



# *POSITIONING EMERGING BIOPHARMA FOR INVESTORS*

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Essential criteria biopharmaceutical investors seek  
when evaluating compounds and companies

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Dear Industry Colleagues,

There continues to be an unprecedented number of biopharmaceutical deals happening right now. In 2014, life science companies raised more than \$8 billion from venture capital firms, a 28 percent increase over 2013<sup>1</sup> and the highest level since 2007.<sup>2</sup> Simultaneously, pharmaceutical companies have become more aggressive in the acquisition space as a way to replenish their pipelines.<sup>3</sup> In 2014, more than \$220 billion was spent on drug company acquisition.<sup>4</sup>

Currently, 80 percent of the new biopharmaceutical projects that are in the global development pipeline have originated in academia and small-to mid-sized companies. These emerging companies have many challenges in furthering their development of new and exciting projects. Whether a company seeks to out-license, commercialize a compound, or position itself for acquisition, success often depends on investments. These investments can come from fully integrated pharmaceutical companies and/or venture capitalists (VCs). And, ultimately, the company's success in securing investment can mean the development of new treatments for the patients who need them most.

Even with current life science investment levels so high, competition for investment is fierce. The *how* and *why* of investing has largely been undiscussed. PAREXEL is proud to release a new research report called *Positioning Emerging Biopharma for Investors*. Having this information is essential for companies trying to better position themselves for investors and seize the current investment trends. This report is the first to explore the current biopharmaceutical investment strategy of venture capitalists and fully integrated pharmaceutical companies.

As a pioneer in clinical research outsourcing, PAREXEL is committed to simplifying the journey between science and new treatments. Feel free to call us today as we are happy to present these findings in greater detail.

**ROLAND ANDERSSON**  
SENIOR VICE PRESIDENT, PAREXEL

<sup>1</sup>Source: St. Louis Business Journal, February 2015

<sup>2</sup>Source: <http://finance.yahoo.com/news/venture-capital-dollars-invested-life-142400503.html>

<sup>3</sup>PharmaExec, November 2014

<sup>4</sup>InvestorPlace.com, January 2015



*PAREXEL CONDUCTED A SURVEY TO HELP CEOs OF EMERGING COMPANIES UNDERSTAND HOW TO BETTER POSITION THEMSELVES FOR INVESTORS.*

# INTRODUCTION

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## What do investors seek when evaluating investment in compounds and companies?

As much as 80 percent of the new biopharmaceutical projects that are in the global development pipeline have originated in academia and small-to mid-sized companies. Yet, emerging biopharmaceutical companies face enormous pressures from high development and commercialization costs, and increasing regulatory and reimbursement issues.

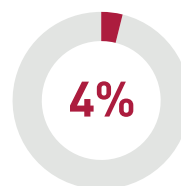
For more than 30 years, PAREXEL has been helping biopharmaceutical companies of all sizes intelligently navigate the competitive landscape based on our in-depth understanding of the industry and investor mindsets. Working with emerging companies is in our DNA.

PAREXEL understands that whether a company seeks to out-license, commercialize a compound, or position their company for acquisition, their success often depends on investments from fully integrated pharmaceutical companies (FIPCOs) and/or venture capitalists (VCs).

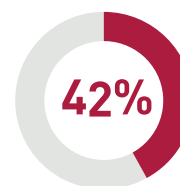
To help CEOs at emerging companies understand how to better position themselves for investors, PAREXEL conducted a survey in October 2014 to examine how FIPCOs and VCs make investment decisions in pre-commercialized compounds and companies.

The research shows that competition for investment in pre-commercialized compounds (those that have not yet reached the marketplace) or emerging companies is fierce. The average deal-to-investment ratio—the number of deals funded in the recent 12-month period—is 4 percent (3 percent for FIPCOs and 8 percent for VCs). Approximately 42 percent (investment dollars) of initial investments are made with compounds during Phase I/IIa.

### INVESTOR INSIGHTS



DEAL-TO-INVESTMENT RATIO

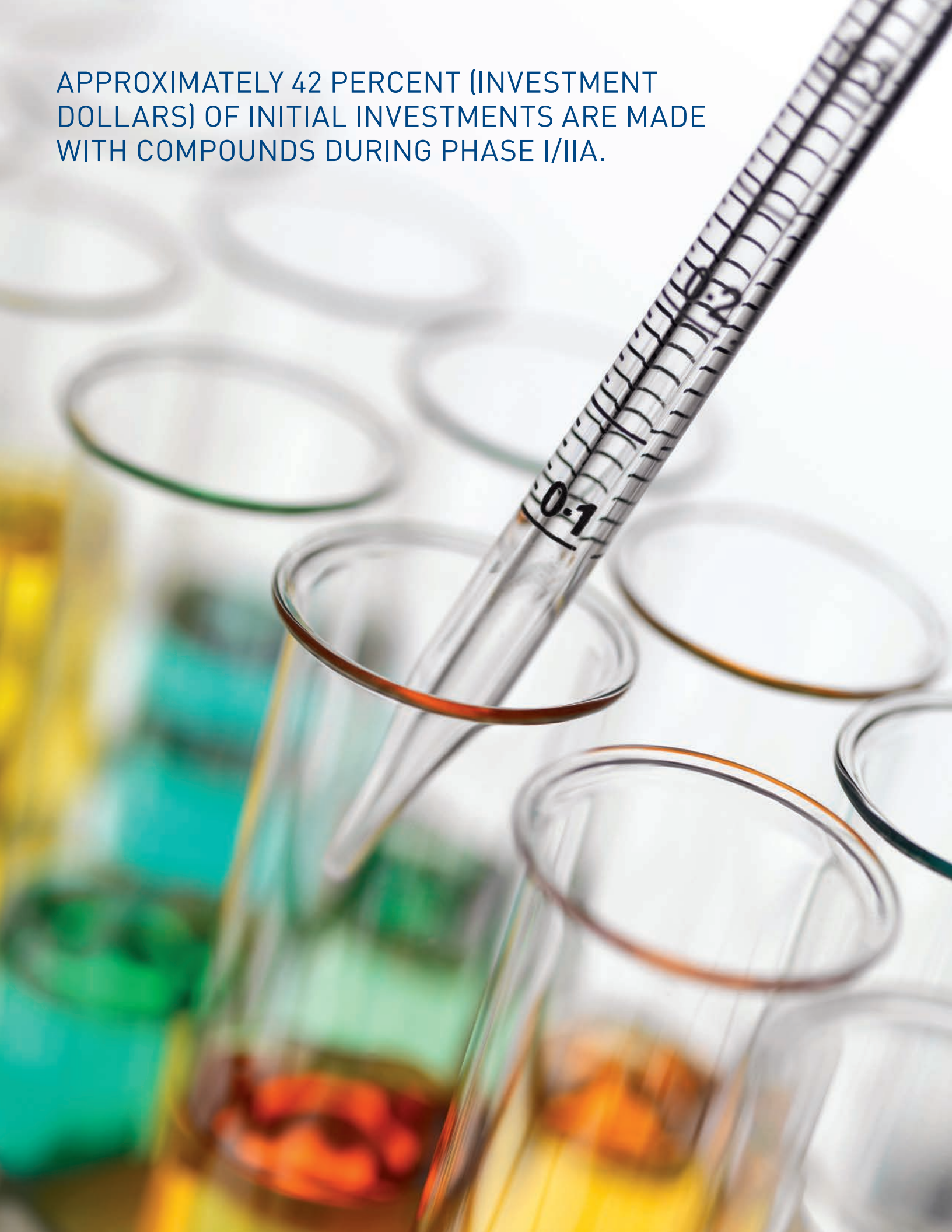


PHASE I/IIa AS % INITIAL INVESTMENT

For this research, PAREXEL surveyed 61 investment professionals: 34 respondents from FIPCOs and 27 respondents from VC/private equity firms. 43 respondents were located in North America and 18 respondents were located in Western Europe. These respondents were screened to have appropriate decision-making responsibilities for deal analysis and pharmaceutical investments.



