



Biotechnology Industry Pulse

Biotech industry executives' perspectives on the industry's health and future

August 2009

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Executive Summary

Key findings for the Clinical Development Industry

In our previous ISR reports (*CRO Benchmarking – March 2009*, *Biotech CRO Benchmarking – May 2009*) we introduced the concept of the SVI™ or Service Variability Index. The SVI revealed a couple things worth noting here as it has ramifications to some of the key findings from this research. First, the SVI showed us that not all service providers service biopharmaceutical companies in the same way. While that might not be headline material, it did, for the first time quantify what has been widely hypothesized in the industry for years. Second, the SVI highlighted the importance of setting expectations. Everybody knows that clinical development activities are not an exact science, but if sponsors and service providers communicate and set proper expectations, then both parties can be satisfied with the end product. What do these points have to do with this research effort? Well...

Material Changes

In this time of rapid industry change (financing, consolidation, regulation, survival) meeting expectations becomes much harder because the status quo is constantly changing. For service providers this means that what you thought you knew about your customers might not be accurate today and should be challenged. Thought you knew your biotech customers, think again? For biotech companies this means that their priorities and areas of focus are probably in flux. Combine the two and you see how difficult it could be come to manage expectations.

Myriad of Development Options

Biotech companies, for better or worse, have many clinical development options open to them, and they like them all. One of the most valuable findings from this research shows that there is definitely NOT a preferred clinical development model for biotech companies. None of the options garnered more than 18% of the preference “share.” What’s needed is a better understanding of why biotech companies have these preferences, what are their motivations, preferences, and prejudices? Once you identify biotech sponsors’ motivations, then service providers and other biopharmaceutical sponsors can adequately understand and meet their expectations.

Needs-based Market Segmentation

Given the recent changes in biotech corporate actions, their multiple development preferences, and knowing the differences between how Executives and Clinical operations decision-makers feel about how best to develop their clinical assets, it makes partnering with or being a provider to the biotech industry very dynamic. As a service provider or potential partner, perhaps the worst/ most dangerous thing you can do is to lump all biotech companies into a single market segment.



Our advice: take the time to get to know your current and/or potential biotech customers'/ partners' motivations. You will be better off targeting a few biotech companies that have needs that match those your company is most capable delivering on. This way both parties have the best chance of meeting each other's expectations. Trying to reach biotech companies with a mass market, undifferentiated, or general selling proposition is an uphill battle. There is no such thing as a typical biotech solution/ offering.

Key findings for Biotech companies

Access to Capital

According to your peers, access to capital will get easier in the coming 12 months. Over half of the respondents (60%) indicated that in the next 12 months gaining access to capital will be easier than it is today, while only 11% indicated that it would be harder.

Compound Valuation

The past 12 months have seen only a slight decrease in the value of compounds in development. However our analysis does show that companies that have accelerated their clinical development activities over the past 12 months report a much higher increase in the valuation of the compounds. The take-away is that if you have good compounds you can continue to demand solid valuations.

“Consumer Confidence”

Given the improving outlook for funding coupled with only a slight decrease in developmental compound valuations, one would expect industry confidence to be fairly high. However, biotech companies are still very cautious about the health and future of small, VC-funded biotech companies in the next 24 months.

Consolidation

There definitely exists a perception in the industry that industry consolidation is far from over. When posed with the question as to how many stand-alone companies will be operating independently in the United States and Europe in 2011, respondents indicated there would be 40% fewer companies.

Key findings for Service providers

Due Diligence

Biotech companies indicated they have found it much easier in the past 12 months to find a suitable service provider. Both the CRO industry and the Biotech industry have faced their share of hard times recently and with biotech companies not overly confident in their future, with more consolidation looming, service providers are going to have to make sure they take projects from viable entities or face disruptions to their operations and financials.

Coin Toss

Following on from the previous point, biotech companies are fairly uniformly split as to their recent clinical development activities. One might have assumed that most biotech companies had slowed their clinical development activities in the past 12 months, however our research shows that over one-third (34%) have actually accelerated their clinical development activities with 42% having slowed them. Again, while not always possible, this makes picking the right customer much more important than it was when a rising tide raised all ships.

