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Outsourcing in
Life Sciences
*A Survey of
BayBio Members*



FOREWORD

This report represents an empirical assessment of clinical development outsourcing among BayBio members and life science and pharmaceutical firms outside the San Francisco Bay area. It looks at practices and decisions controlling clinical development outsourcing today and provides insights for companies that want to realize the full benefits of outsourcing.

For several years, Booz & Company has worked with clients to devise outsourcing strategies and implement novel, broad-reaching outsourcing alliances across clinical development and other research and development activities. Clinical research organizations (CROs) have become increasingly important development partners for pharmaceutical developers of all sizes. Yet relationships are not always ideal, and both sides of these

partnerships express frustration over lost opportunities.

This issue has consistently been of interest to BayBio, which strives to help its membership develop fruitful relationships with CROs and other industry players. We hope this report provides a useful sense of the trends at work and some guidance for industry leaders looking to define approaches to clinical development outsourcing.

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EXECUTIVE SUMMARY

Emerging life science companies and large pharmaceutical firms have much to gain from outsourcing clinical development programs. Until recently, research and development represented the core of a life science company and was considered too valuable to hand off to others.

Today, under growing business pressure to cut costs and speed development of new products, the industry is increasingly turning to outside clinical research organizations (CROs) to provide specific capabilities and added capacity when needed. Clinical development outsourcing is likely to continue to grow and spread to different parts of the globe as drugmakers seek long-term strategic partnerships with outsourcers, including IT providers.

INTRODUCTION

BayBio members outsource a significant portion of clinical development to CROs in the United States and abroad. Recent discussions with BayBio members and Booz & Company clients suggest that companies may be looking to increase the amount of work they outsource and that the structure of CRO partnerships is evolving. Further, new CRO solutions in emerging markets raise the question of where future clinical outsourcing activities will take place.

In July 2011, BayBio and Booz & Company agreed to launch a collaborative study to gain insight into clinical development outsourcing practices among BayBio members. This empirical work is based on a short Web survey and a series of interviews conducted by members

of Booz & Company's life science practice. Key findings include the following:

- Survey respondents expect growth in R&D outsourcing.
- Though the majority of outsourcing is in the United States and western Europe today, future growth is expected to occur overseas, largely in China and India.
- Internal business pressures, including a lack of internal capabilities and capacity and a need to cut costs, were the most frequently cited reasons that firms decide to outsource.
- Growth in outsourcing will be accompanied by a focus on reliable, on-time, accurate services. Drug developers report they are willing to pay more for high-quality service.
- Companies outsource to reduce costs, access new patient samples, and meet regulatory requirements.
- CROs help compensate for internal constraints and should become long-term strategic partners offering top-quality service.
- Most respondents find that CROs have significant opportunities to create value, particularly if they deal with patient recruitment issues, respond to specific customer needs, have regulatory expertise and communications savvy, and create flexible service plans catering to small companies.
- When selecting an outsourcing vendor, the majority of respondents (61 percent) seek a long-term strategic relationship rather than a looser transactional or partnership arrangement.
- High-quality, reliable service is paramount to price, geography, and both regulatory and technological expertise.
- Finally, BayBio members are interested in IT-enabled offerings, but only if the central issue of security is clearly solved.

LIFE SCIENCE OUTSOURCING TRENDS

Life science companies have emerged from the genetic revolution that was ushered in during the 1980s and are gaining momentum as new and powerful technological breakthroughs create commercial blockbuster drugs and new market opportunities.

At first, life science companies were primarily research-based organizations, with strong laboratory capabilities but little in the way of clinical development, trial management, and go-to-market capabilities. In addition, early-stage life science companies lacked manufacturing capabilities because their focus was on small product lots required for research and initial clinical work.

To make up for these capability shortfalls, companies either added people and processes as needed or partnered with larger pharmaceutical companies that already had deep and broad capabilities. Pharmaceutical companies and emerging life science firms turned to licensing, joint development, equity investments, and, in some cases, mergers.