APPROXIMATELY 42 PERCENT (INVESTMENT DOLLARS) OF INITIAL INVESTMENTS ARE MADE WITH COMPOUNDS DURING PHASE I/IIA.



# KEY FINDINGS

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## **PAREXEL's survey of investment professionals at FIPCOs and VC/private equity firms in the U.S. and Europe revealed striking similarities and notable differences.**

- Investment in new compounds and companies is competitive. Over a 12-month period, FIPCO companies are more active in both deal evaluation and investments, but VC companies invest in a higher proportion of deals they consider.
- It was interesting to learn that 42 percent of initial investments are made with compounds during Phase I/IIa proof-of-concept trials.
- Both FIPCO and VC investors indicate clinical performance (safety and efficacy) is by far the most important attribute when evaluating compounds.
- Commercialization, pricing and competition analysis emerge as very important considerations when evaluating both compounds and companies.
- When evaluating companies for investment, both financial performance and cost management emerge as important considerations.

### **When asked what advice they would give the CEO of a biopharmaceutical company looking to out-license or sell a pre-commercialized compound, FIPCO respondents suggested:**

- Make sure the data is transparent
- Understand clinical trial costs and the competitive market
- Be objective about the product's potential

### **When asked what advice they would give the CEO of a biopharmaceutical company seeking to out-license or sell a pre-commercialized compound, VC respondents suggested:**

- Be objective about a compound's likelihood for success
- Have a well-presented data package
- Understand development costs

# INVESTMENT VOLUME & DISTRIBUTION

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## **FIPCOs are more active in both deal evaluation and investments, but VCs invest in a higher percentage of the deals they evaluate.**

Investors were asked approximately how many investments in compounds, products or companies they had formally analyzed in the past 12 months. On average, FIPCOs had looked at 415 deals, nearly five times as many deals as VCs, who had examined on average 84 deals. FIPCOs are able to evaluate more deals because they often have larger investment staff compared with VCs.

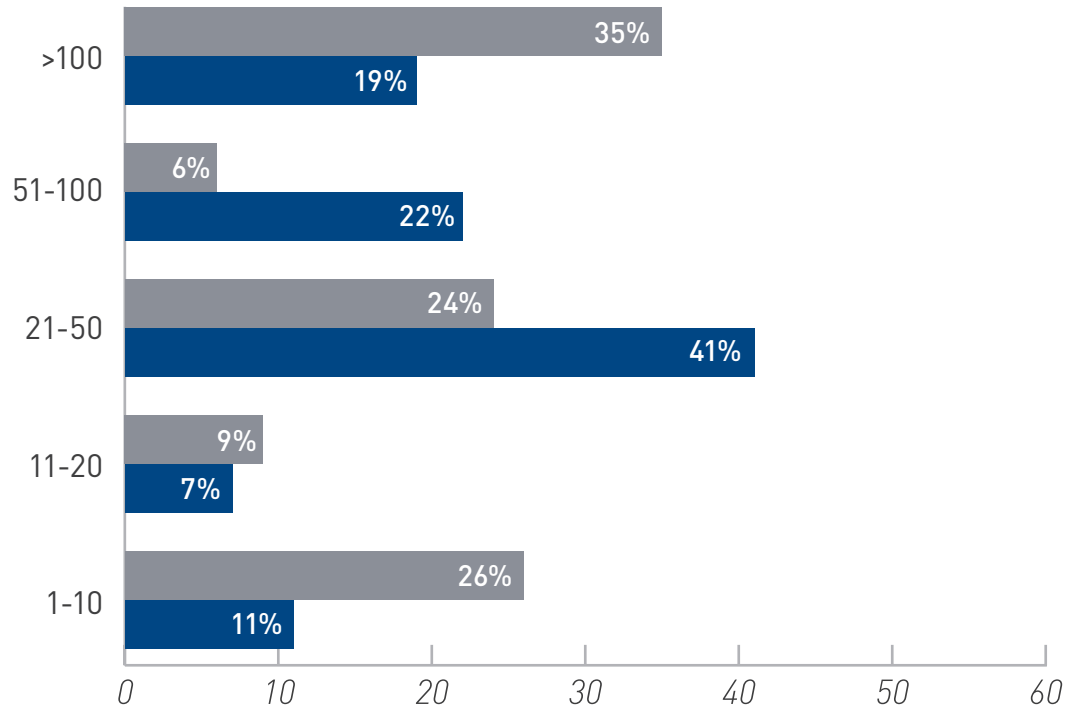
## **DEAL-TO-INVESTMENT RATIO**

FIPCOs are more active in both deal evaluation and investments, but VCs invest in a higher percentage of the deals they evaluate.

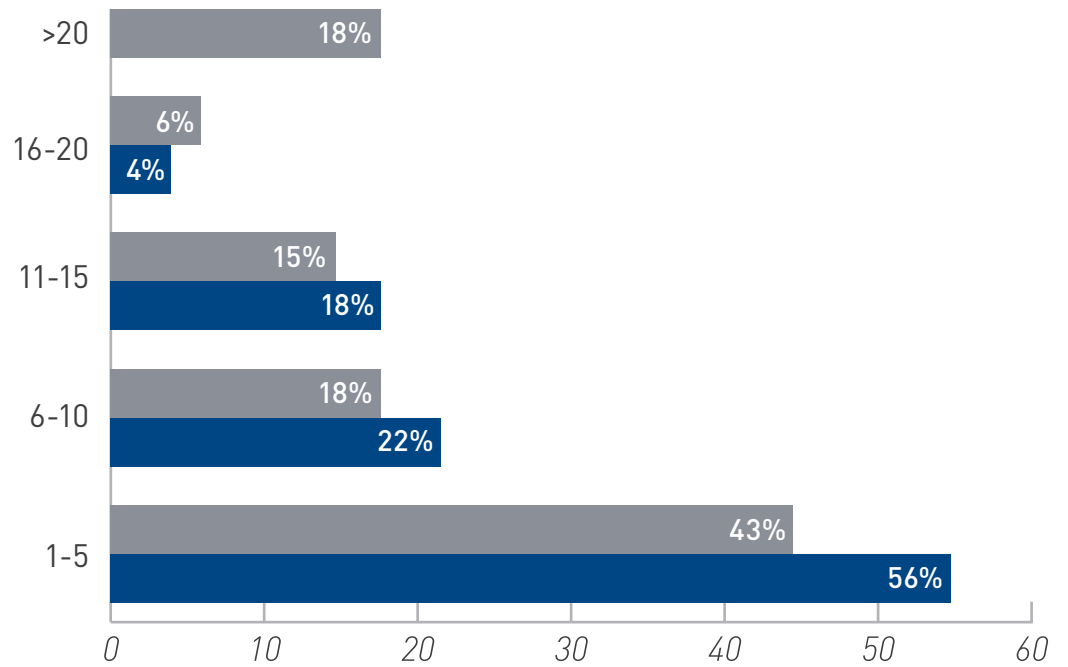
Of the deals analyzed, FIPCOs invest on average in 3 percent and VCs invest on average in 8 percent. The average deal-to-investment ratio of all participants is 4 percent (an average based on the number of respondents per group). The difference between FIPCO and VC investments is likely due to VCs' willingness to spread risk among multiple companies based on the potential for reward. However, FIPCOs have become more aggressive in the acquisition space as a way to replenish their pipelines.