Moving Target

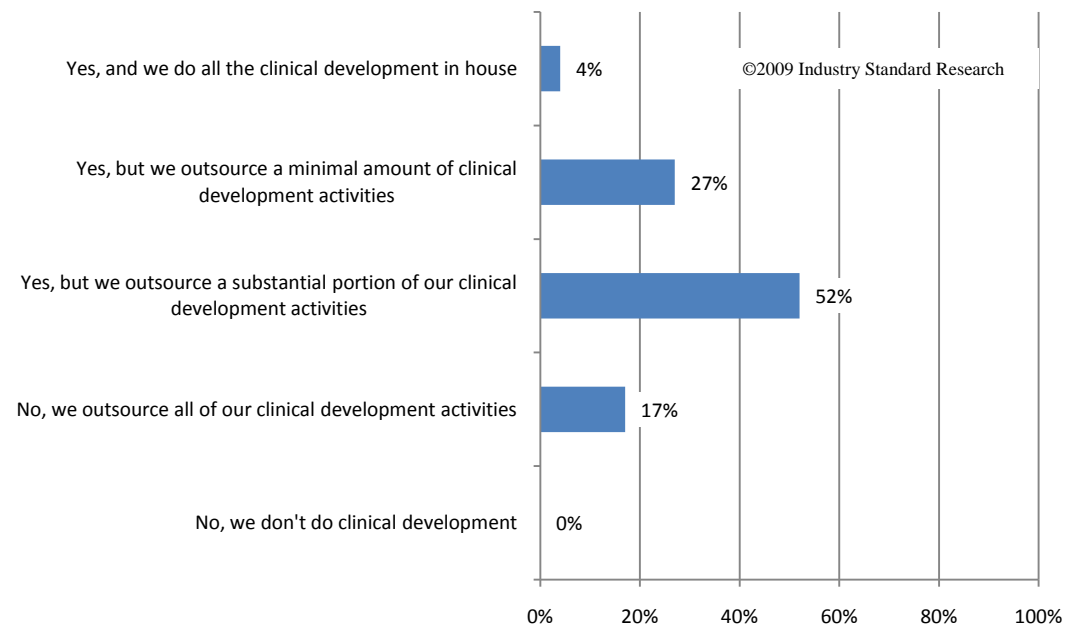
Roughly half of the biotech respondents indicated that their company has altered their CRO strategy in the past 12 months and 54% indicated that the financial health of the CRO has played a greater role in service provider decision-making.

Charts and Graphs

Respondent Demographics

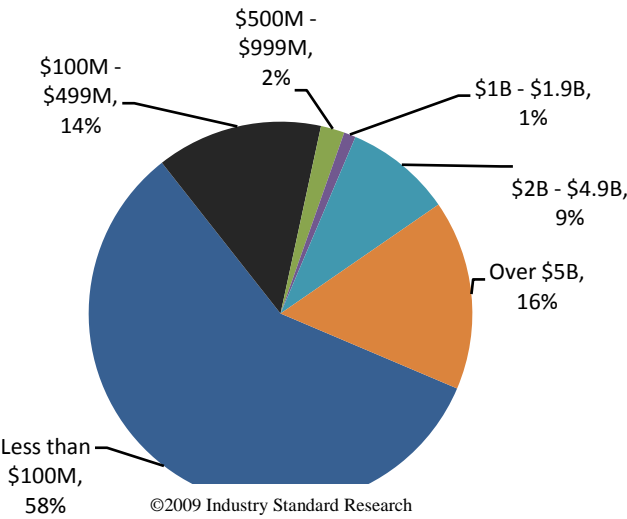
Drug Development Capabilities

Does your company have the **internal** capability to conduct clinical **development** activities?
(Base = 112 respondents)



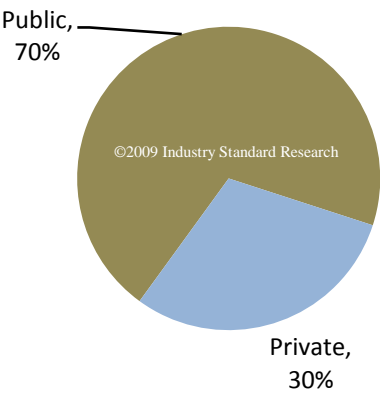
Annual Revenue

For categorization purposes only, what was your company’s approximate **annual revenue** in 2008 (\$US)? (Base = 112 respondents)



