.

Conclusion

Among the 50 different topics extracted from the 100K+ Press Releases:

- Clinical Trial Outcomes stand out for their significant impact on stock price performance compare to any other Event excepted Merger and Acquisition
- The binary nature of clinical trials outcomes directly influence stock prices, resulting in immediate positive or negative adjustments
- These effects are more pronounced in less mature biotech companies compared to larger pharmaceutical firms
- Phase 2 clinical trials tend to have a stronger impact on stock prices than Phase 3 trials
- The classification of Clinical Trial Outcomes disclosure (interim results, topline results...) improves results accuracy
- Market participants generally anticipate the direction of these events

Further analysis is needed, particularly using the identification of the Therapeutics related to the Event and linkage to other datasets contain in the dataset, to fully understand these dynamics.

About Lend-RX Technology

About Lend-RX Technology provides an AI-powered global therapeutic intelligence platform that revolutionizes healthcare data analysis and research. Leveraging powerful Natural Language Processing, this platform gathers, aggregates, and analyzes millions of documents from validated sources and medical professionals on social media to offer context, sentiment, and subject analysis. This enables us to uncover explicit cause-and-effect relationships between indicators and events, enriched with medical semantic analysis and predictive analytics.

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Addendum

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