## DEALS ANALYZED, PAST 12 MONTHS



## INVESTMENTS, PAST 12 MONTHS

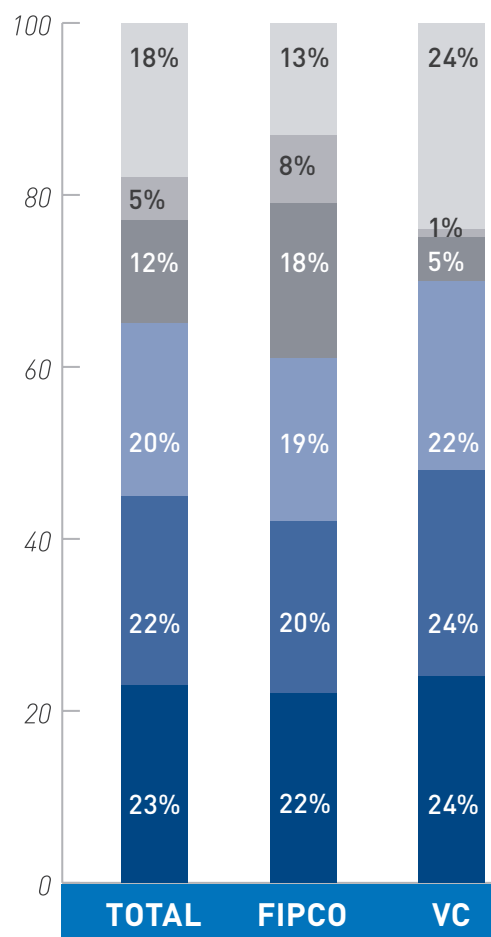
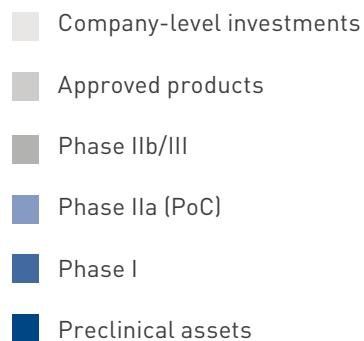


## INVESTMENT DISTRIBUTION

The majority of investments among survey respondents were made in early clinical studies (prior to or just after the completion of proof-of-concept (PoC)).

The research shows that FIPCOs are more likely than VCs to invest in Phase IIb/III products. In addition, the development costs and the timeline associated with increasing the number of patients are prohibitive for most VCs. FIPCOs, on the other hand, typically avoid the risks associated with early-stage development, excel at later-stage clinical development and can work on longer timelines.

Sixty-five percent (investment dollars) of investments are made within preclinical through Phase IIa, with just over 40 percent of the investments made with compounds during Phase I/IIa. VCs invest more frequently in earlier phase compounds because they often invest broadly, early-stage investments can be cheaper, and the potential reward greater.





THE RESEARCH SHOWS THAT FIPCOs ARE MORE LIKELY THAN VCS TO INVEST IN PHASE IIB/III PRODUCTS. THE DEVELOPMENT COSTS AND THE TIMELINE ASSOCIATED WITH INCREASING THE NUMBER OF PATIENTS ARE PROHIBITIVE FOR MOST VCS.

# *ATTRIBUTES CONSIDERED FOR INVESTMENT IN COMPOUNDS*

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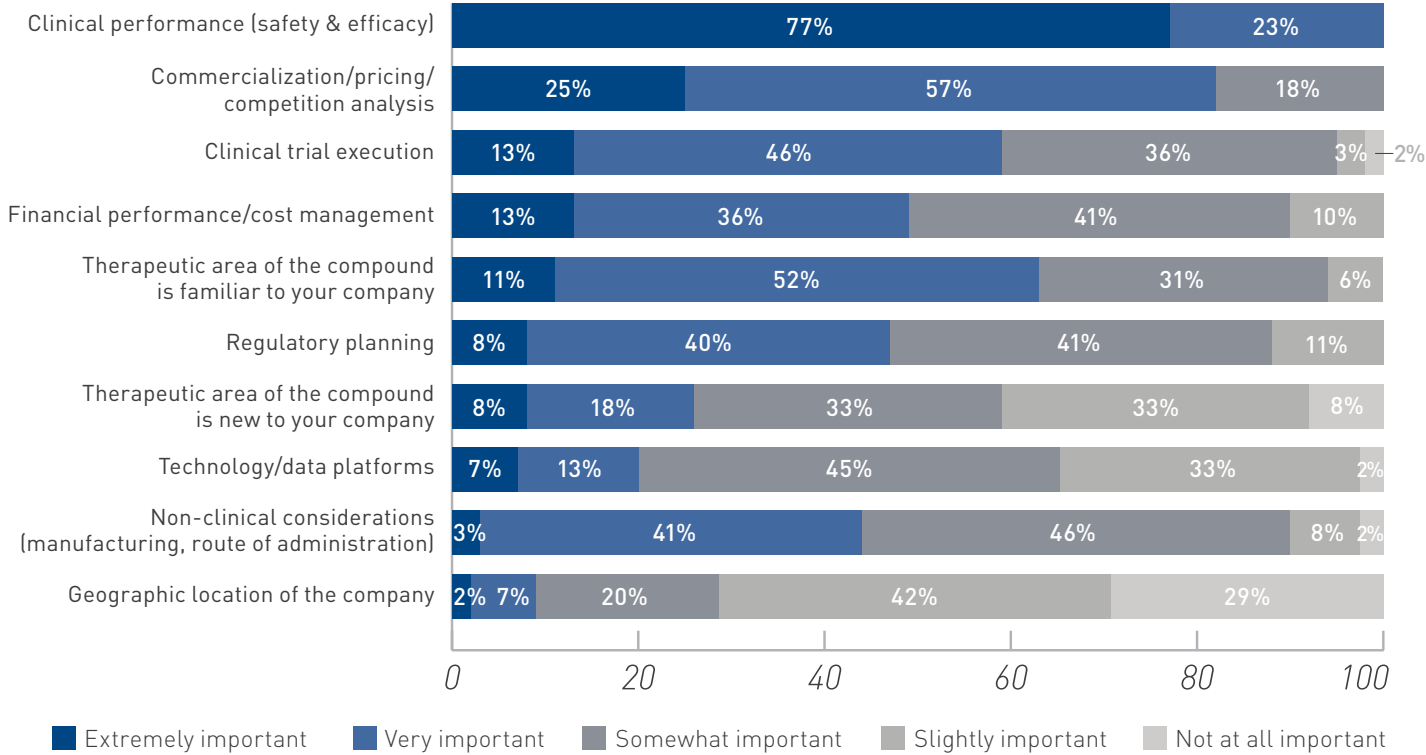
## **Respondents were asked to rate the importance of various criteria when evaluating the investment potential of a given compound. Insights include:**