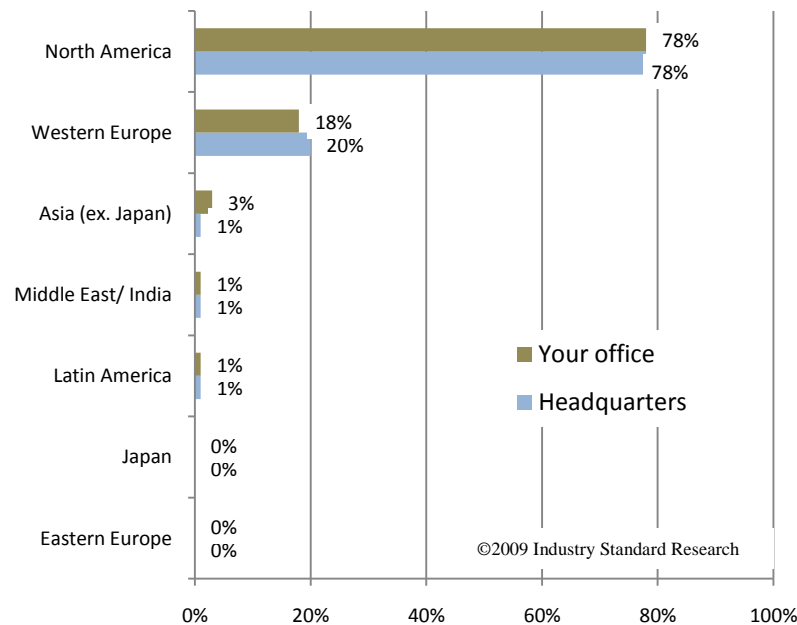
Public vs. Private

Is your company currently **publically** traded or a **private** company? (Base = 112 respondents)



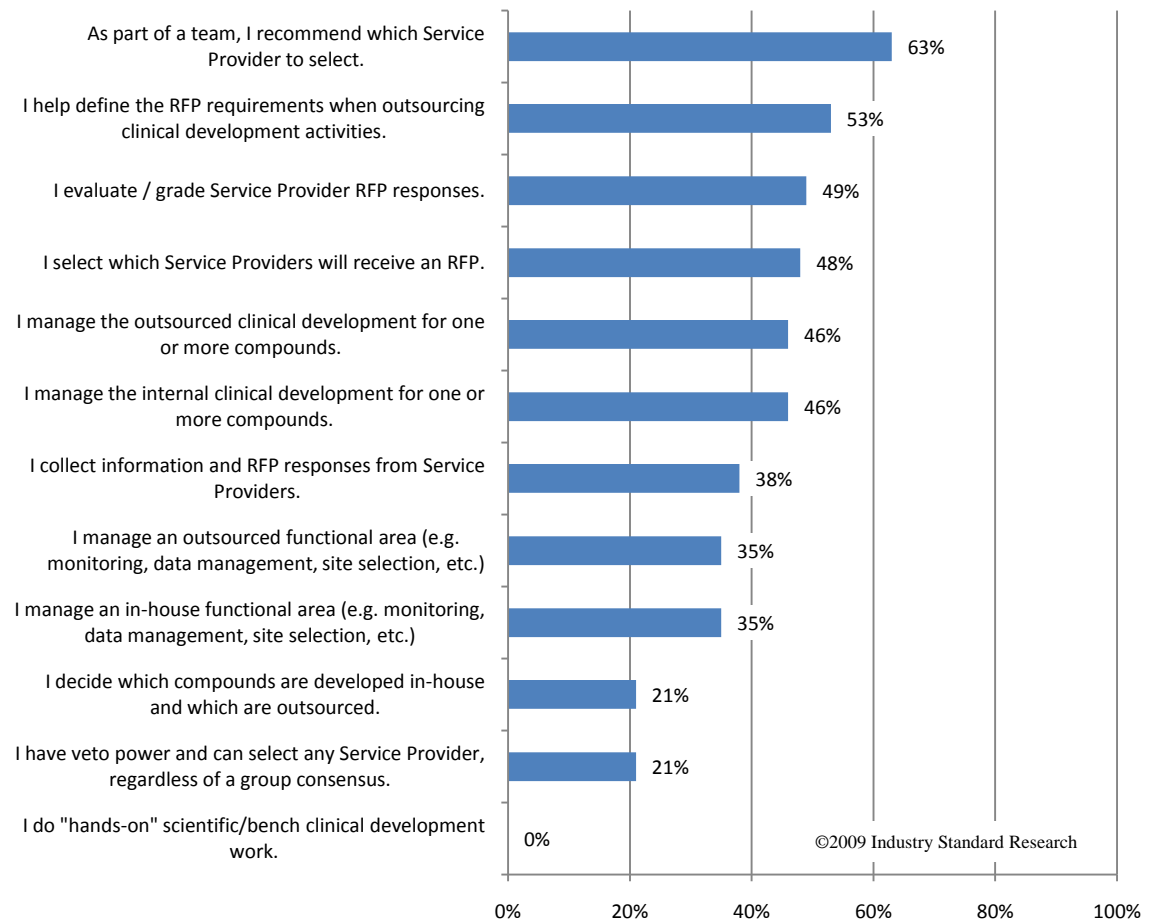
Headquarters Location

Where is your corporate headquarters **located**? (Base = 112 respondents)
 Where is your office **located**? (Base = 112 respondents)



