The 2016 Avoca Report

Strategic Partnerships Under Scrutiny:

A Renewed Look at the State of
Clinical Outsourcing

**SPONSOR & PROVIDER
PERCEPTIONS**

Avoca
THE AVOCA GROUP

October 2016

Introduction

Each year, The Avoca Group surveys industry executives and managers to understand trends in clinical development, with a particular focus on outsourcing dynamics and relationships between research Sponsors and Providers.

In this year's industry review, Avoca examined Strategic Partnerships to explore Sponsor and Provider objectives, expectations and the impact they have had on clinical outsourcing. Specifically, we sought to understand how Sponsor and Provider perspectives have evolved since we last examined the topic in 2012, and how the Strategic Partnership landscape may further evolve in the next five years.

This report summarizes the key findings from our research.

Usage Guidelines

No reproduction of the information in this report may be made without the express prior written consent of The Avoca Group. All inquiries and requests for consent for reproduction and use, including integrating elements of this report into the recipients' own work products (e.g., presentations), should be directed to Lakshmi Sundar via email at Lakshmi.Sundar@theavocagroup.com.

CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP

Clinical Outsourcing and Strategic Partnering Landscape

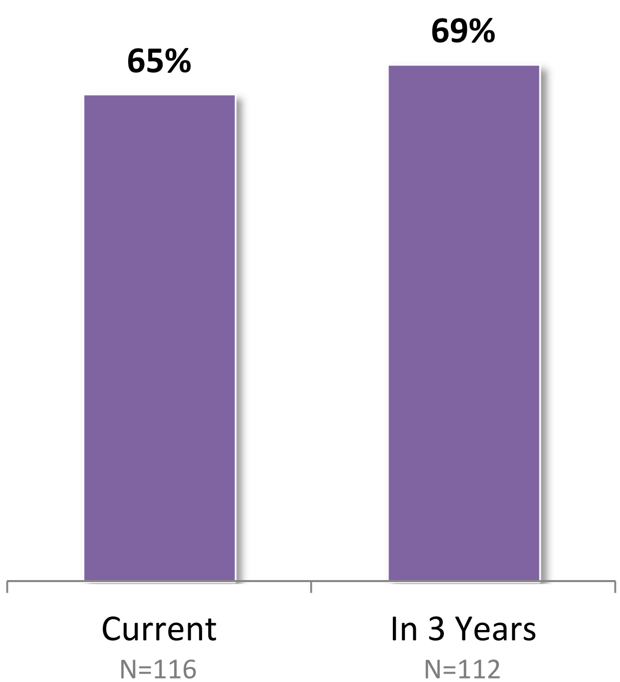
Key Findings:
Clinical Outsourcing and Strategic Partnering Landscape

- Clinical outsourcing continues to increase, with large CROs conducting half of outsourced work.
- Sponsor-Provider relationships vary, with nearly equal numbers engaging in partnerships, preferred and transactional relationships.
- Over the past five years, the reported utilization of Strategic Partnerships as a clinical outsourcing approach has increased, with mid and large Sponsor organizations reporting the greatest increase in usage.

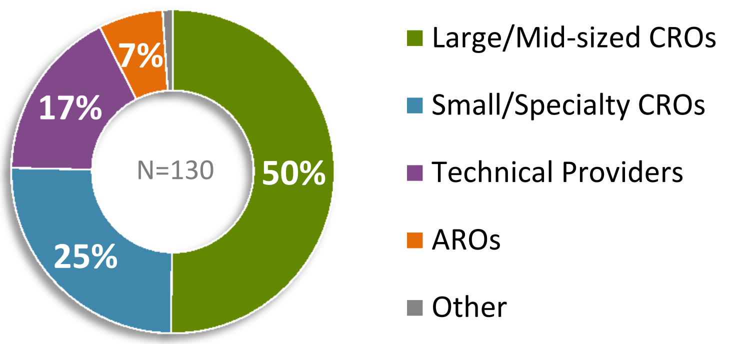
Current State of Clinical Outsourcing

Today, two-thirds of clinical development spend is reported to be outsourced, with a modest increase expected in the near future. Half of these dollars are going to larger CROs; relationship types vary.

