White Paper

Inflection Point: How Clinical Trial Results Impact Biopharma Valuations

Understanding the drivers of value creation to navigate an optimal development path

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Introduction

Developing novel therapies to address unmet patient need is the lifeblood of the biopharmaceutical industry. It is also a capital-intensive and high-stakes endeavour, requiring an estimated $3.1 billion to bring a new therapy to market,[1] with a composite success rate of 11% from phase 1 through regulatory submission.[2]

Clinical trial readouts, therefore, represent major inflection points in this journey, as moments of truth, that resolve uncertainty around an asset's future prospects, including its ultimate potential for revenue generation. Consequently, company valuations respond to clinical trial results — positive and negative — as investors re-calibrate their expectations based on the new information becoming available.[3-6]

In this white paper, we will systematically investigate how clinical trial outcomes impact company valuations and explore the underlying drivers, such as how trial results compare to investors' prior expectations, development phase at readout, therapy area or trial design. We focus on emerging biopharma companies (EBPs), in particular those with <$1 billion market capitalisation, because their valuations are highly responsive to trial results, as most of their value is concentrated in their pipeline which often comprises just a single asset. Unsurprisingly, we found that EBP valuations are much more sensitive to clinical trial readouts, by up to two orders of magnitude, compared to big pharma companies.

Furthermore, we will elaborate on the practical implications of understanding those drivers of value inflection. For example, how such insight may inform strategic decisions and help management teams navigate a company's optimal path that balances value upside vs. incremental clinical risk, such as the optimal timing for exploring partnerships or when to pursue an exit via the M&A route.

Methodology: brief overview

IQVIA performed an event study analysis that quantified the share price reaction to clinical outcomes for more than 2,600 trials from 2017 to 2023.

Our analysis defines the event date as the primary endpoint reported date, i.e., the earliest date of public report of results that addresses the primary endpoints of the trial. Positive and negative outcomes at the primary endpoint reported date were allocated based on the company-reported clinical definition.

A robust statistical model was developed to analyse the change in sponsor company share price at the primary endpoint reported date. The change was calculated as the average at the close prices of two days prior and one day prior to the primary endpoint reported date versus the average at the close prices on the day of the event and the day after.

Sponsor companies and therapeutic areas (TAs) were allocated based on IQVIA official classifications.

Further methodological details are documented in the appendix.

The asymmetry of market response

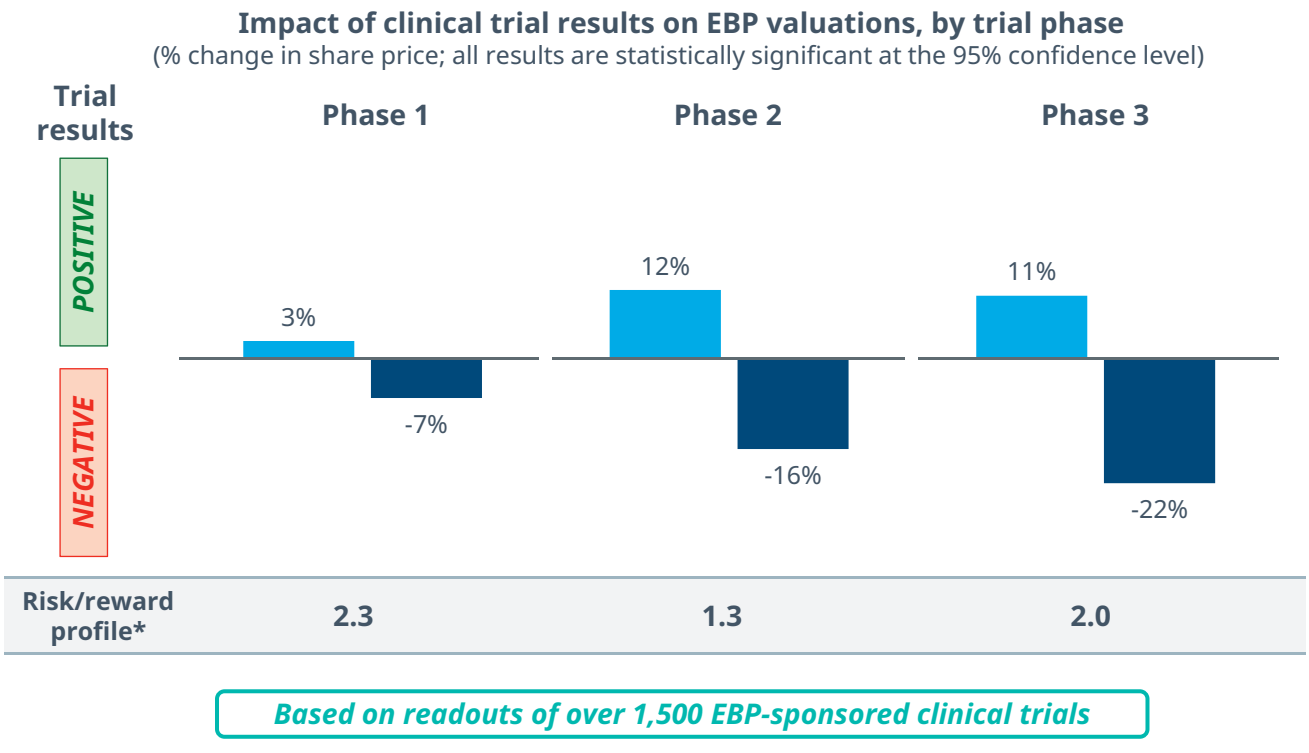
A main focus of our analysis was understanding the market response to positive and negative clinical results for different trial phases along the clinical development path.

We observed an intriguing asymmetry in the statistically significant impact of positive vs. negative clinical trial readouts on company valuations, with negative trial results consistently causing a larger relative market reaction than positive results. This pattern holds true for all trial phases.

Specifically, we found that the impact of negative news was 2.3, 1.3 and 2.0 times higher vs. positive news for clinical trial phases 1, 2 and 3, respectively, implying a most favourable risk-reward profile for phase 2 readouts (see Figure 1).

This consistent asymmetry observed across all trial phases suggests that investors give innovators the benefit of the doubt, on the basis of risk-adjusted expectations. Consequently, any value uplift following

Figure 1: The asymmetry of market response



* Ratio of absolute negative impact / positive impact
Source: IQVIA EMEA Thought Leadership analysis