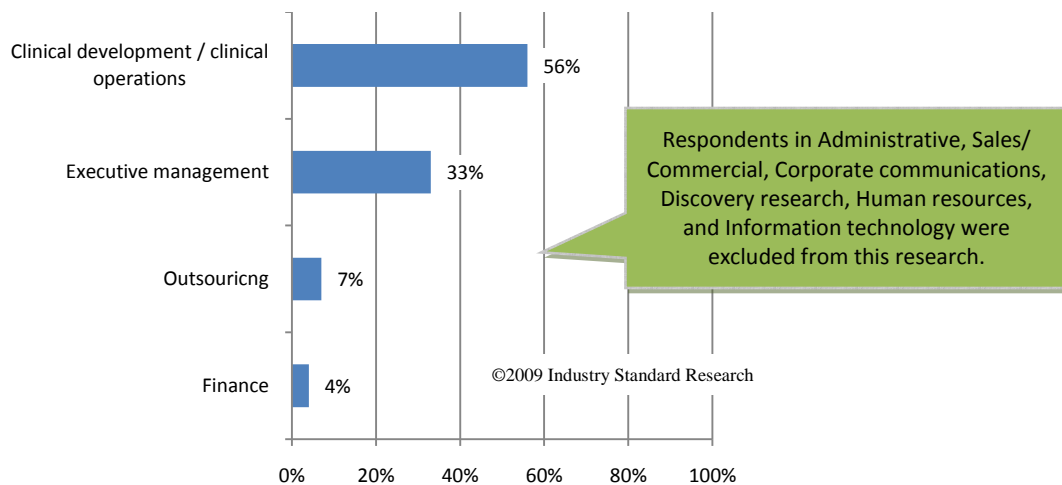
Clinical Development Responsibility

From the following list, please select as many that apply to **your responsibility** for deciding how your company's clinical development is executed? (Base = 112 respondents – Multiple responses allowed)



Department Affiliation

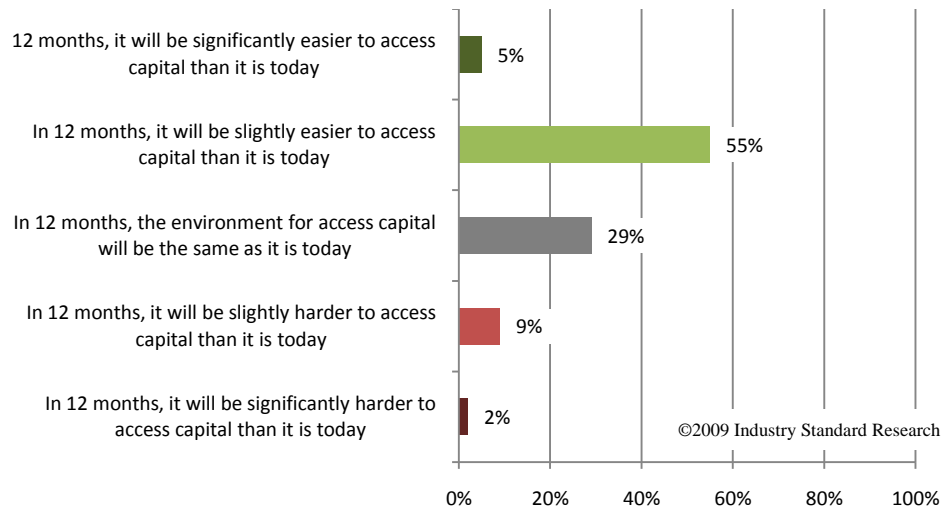
Of the **departments** listed below, which one most resembles the one in which you work?
(Base = 112 respondents)



Finance and Development Trends

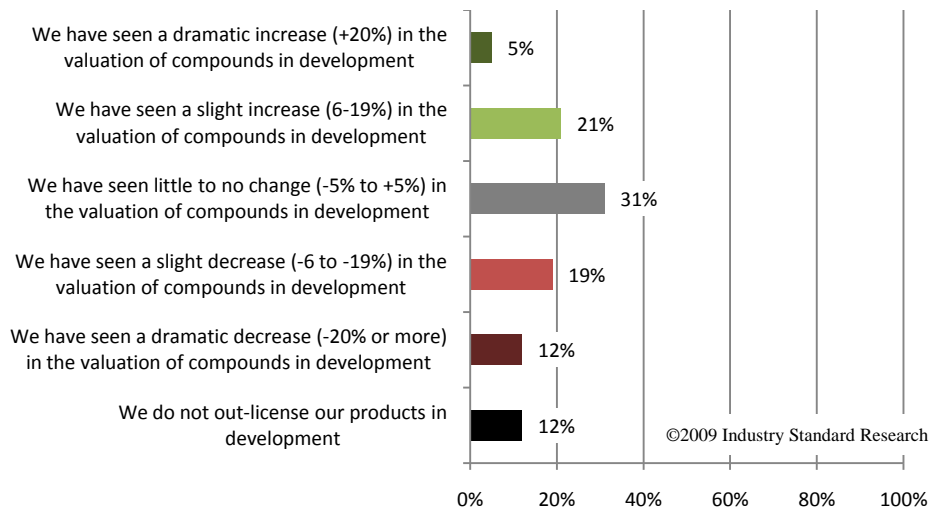
Accessing Capital

It has been well publicized in the industry press that many biotech companies have faced recent hurdles to getting access to additional funding. Regardless of your company's need to raise additional capital, how do you see the environment for accessing capital in the coming 12 months? (Base = 112 respondents)