After this first era of expansion, a few life science companies decided to

“go it alone,” giving rise to third-party providers to fill the capability gap while allowing young life science companies to remain independent and in control of their development trajectory. A dedicated cadre of CROs emerged to provide missing capabilities “on demand,” typically through “work-for-hire” arrangements.

In parallel, the largest pharmaceutical companies were increasingly looking to capture any growth that their own research efforts might enable. Even the largest among them, however, could not reach every global market opportunity. Meanwhile, increasing business and cost pressures were forcing pharmaceutical companies to be selective in the breadth and scale of in-house capabilities. Pharmaceutical companies began to explore the use of CROs to “staff to the peak,” allowing them to vary personnel levels as specific trials demanded additional resources for set periods of time.

Today these two trends—life science companies’ need to add capability, and pharmaceutical companies’ desire to vary and offload capabilities—are fueling the growth of large, capable third-party CROs. These industry players are building out their own capabilities to take on an increasing amount of work for life science and pharmaceutical companies.

In this context, BayBio and Booz & Company decided to explore trends in life science clinical outsourcing. Our main survey questions were the following:

1. Is it true that life science companies expect to increase their clinical outsourcing activities?
2. If so, what are the major drivers of this?
3. Are there geographic reasons for seeking third-party capability assistance?
4. What is the role of CROs in life sciences today, and how is that expected to change going forward?
5. What do the life science companies want to see from their CRO partners? What do they want to see more of? What do they want to see less of?
6. What are the potential partnership arrangements between life science companies and CROs?
7. What arrangements are likely to become more widespread going forward?
8. Beyond clinical development outsourcing, what other emerging capabilities do life science companies look for in research and development?
9. What is the role of the cloud in opening up new avenues for data management, collaborative research, and big-data computing?

SURVEY FINDINGS

Generally, survey respondents expect R&D outsourcing to grow and shift geographically from the United States and western Europe, where most research is done today, to other parts of the world—specifically, China and India.

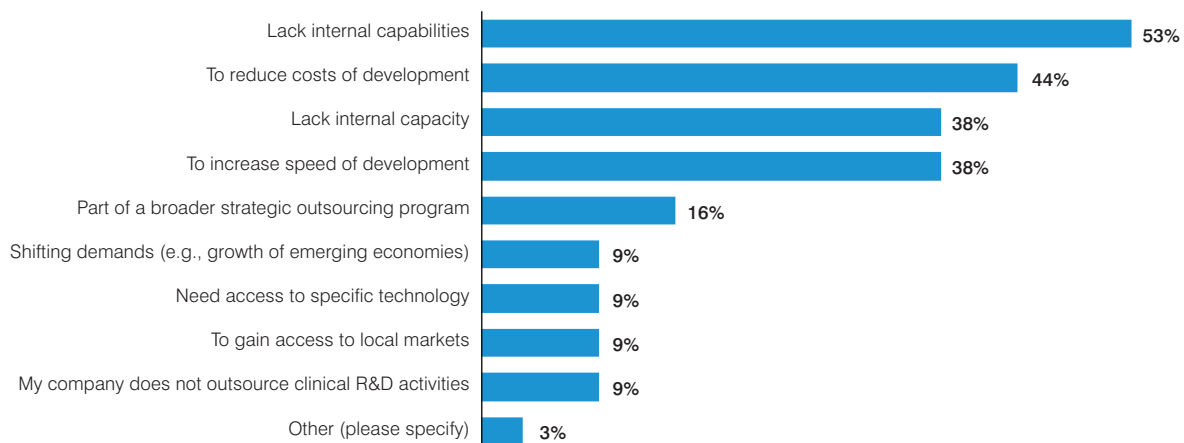
For many companies, a lack of internal capabilities drives the decision to outsource. Companies view using CROs as a way to

compensate for internal constraints, if the CROs can offer a long-term strategic relationship and provide top-quality service.