- Clinical performance (safety and efficacy) is the single most important investment attribute for both FIPCOs and VCs.
- Both FIPCOs and VCs indicate that commercialization, pricing and competition analysis is the second most important attribute.
- All respondents indicate that familiarity with therapeutic area was important when evaluating a compound.
- FIPCOs and VCs both indicate that financial performance/cost management, regulatory planning and non-clinical considerations (manufacturing, route of administration) also are very important when considering compounds.

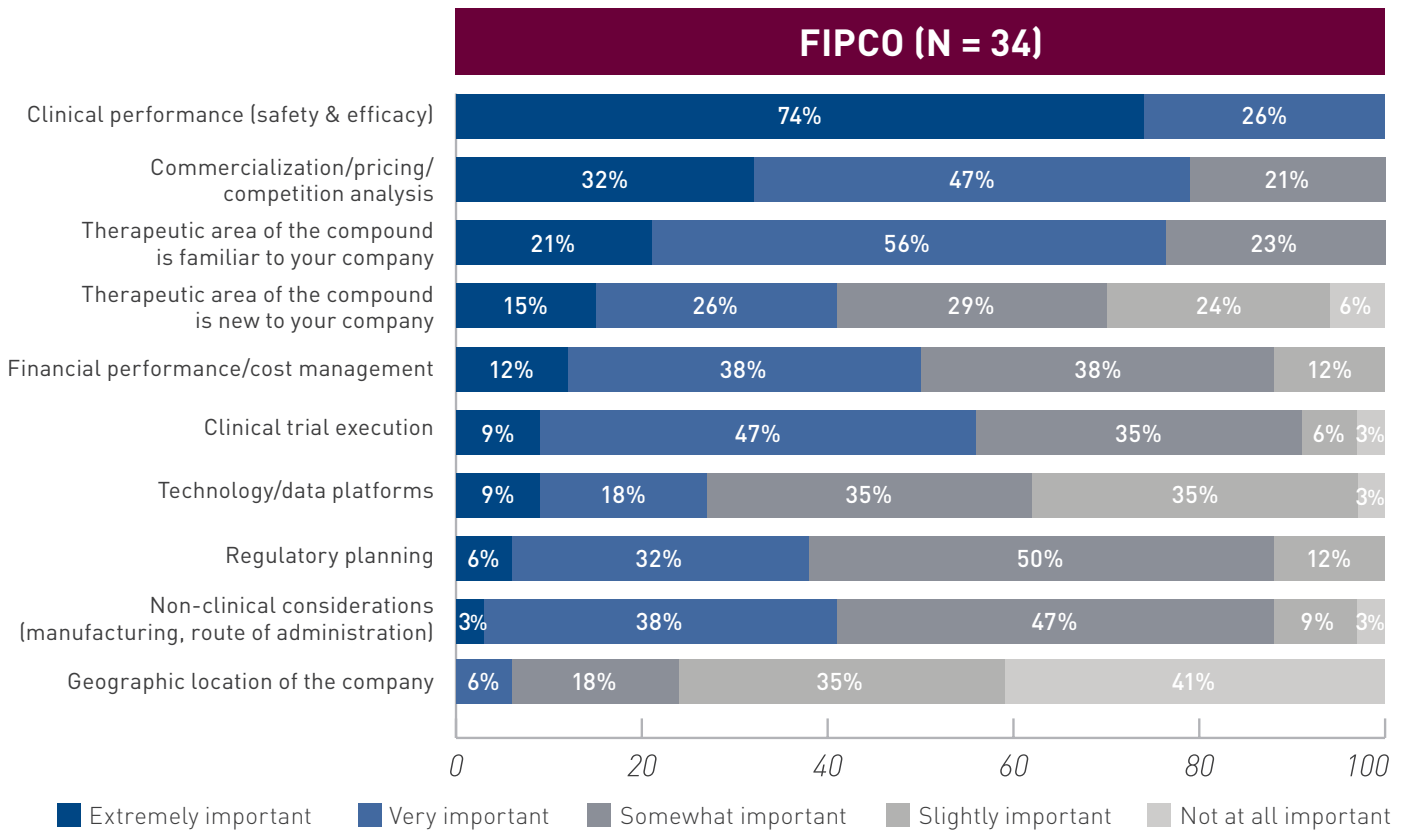


### ATTRIBUTE IMPORTANCE WHEN EVALUATING COMPOUNDS

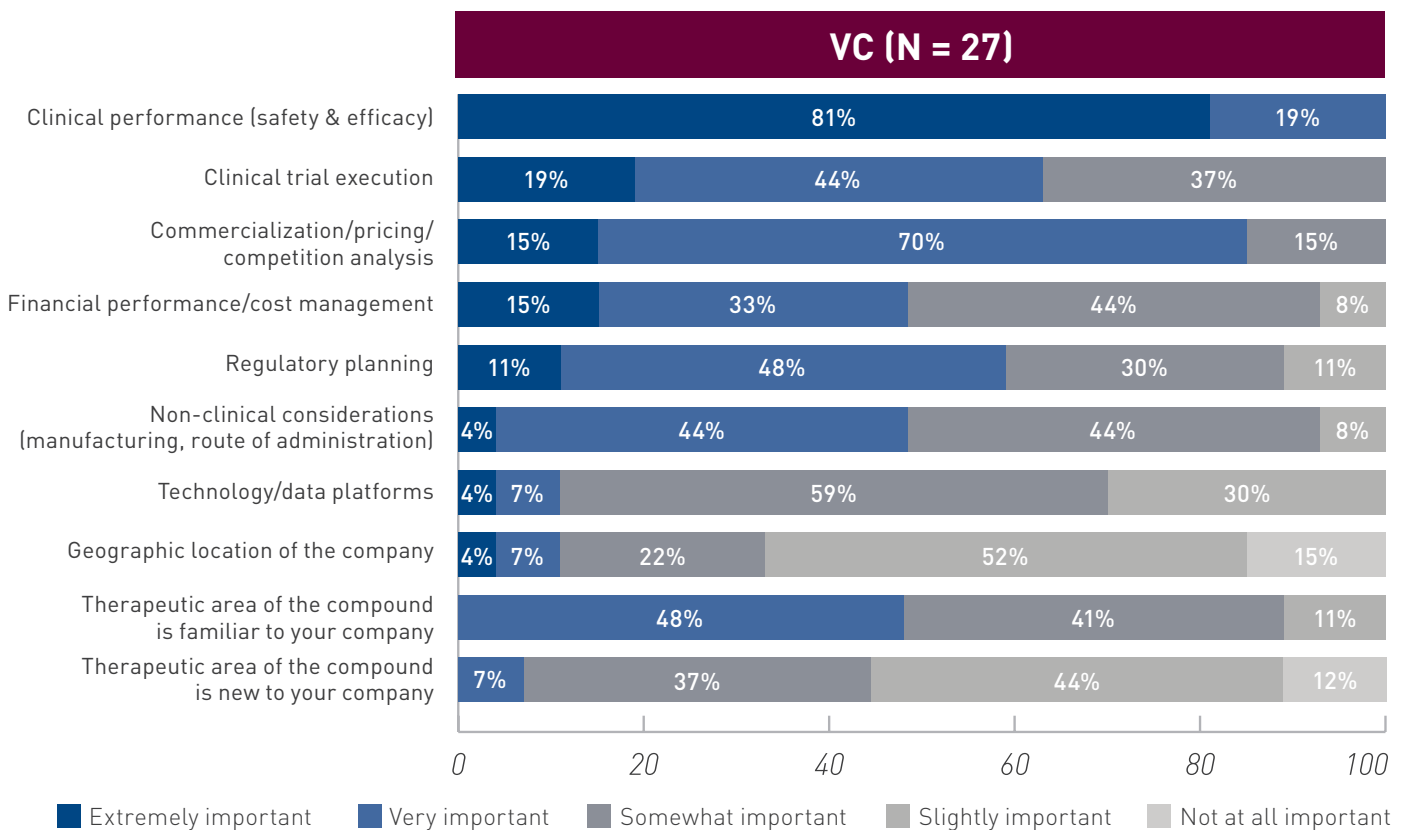
#### ALL RESPONDENTS (N = 61)



## ATTRIBUTE IMPORTANCE WHEN EVALUATING COMPOUNDS



## ATTRIBUTE IMPORTANCE WHEN EVALUATING COMPOUNDS





## DIFFERENCES BETWEEN FIPCOs AND VCs WHEN EVALUATING COMPOUNDS

While clinical performance (safety and efficacy) is by far the most important investment attribute for both FIPCOs and VCs, there were differences in how they considered other compound attributes.

FIPCOs are more likely than VCs to indicate familiarity with therapeutic area is a top-three investment attribute.