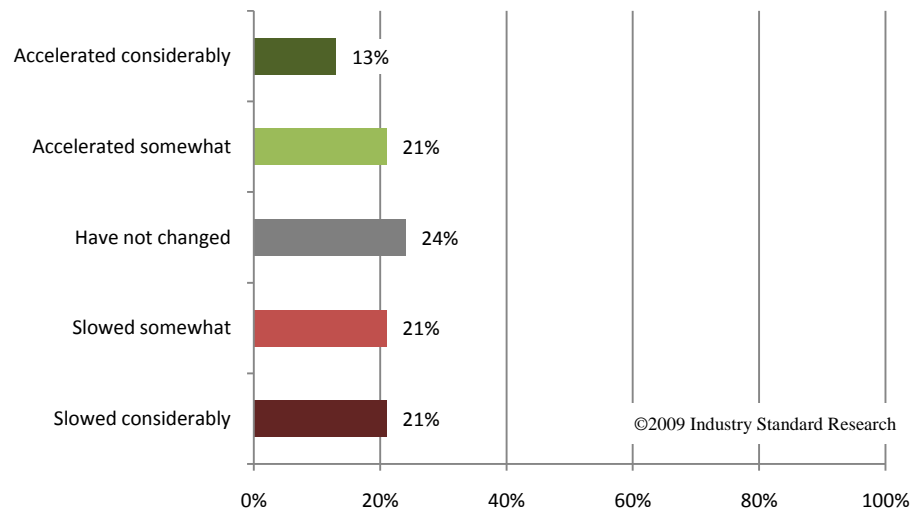
Compound Valuations

It has also been well publicized that large pharmaceutical companies are facing a shortage of good drug candidates in their pipelines, but are also hurting financially. In the past 12 months, what impact has this had on the **valuations you are seeing for your compounds in development?** (Base = 112 respondents)



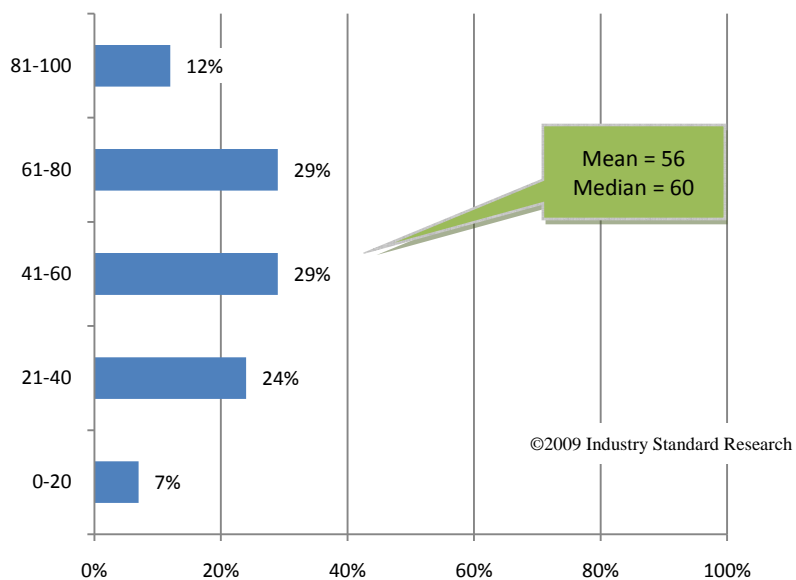
Clinical Development Progress

Over the past 12 months, have your company's **clinical development activities**....? (Base = 112 respondents)