Internal company pressures were the most frequently cited reasons that firms decide to outsource (*see Exhibit 1*). Fifty-three percent of respondents reported that they would turn to outsourcing to make up for a lack of internal capabilities

Exhibit 1
Reasons for Outsourcing Clinical Development Activities

**WHAT ARE THE KEY REASONS THAT YOU CHOOSE TO OUTSOURCE CLINICAL DEVELOPMENT ACTIVITIES?
(FREQUENCY OF ANSWER—MULTIPLE ANSWERS ALLOWED)**



Source: Booz & Company and BayBio Outsourcing Survey 2011; Booz & Company analysis

or capacity while 44 percent cited a desire to reduce costs of development.

Increasing use of CROs is likely to be accompanied by a focus on quality. Pharmaceutical and biotechnology managers said they are willing to pay more for outsourcers that

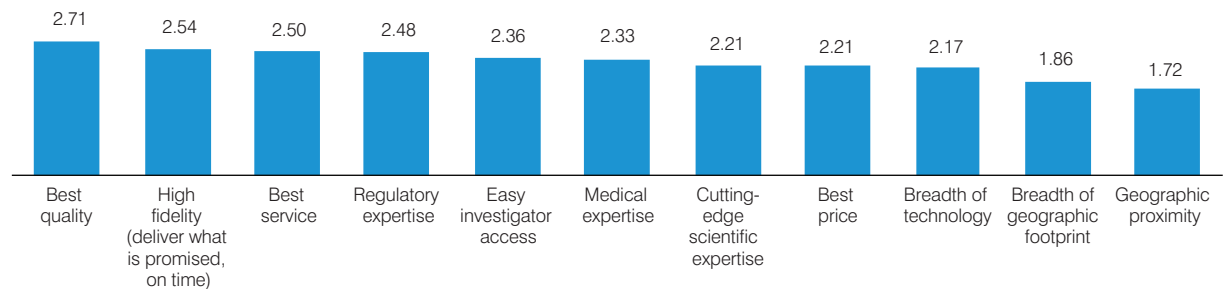
provide reliable, on-time, and accurate services (*see Exhibit 2*). Life science companies look to CROs to lower costs, access new patient samples, and comply with complex regulatory requirements.

Most respondents believe that using CROs could improve their value

proposition. Life science executives surveyed were most interested in using CROs that are able to deal with patient recruitment issues, respond to specific customer needs, demonstrate strong regulatory and communications expertise, and offer flexible service designed for small companies.

Exhibit 2
CRO Selection Criteria

WHEN THINKING ABOUT CRITERIA TO SELECT POTENTIAL VENDORS FOR OUTSOURCING OF CLINICAL DEVELOPMENT ACTIVITIES, HOW WOULD YOU RATE EACH OF THE FOLLOWING? (AVERAGE SCORE OF RESPONSES)



3 = Basic qualifier (vendor *must* have)
2 = Competitive differentiator (vendor *should* have)
1 = Not important

Source: Booz & Company and BayBio Outsourcing Survey 2011; Booz & Company analysis

When selecting an outsourcing vendor, the majority of respondents (61 percent) are interested in developing a long-term strategic relationship, not simply maintaining a loose transactional or partnership arrangement (see Exhibit 3). The

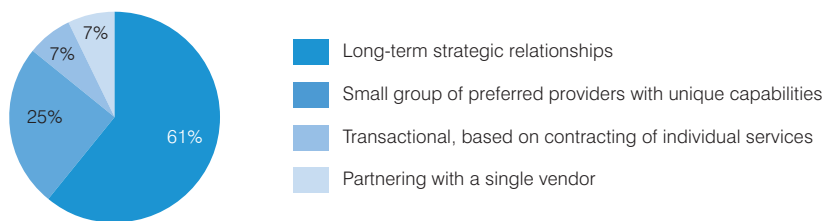
most important characteristic for a vendor is the ability to provide high-quality, reliable research and development work, described by respondents as “best quality,” “high fidelity,” and “best service.” This capability is paramount to price,

geography, and both regulatory and technological expertise.