VCs indicate clinical trial execution is extremely important compared with FIPCOs. If a company has signed a deal that includes payments upon the completion of key development milestones and is able to meet those milestones, the company is demonstrating to the market that its product is valuable and management is capable of meeting goals. This has the potential to increase the overall value of the compound when the company seeks further funding or enters into licensing agreements.

Non-clinical considerations such as manufacturing and route of administration also are important for both FIPCOs and VCs.

**VCs INDICATE CLINICAL TRIAL EXECUTION IS  
EXTREMELY IMPORTANT COMPARED WITH FIPCOs.**

# ATTRIBUTES CONSIDERED FOR INVESTMENT IN COMPANIES

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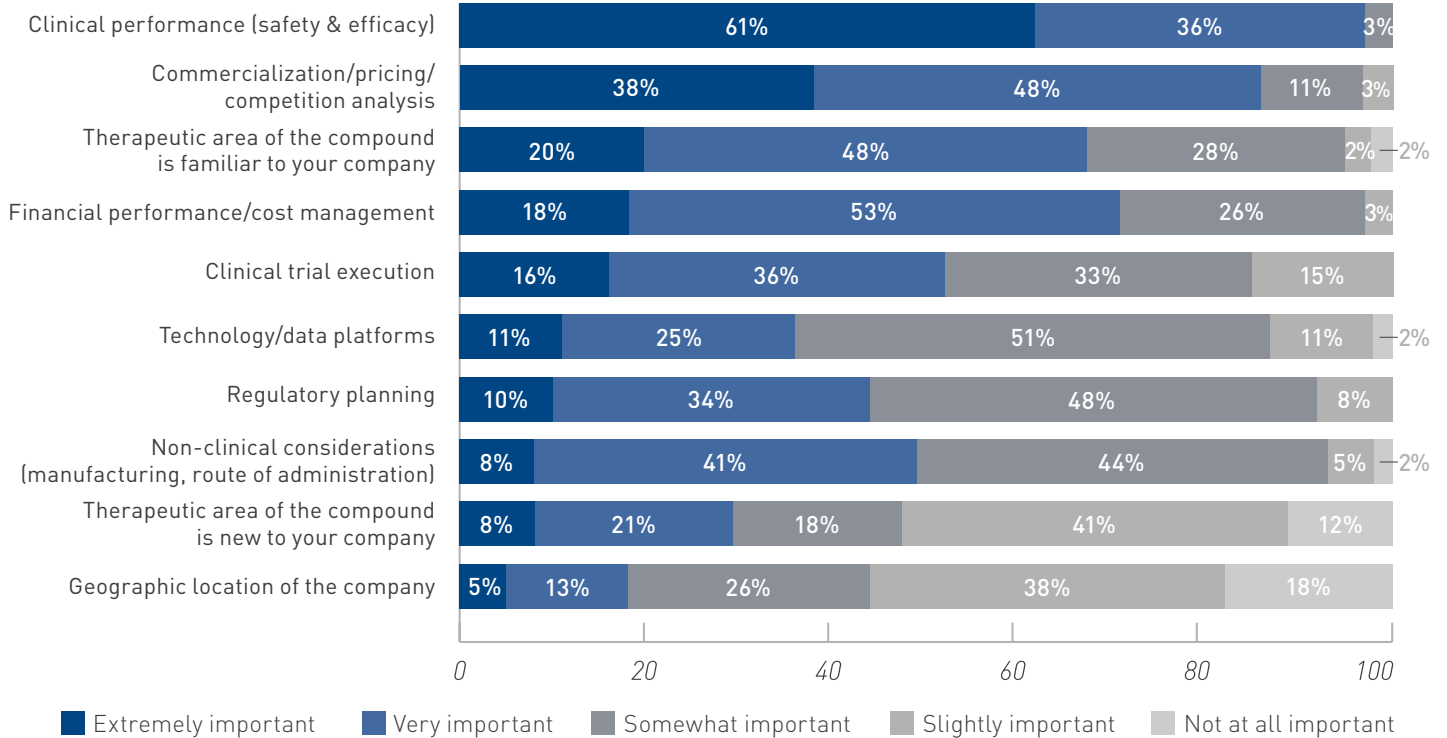
## **Respondents were asked to rate the importance of various criteria when evaluating the investment potential of a company. Insights include:**

- Clinical performance (safety and efficacy) is the most important attribute for both FIPCOs and VCs.
- Consistent with compound evaluations, commercialization, pricing and competitive environment are also very important for all investors when assessing companies.
- Familiarity with a therapeutic area is the third most important attribute when evaluating a company for both FIPCOs and VCs
- For FIPCOs and VCs, familiarity with non-clinical considerations such as manufacturing and route of administration are very important when evaluating a company.