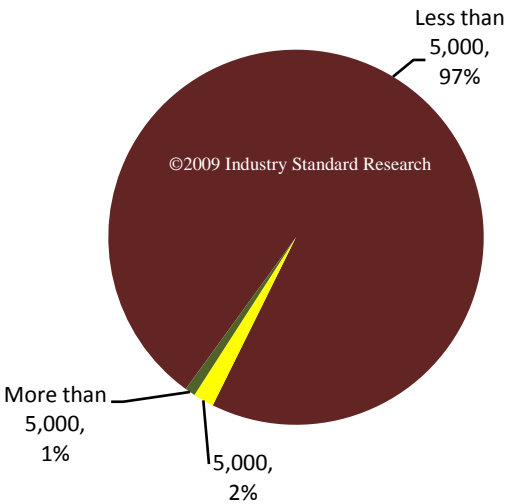
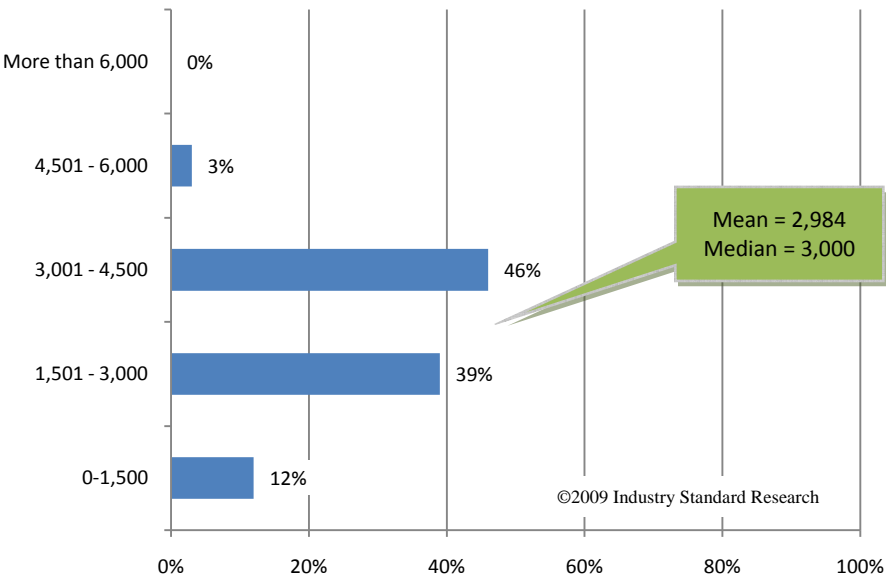
Confidence in the Model

Using a 100 point scale where 100 is "extremely confident" and 0 is "not at all confident" how **confident are you in the sustainability** of the small, VC-funded biotech industry over the next 24 months? (Base = 112 respondents)



Number of Biotech Companies in 2011

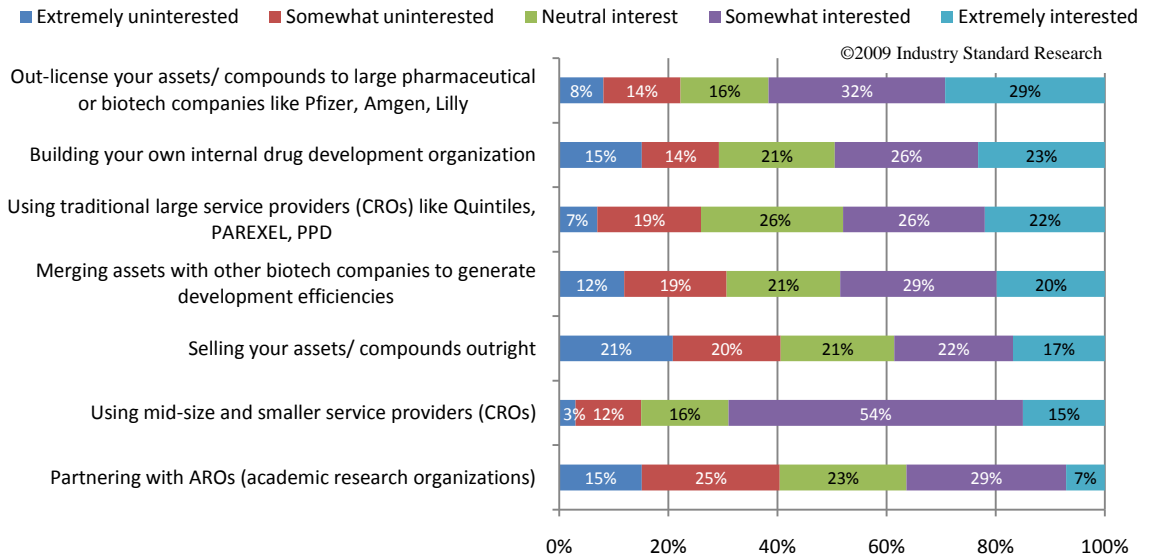
Let's assume for argument's sake that there are 5,000 biotech companies currently operating in the United States and Europe. How many do you think will be **operating as stand-alone entities** come January 2011? (Base = 112 respondents)