When asked about the outlook for outsourcing, an overwhelming number of survey respondents said they expect growth. Two-thirds

Exhibit 3
Preferred CRO Relationship Structure

PLEASE SELECT ONE ANSWER FROM THE FOLLOWING: IN AN IDEAL WORLD, WHAT FORM WOULD YOUR CRO RELATIONSHIPS TAKE? (ABSOLUTE RESPONSES)



Source: Booz & Company and BayBio Outsourcing Survey 2011; Booz & Company analysis

anticipate “more” outsourcing in the future (see Exhibit 4). A number of factors underlie this expectation. First, limited budgets at biotechnology and pharmaceutical firms will push companies to reduce costs by outsourcing. In addition, life science

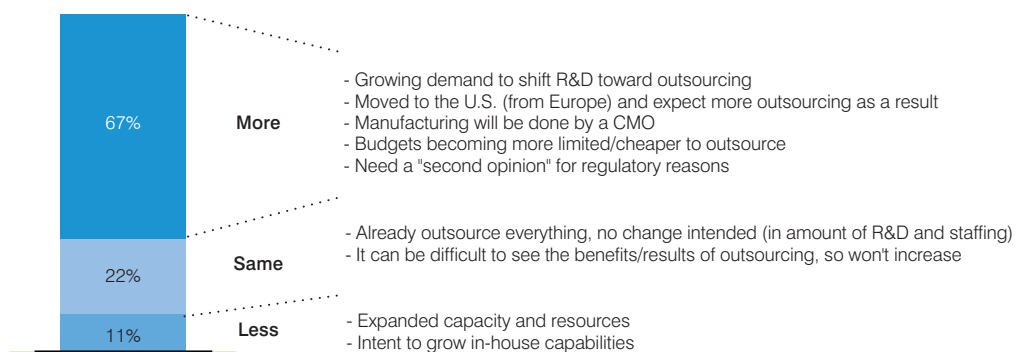
companies could use outsourcing vendors as an unbiased external party in clinical study design and execution. Third, growing acceptance of R&D outsourcing and the use of overseas vendors makes firms more comfortable with the deci-

sion to outsource. Only 11 percent expect less outsourcing, citing growing internal budgets and the intent to grow capabilities in-house.

Though the majority of clinical trials currently are done in the

Exhibit 4
Expected Trends in Clinical Development Outsourcing

HOW DO YOU EXPECT YOUR OUTSOURCING PREFERENCES TO CHANGE IN THE FUTURE (MORE, LESS, THE SAME) AND WHY? (RELATIVE RESPONSES AND OPEN ANSWERS)



Source: Booz & Company and BayBio Outsourcing Survey 2011; Booz & Company analysis

United States, China and India are most often identified as countries where growth is expected (see Exhibit 5). Some growth will occur in Europe, but the number of U.S. trials will be flat going forward, according to those surveyed. By geography, the location of trials today is inversely correlated

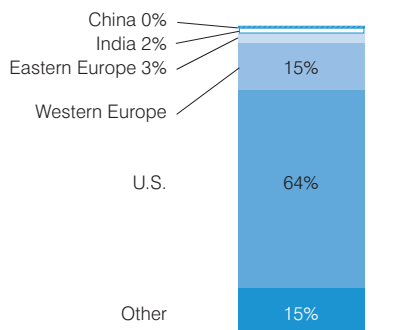
with growth expectations. China and India conduct very few trials now but are projected to experience the most growth in the next two to three years.

The research shows that companies send trials overseas for three main reasons: as part of a regulatory

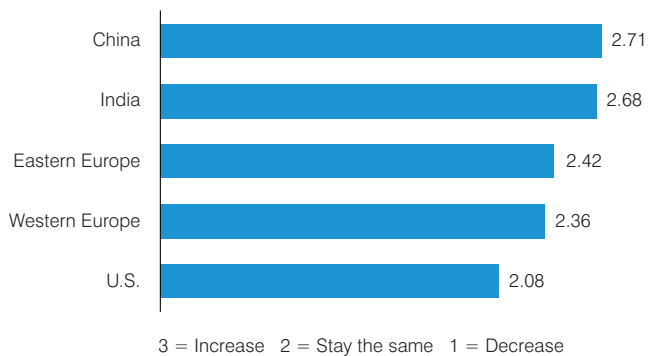
approval strategy (36 percent), to cut costs (23 percent), and to gain access to patient samples (23 percent). No response dominates, suggesting that a variety of underlying preferences of biotechnology and pharmaceutical firms will drive outsourcing overseas (see Exhibit 6, page 9).