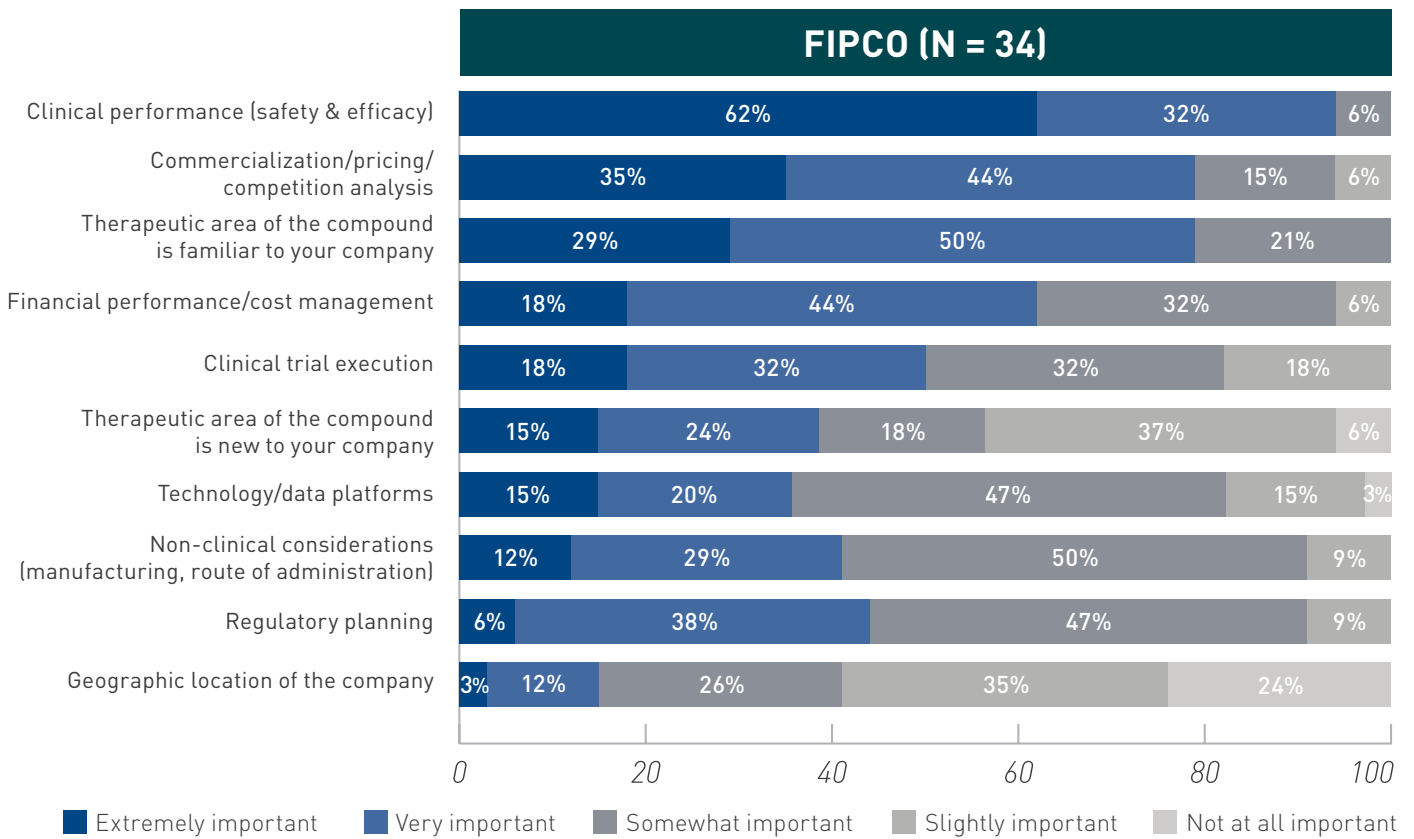


## ATTRIBUTE IMPORTANCE WHEN EVALUATING COMPANIES

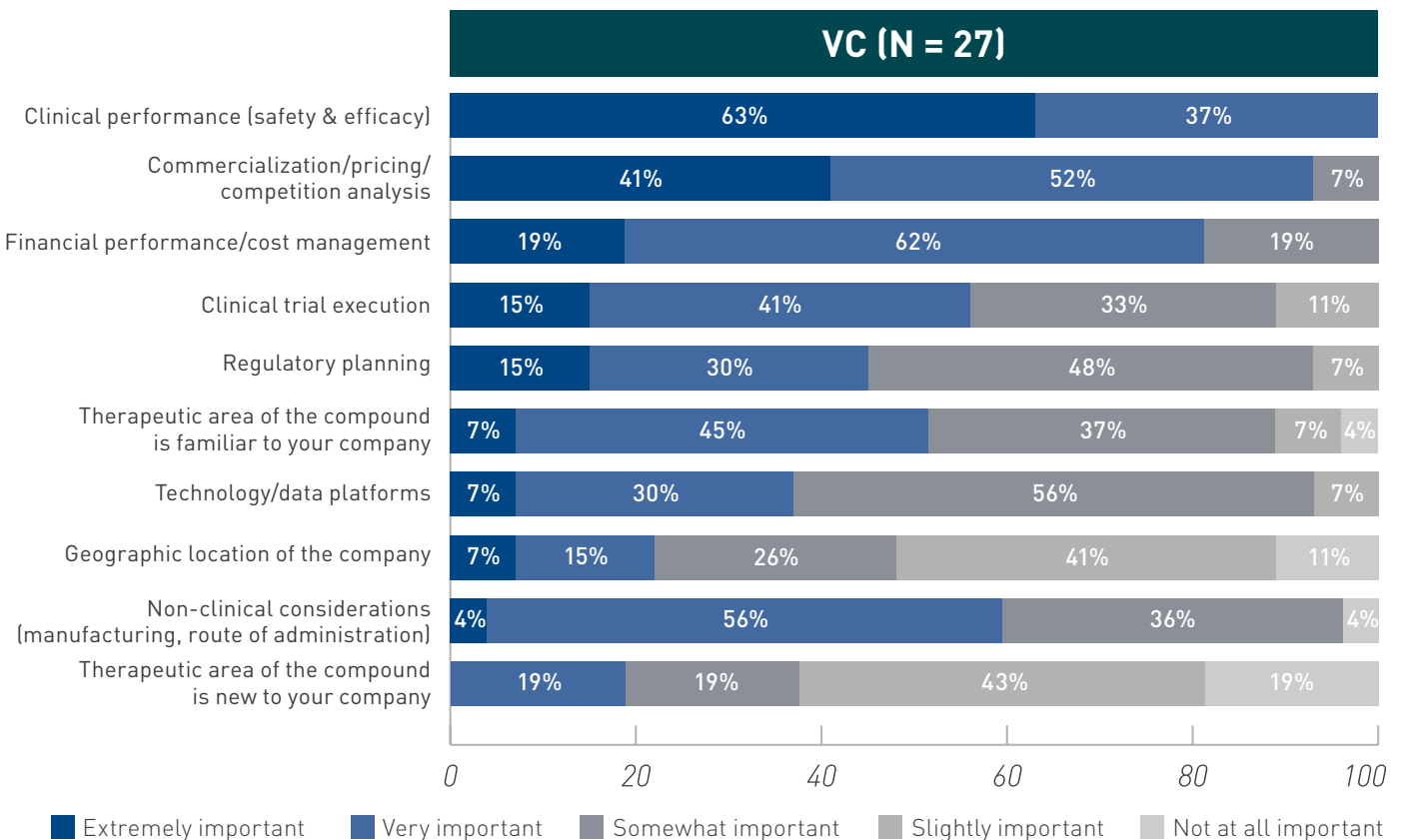
### ALL RESPONDENTS (N = 61)