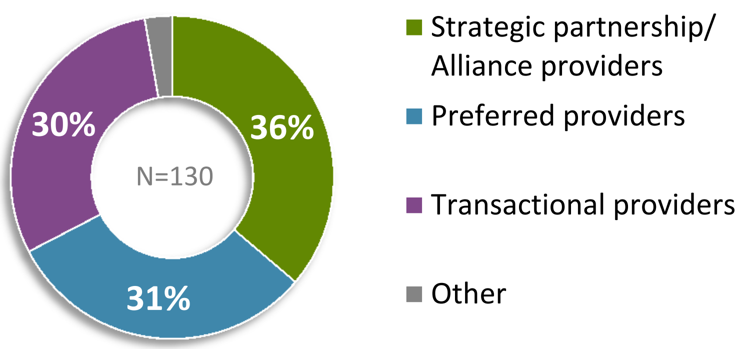
Proportion of Outsourced Clinical Development Spend Among Sponsors



Spend by Provider Type



Spend by Provider Relationship



Approximately what percentage of your company's spend on clinical development was outsourced in 2015, and what do you expect the percentage will be 3 years from now? Approximately what percentage of your company's outsourced spend on clinical development was allocated to each of the following types of Clinical Service Providers in 2015? Thinking of the Clinical Service Providers your company has used in 2015, approximately what percentage of your outsourced spend was awarded to providers with which your company has each of the following types of relationship?

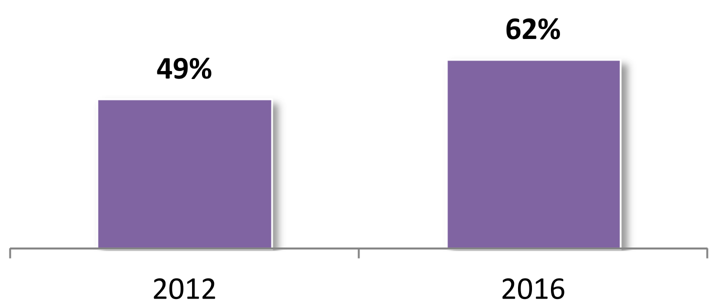
CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP

Evolution of the Strategic Partnering Landscape

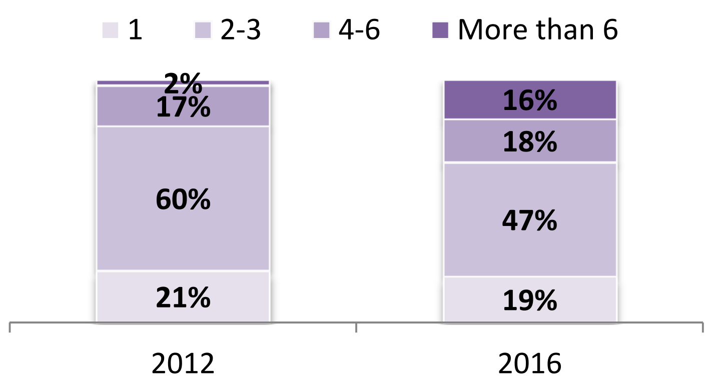
Strategic Partnering (SP), and the number of such relationships, is reported to have increased since 2012. Among those not engaging in SPs, lack of proper resources to establish and manage the partnership were top reasons.