Exhibit 5
Current and Future Geographic Patterns for Clinical Development Outsourcing

WHAT PERCENTAGE OF YOUR TRIALS ARE CURRENTLY BEING CONDUCTED IN THE COUNTRIES LISTED BELOW? (RELATIVE RESPONSES)



HOW DO YOU SEE THE MIX OF CLINICAL TRIALS SHIFTING ACROSS THE FOLLOWING GEOGRAPHIES IN THE NEXT 2 TO 3 YEARS? (AVERAGE SCORE OF RESPONSES)



Note: "Other" includes the rest of Asia, Canada, Australia, New Zealand, and South America. Numbers may not add up due to rounding.
 Source: Booz & Company and BayBio Outsourcing Survey 2011; Booz & Company analysis

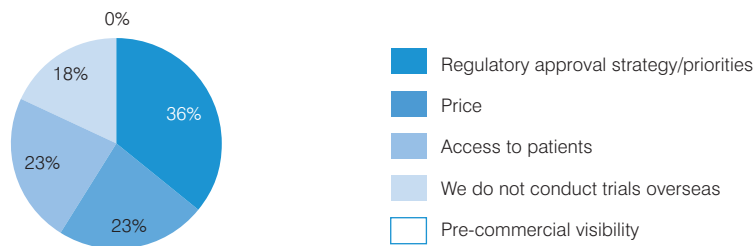
In short, our study suggests that clinical development outsourcing will continue to expand. As the outsourcing market matures, however, we expect to see a shift in the nature of outsourcing relationships—from transactional to strategic—as drug developers decide which capabilities should be outsourced and which should stay in-house.

In parallel with the BayBio survey, Booz & Company has done a more in-depth study in collaboration with ICON, a leading CRO. Based on interviews with key industry executives, this research sheds additional light on the drivers and constraints for clinical development outsourcing. Findings from the ICON study are as follows:

- While pharmaceutical executives differ significantly in their views and preferences for CRO partnerships, the trend toward outsourcing will continue to increase.
- Current outsourcing strategies vary along four key dimensions: what work is outsourced, why it is outsourced, how outsourcing is

Exhibit 6
Primary Reasons for International Outsourcing of Clinical Development Activities

**WHAT IS YOUR PRIMARY REASON FOR CONDUCTING TRIALS OVERSEAS?
(RELATIVE RESPONSES)**



Source: Booz & Company and BayBio Outsourcing Survey 2011; Booz & Company analysis

done, and the level of innovation required from a CRO.

- Drug companies tend to retain design and analytic competencies while outsourcing clinical monitoring activities, data management, and central labs.
- Only half of those interviewed appear to have thought through a broad-based, strategic approach to clinical outsourcing.
- Several companies find that in spite of their best intentions to establish strategic partnerships with CROs, dialogue remains at an operational level.

Pharmaceutical companies welcome the opportunity to align capabilities with CROs at a strategic level. They are looking to work with CROs that have clearly defined capabilities, such as high-quality service and execution, talent models that

encourage retention, and the ability to use proprietary data to enhance recruiting and efficiency.