## ATTRIBUTE IMPORTANCE WHEN EVALUATING COMPANIES



## ATTRIBUTE IMPORTANCE WHEN EVALUATING COMPANIES



## DIFFERENCES BETWEEN FIPCOs AND VCs WHEN EVALUATING COMPANIES

While clinical performance (safety and efficacy) is by far the most important investment attribute for both FIPCOs and VCs, there were differences in how they considered other companies for investment.

For example, both FIPCOs and VCs indicate that financial performance and cost management are very important, however for VCs, this is a top-three investment criteria. Since VCs typically invest in a number of companies, it is critical that the team in which they are investing has experience and is credible, the market size is substantial, and the product has the potential to offer substantial returns.

As with their investments in compounds, FIPCOs are more likely than VCs to indicate familiarity with therapeutic area is a top investment attribute. This is because the investment must fit their overall product strategy.

Clinical trial execution and regulatory planning are also more important for VCs than FIPCOs. Since the cost of clinical trials requires a significant investment, understanding the clinical development and regulatory path are of increased importance for VCs.

**BOTH FIPCOs AND VCs INDICATE THAT FINANCIAL PERFORMANCE AND COST MANAGEMENT ARE VERY IMPORTANT BUT FOR VCs, THIS IS A TOP-THREE INVESTMENT CRITERIA.**

# TRADE-OFF SCENARIOS

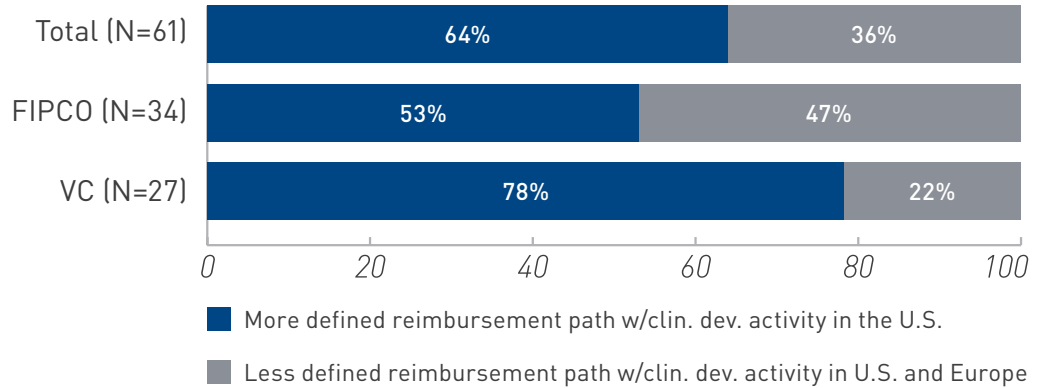
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## **Survey respondents were posed a series of scenarios that offered different investment choices:**

- VCs prefer products that have a defined reimbursement path (with clinical activity only in the U.S.) compared to a product with a less defined reimbursement path (with development activities in both the U.S. and Europe).
- Both FIPCOs and VCs prefer products with a novel mechanism of action (MoA).
- FIPCOs are more interested in a well researched target product profile (TPP) while VCs are more interested in achieving timely execution of clinical development milestones.
- Both FIPCOs and VCs prefer biologically produced products compared with chemically derived compounds.

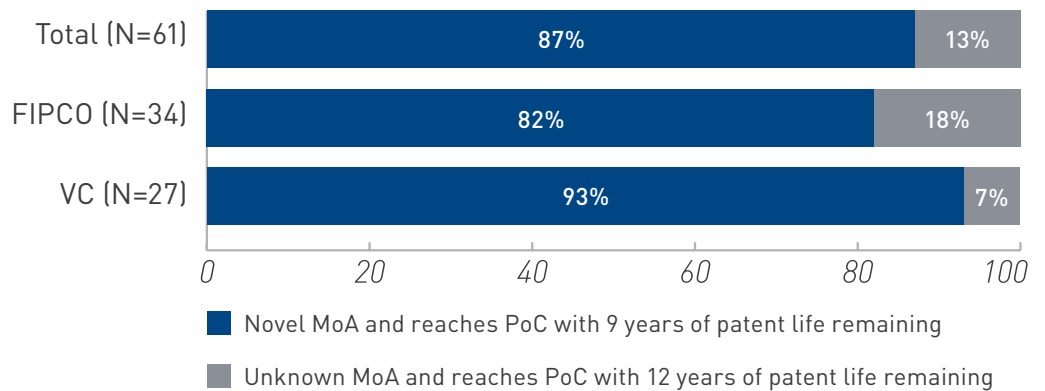


## VC INVESTORS PREFER PRODUCTS WITH A DEFINED REIMBURSEMENT PATH



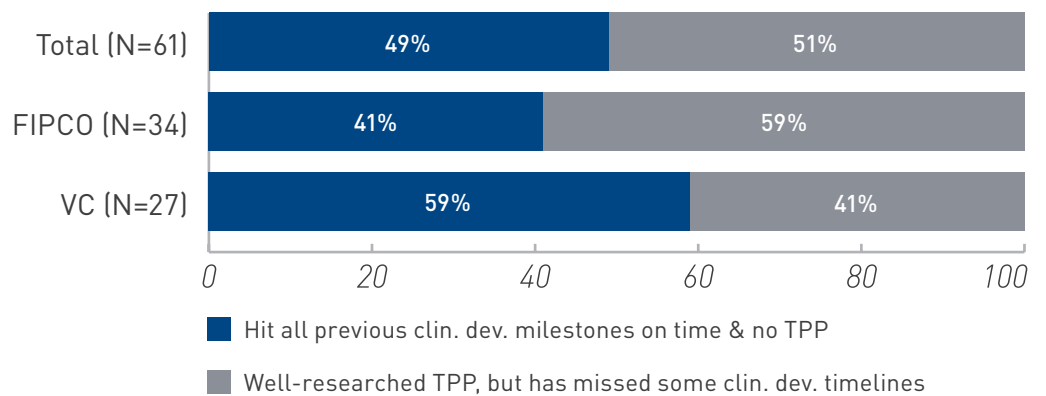
VC respondents are more likely than FIPCOs to prefer a product with a defined reimbursement path (with clinical activity only in the U.S.) compared with a less defined reimbursement path (with development activities in both the U.S. and Europe). For VCs focused on the U.S. and Europe, the U.S. may offer more attractive investment returns based on the current reimbursement paradigm. For FIPCOs with a global footprint, investments in novel products with defined reimbursement paths may help fill global development pipelines.