Development Strategies

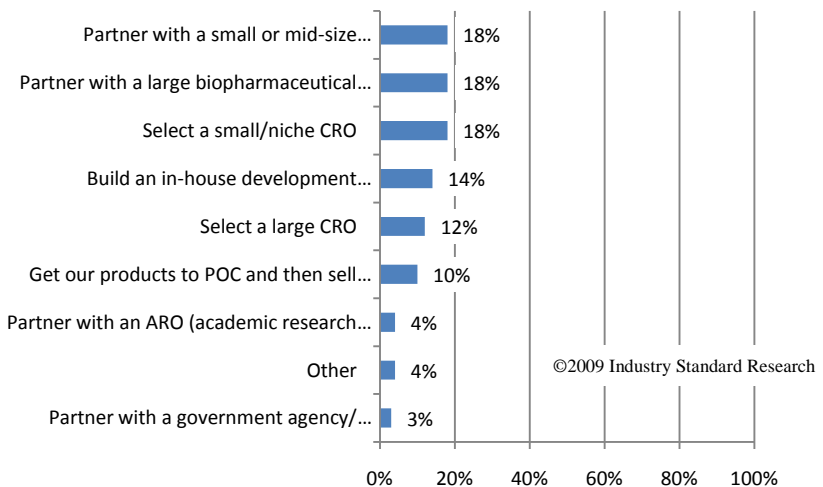
Model Interest

Given that some of the more traditional avenues to drug development could be facing problems, from the list below please indicate any change in your company's stance or **relative interest in using each drug development model/partner**. (Base = 112 respondents)



Model Preference

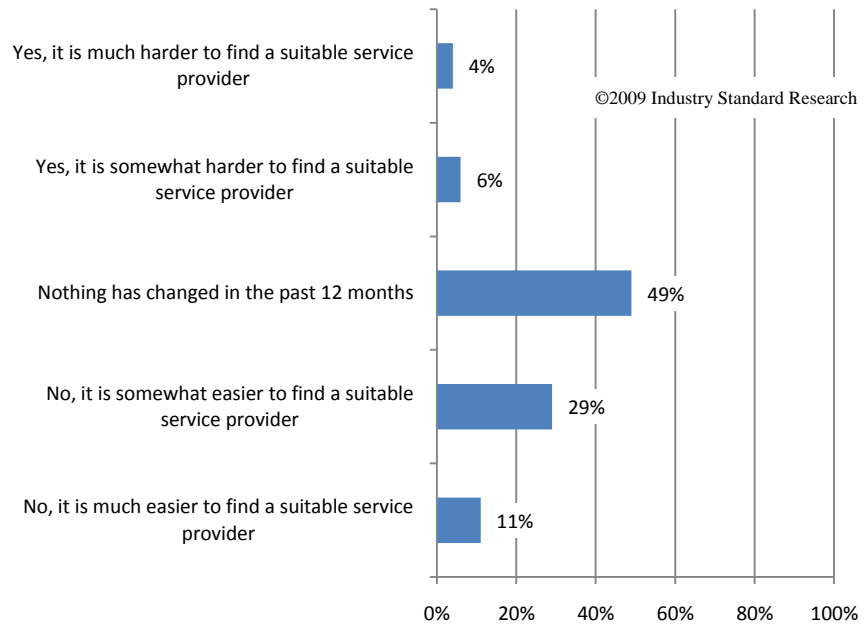
Given the current financial and environmental influences affecting the biopharmaceutical industry, political regulation uncertainty, and your company's own unique situation, how would you **personally choose to develop the clinical assets at your company**? (Base = 112 respondents)



CRO Usage Trends

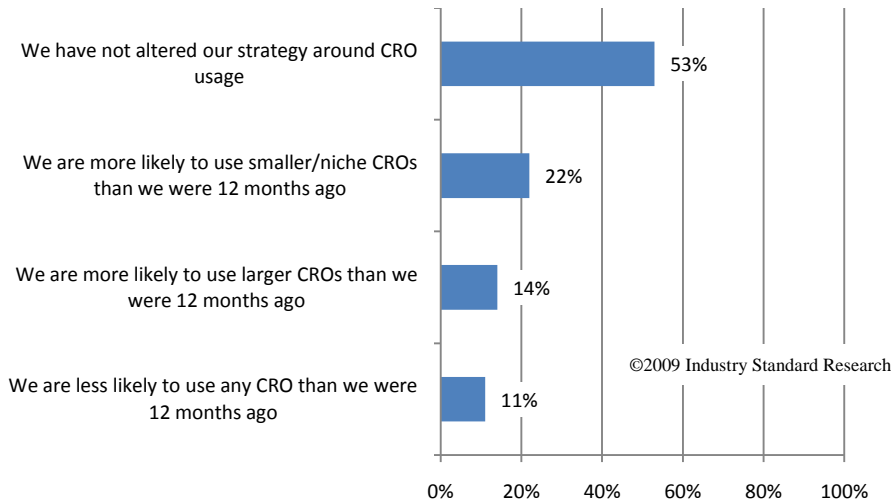
Service Provider Access

Over the past 12 months many service providers (CROs) have been struggling to meet their financial expectations. Have you found it **difficult to find service providers** that will take on a project from a biotech company? (Base = 112 respondents)