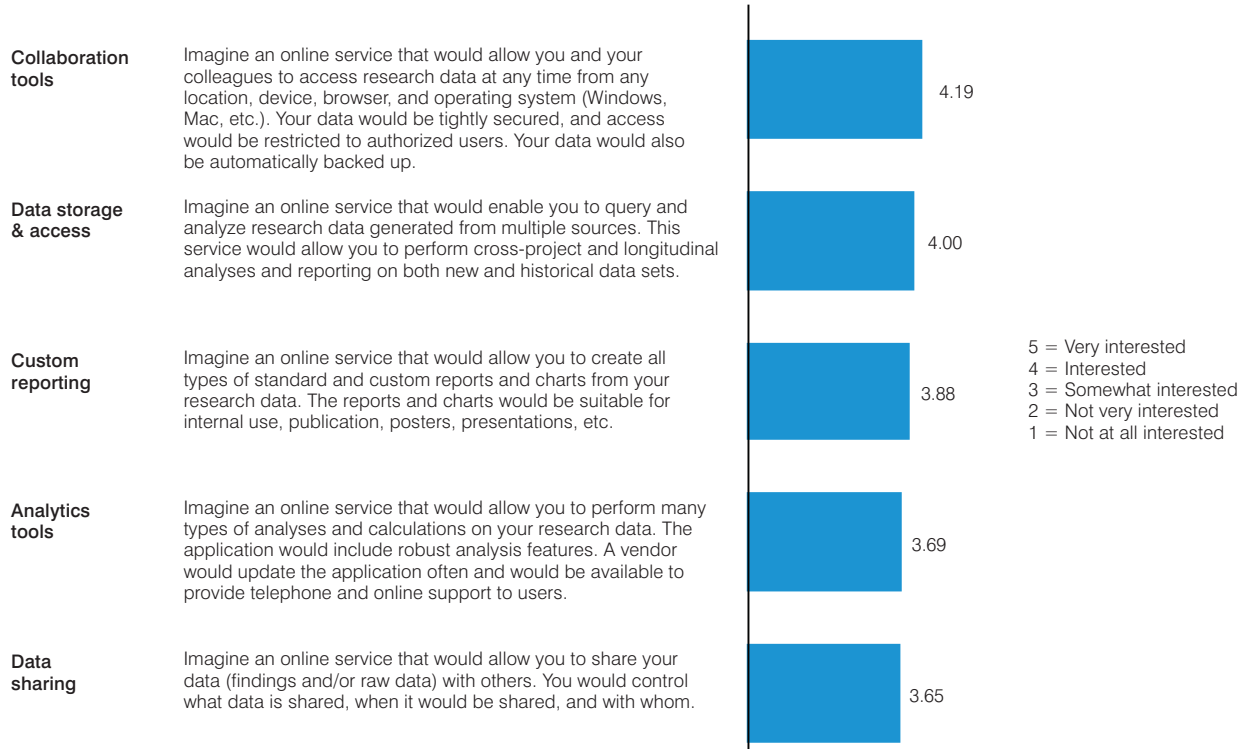
In addition to our focus on the broader issue of clinical research and development outsourcing, our study asked BayBio members specific questions regarding their views on the emerging use of third parties for data collection, management, and analysis. Following breakthroughs in cloud computing, big-data analytics, and collaborative workflow technologies, IT companies increasingly are approaching the industry to take on some of the burden of clinical research and development, and we sought to assess respondents' views on this topic. We presented a list of new products and services and asked BayBio members which would interest them. Most respondents expressed at least some interest in collaboration tools and data storage and access (*see Exhibit 7, page 11*).

We then asked BayBio members to detail what would be most important to them in these new IT-enabled approaches to clinical research and development. The response was in line with what Booz & Company sees in other industries considering transitions to cloud-based offerings.

First, security is a critical issue that must be addressed before BayBio members will consider migrating any data and analysis to a third-party platform. Interviews confirm that this concern stems not only from the regulatory framework surrounding life science data collection and use but also from the competitive advantage derived from confidential data and insights in this industry. However, BayBio members point to a wide range of factors they consider important in future decisions regarding IT-enabled offerings (*see Exhibit 8, page 11*).