## INVESTORS PREFER PRODUCTS WITH A NOVEL MECHANISM OF ACTION (MOA)



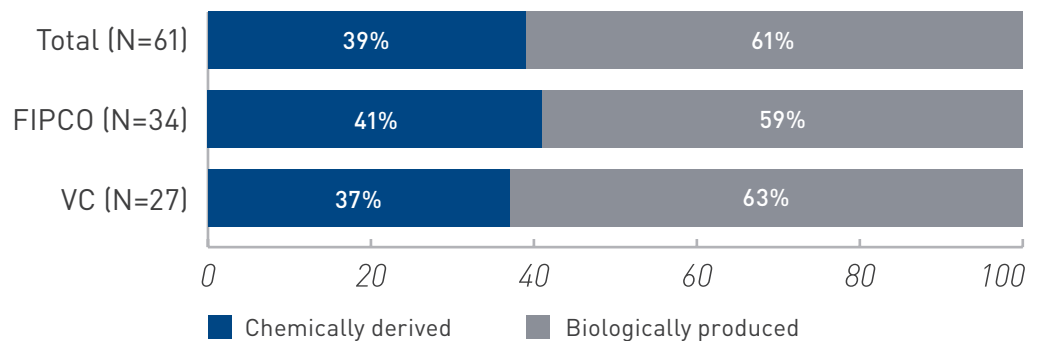
Three out of four respondents indicate they would prefer to invest in an asset that has a novel MoA and reaches PoC with nine years of patent life remaining compared with an asset that has an unknown or "me-too" MoA and reaches PoC with 12 years of patent life remaining. Since MoA can be a differentiator, an investor could foresee deriving greater value from a compound with novel MoA and a shorter patent life.

## VC INVESTORS PREFER PRODUCTS WITH A TARGET PRODUCT PROFILE (TPP)



Slightly more respondents prefer a compound with a well-defined TPP developed, even if some clinical development timelines have been missed. While this is more important for VCs than FIPCOs, it demonstrates that investors want to understand the product characteristics, clinical study results and its targeted patient population. In addition, a TPP helps give the investor a perspective on the development timelines that are ahead for the product. This is of particular importance for VCs whose return on investment often depends on completion of milestones.

## INVESTORS PREFER BIOLOGICALLY PRODUCED PRODUCTS



The majority of respondents prefer biologically produced products compared with chemically derived compounds. As biologics are capable of targeting complex diseases, the perception among investors could be that they are more valuable compared with chemical compounds. However, biologics can be more difficult and costly to produce and develop, but could achieve a higher return on investment with the right strategic development and commercialization plan.



VC RESPONDENTS ARE MORE LIKELY THAN FIPCOs TO PREFER A PRODUCT WITH A DEFINED REIMBURSEMENT PATH (WITH CLINICAL ACTIVITY ONLY IN THE U.S.) COMPARED WITH A LESS DEFINED REIMBURSEMENT PATH (WITH DEVELOPMENT ACTIVITIES IN BOTH THE U.S. AND EUROPE).

# *INVESTOR ADVICE TO COMPANIES*

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INVESTORS NOTED THAT COMPANIES SEEKING AN INVESTMENT SHOULD BE PREPARED TO PROVIDE AN OBJECTIVE UNDERSTANDING OF THEIR COMPOUND'S PROBABILITY FOR SUCCESS: HOW MUCH IT WILL COST TO DEVELOP AND COMMERCIALIZE, HOW IT WILL FIT INTO THE COMPETITIVE MARKET LANDSCAPE AND WHETHER IT WILL BE APPROVED BY THE REGULATORY AUTHORITIES AND REIMBURSED BY PAYERS.

**When asked to give advice to a CEO looking to sell a compound or position a company for acquisition, it became clear that investors want transparency, realistic projections and an understanding of development costs. Those surveyed suggested that executives:**

### **BE TRANSPARENT**

- “Clearly spell out what the upside and downside risks are of the asset. What can make or break the product as these are the wild cards that are difficult to model.”
- “Be transparent with efficacy: risk trade offs.”
- “Weave the full story, including preclinical justification/rationale. Be fully prepared to disclose and talk through in detail patient-level data from all completed and, where applicable, ongoing clinical trials.”

### **BE REALISTIC**

- “To not think that your compound will definitely cure cancer. Have an objective understanding of the probability of success of your candidate. This just jump-starts our discussions.”
- “We see hundreds of deals/compounds each year, so how do you make yours stand out, what makes yours different from the others, take a step back and look at your product objectively, have others analyze it objectively.”

### **PACKAGE ROBUST DATA**

- “Data data data—preclinical, pharmacology, MoA, strong understanding of PK/PD, clinical and regulatory environment, competition—must have all this packaged together to enable good partnership/M&A discussions.”
- “The data package has to be clean, accurate and robust. We have to be able to make quick sense out of what we are seeing. Do not skimp on collection and presentation of preclinical and clinical data.”

### **UNDERSTAND DEVELOPMENT COSTS**

- “Have a nailed down projection for how much it will cost to progress the asset through PoC.”
- “You have to know what the time and costs are for the next rounds of development.”
- “Have realistic expectations about the amount of capital and time required to advance compound from clinic to market.”



81

LOCATIONS

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51

COUNTRIES

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16,530

EMPLOYEES

**PAREXEL International is a leading global biopharmaceutical services company, providing knowledge-based contract research, consulting, medical communications, and technology solutions and services to the worldwide pharmaceutical, biotechnology and medical device industries.**

PAREXEL's offerings span the entire drug development and commercialization spectrum—from Phase I to IV clinical research services to regulatory outsourcing, integrated product development and other consulting services. Through its informatics business, PAREXEL delivers integrated platforms and applications, as well as clinical data services, to make drug development faster, more accurate, and efficient.

For more than 30 years, PAREXEL has focused on its mission of helping customers prevent and cure disease. To simplify the drug development journey, the Company applies its global expertise, offers innovative, integrated technology solutions and builds deep, long-term partnerships with sponsors. Headquartered near Boston, Massachusetts, PAREXEL operates in 81 locations in 51 countries, and has approximately 16,530 employees around the world.

For more information, visit [www.PAREXEL.com](http://www.PAREXEL.com).



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**We are always available  
for a conversation.**

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## **ABOUT THE INVESTOR RESEARCH**

For this report, independent research firm Industry Standard Research, conducted an online survey of 61 senior-level investment professionals, representing fully integrated pharmaceutical companies and venture capital/private equity firms. It included both quantitative and qualitative questions to better understand the questions that investors ask when evaluating an investment in pre-commercialized compounds or companies.

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