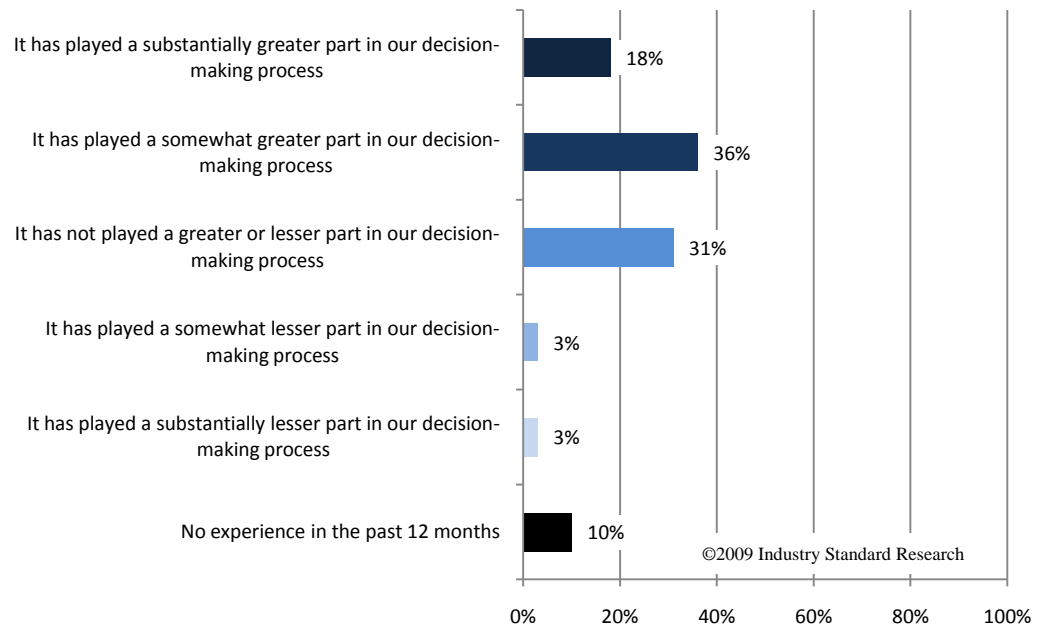
Changes in Development Strategy

Given some of the financial issues faced by many service providers, **have you altered your clinical development strategies** to account for this? Please select from the list below, the statement that best represents your current view or propensity. (Base = 112 respondents)



CRO Financial Strength

Over the past 12 months and as part of your evaluation of service providers (CROs), how important has it become to **evaluate their financial strength** as part of your decision-making process? (Base = 112 respondents)



About Industry Standard Research

Industry Standard Research (ISR) is a full service market research firm that specializes in delivering high quality research products and services to the pharma and pharma services industries. The value of our deliverables exceeds that of other research providers in part, owing to a decade of experience in the industry and in part, because of our high standards for the collection and analysis of information.

ISR maintains a focus on two service-product areas:

1. High quality syndicated reports based in substantial primary market research. The topics of these reports will be of broad market appeal such as customer satisfaction and topics of timely interest to the industry.
2. Custom market research. These are typically primary market research services delivered within the pharma services industry. We have unique and specialized skills in
 - service quality measurement
 - customer satisfaction and relationship assessment programs
 - new service / service enhancement evaluation

Recent Publications from ISR

- The 2009 CRO Quality Benchmarking Study (March, 2009)
- The 2009 CRO Quality Benchmarking Study – *CRO Selection for Biotechnology Companies* (May, 2009)

Syndicated Reports Coming Soon from ISR

September 28, 2009

An in-depth analysis of the rocky road of patient and investigator recruitment. The report will capture the experienced perspectives of 3 different stakeholders: (1) Investigators, (2) Trial Participants, and (3) Pharma/Biotech/CROs. Investigators and Trial Participants detail their motivations and barriers to participating in clinical trials and answer the important question, "If you were in charge of increasing participation in clinical trials for a drug development company, what would you do?" All stakeholders shed light on which strategies are most and least successful as well as identify any "bleeding edge" recruitment strategies.

Who should consider this report? Any pharma, biotechnology, or CRO company manager with responsibility for operational delivery of clinical trials.

Q4, 2009

Clinical Development Staff Quality and Retention – This report builds from the findings in the 2009 CRO Quality Benchmarking report and will focus on how the shifting of clinical development strategies impacts pharma and CROs. It will also gauge perceptions around how the quality of pharma internal development staff compares with CRO staff. With lay-off announcements hitting the wires daily and the baby boomers retiring, is the pharma industry in danger of losing its intellectual capital?

Who should consider this report? Pharma, biotechnology, and CRO companies who want to know who leads the pack in terms of staff quality, turnover, experience and perceived performance.

To find out more about Industry Standard Research, visit www.ISRreports.com. Or contact us toll free in the United States at 1.877.274.0590 or internationally at +1.919.301.0106 or by email at info@ISRreports.com.



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