Exhibit 7
Service Preferences in Data Collection, Management, and Analysis

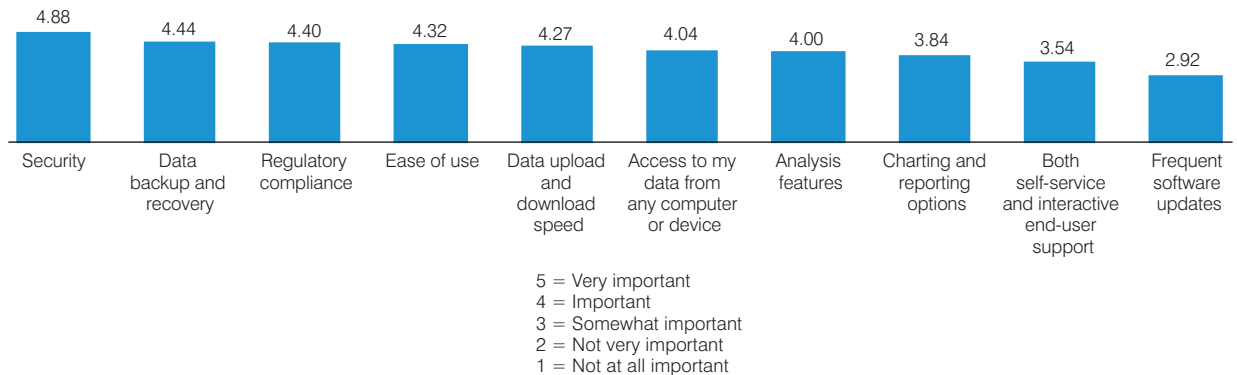
**HOW INTERESTED WOULD YOU BE IN THE FOLLOWING SERVICES?
 (AVERAGE SCORE OF RESPONSES)**



Source: Booz & Company and BayBio Outsourcing Survey 2011; Booz & Company analysis

Exhibit 8
Criteria for Online Services for Data Collection, Management, and Analysis

**HOW IMPORTANT ARE THE FOLLOWING FEATURES REGARDING THE ONLINE (INTERNET-BASED) SERVICES MENTIONED
 IN THE PREVIOUS QUESTION?
 (AVERAGE SCORE OF RESPONSES)**



Source: Booz & Company and BayBio Outsourcing Survey 2011; Booz & Company analysis

SUMMARY OF FINDINGS

In conclusion, key findings of our survey of BayBio life science companies suggest continued growth in clinical development outsourcing, with a significant amount of growth occurring overseas. The need for external capacity and capabilities is a key driver of outsourcing today, with a significant focus on reliable, on-time service.

Current CRO relationships appear to leave significant room for improvement. Patient recruitment, customer-centricity, regulatory compliance, and flexibility of service plans were mentioned as particular areas in which CROs could do a better job. Overall, as companies look to CROs as the answer to internal constraints, they would also like to shift emphasis from today's transactional relationships to long-term strategic development partnerships.

Finally, BayBio members are also interested in IT-enabled offerings, but only if the central issue of security is resolved.

References

"Big Pharma's Uncertain Future," by Alex Kandybin and Vessela Genova (*strategy+business*, Nov. 23, 2011). www.strategy-business.com/media/file/00095-Big-Pharma-Uncertain-Future.pdf

"Nimble Partnerships in the Pharma Industry," by James McSweeney, Matthew Le Merle, Anna Pettersson, and Tara Churik (Booz & Company, 2011). www.booz.com/media/uploads/BoozCo-Partnerships-Pharma-Industry-CRO.pdf

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Acknowledgments

The authors would like to acknowledge the contributions of the BayBio member companies that participated in Booz & Company's Web-based survey and one-on-one interviews, which form the research basis for this report. Additionally, we would like to thank those companies that made themselves available for in-depth interviews that validated the empirical survey findings.

Finally, we would like to thank the following individuals for their valuable contributions to the study and this Leading Research: Alex Corzo, Ford Kerr, Chris Pencavel, Anna Pettersson, and Brian Robinson of Booz & Company and Jeanne Bertonis, Travis Blaschek-Miller, and Misha Tsirulnikov of BayBio.

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