SPONSOR

% with Strategic Partnerships with Providers

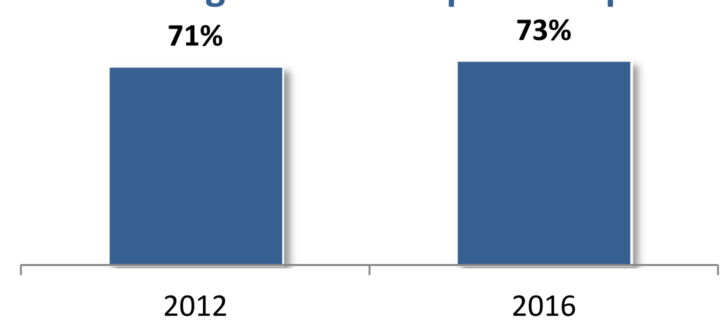


Current Number of Strategic Partnerships

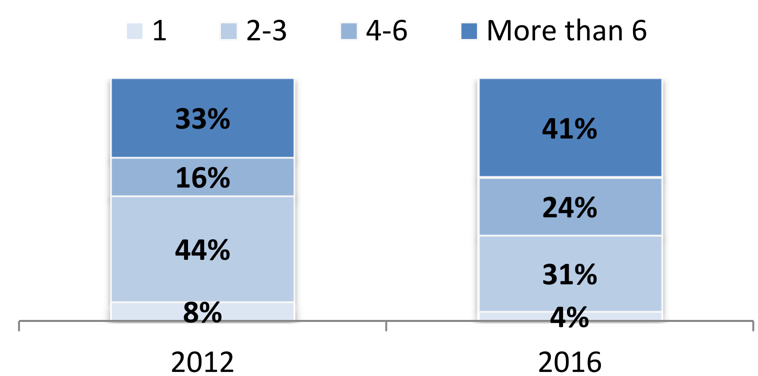


PROVIDER

% with Strategic Partnerships with Sponsors



Current Number of Strategic Partnerships



N: Sponsors=126/68; Providers=83/49

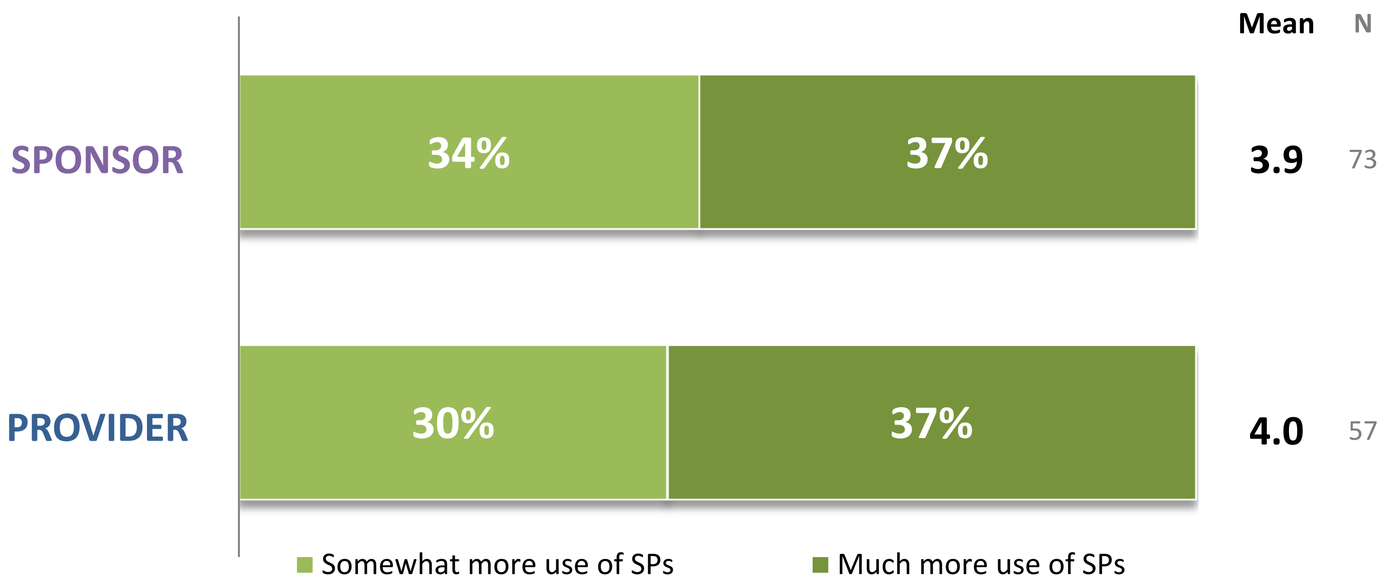
Does your current company have, or has it had, any strategic partnerships with Clinical Service Providers/Sponsors? How many SPs with Clinical Service Providers/Sponsors does your company currently have? (2012 results based on one response per company)

CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP

Five Year Trend in Strategic Partnering

Sponsor and Provider perceptions of the utilization of SPs align well to reported numbers of these relationships, and are also closely aligned to each other. Larger Sponsor organizations reported a greater increase of SPs than did smaller.

Change in Use of Strategic Partnerships in Past 5 Years



Sponsor Size	Mean
Large/Mid *(N=53)*	4.1
Small *(N=18)*	3.1

Compared to 2010, how, if at all, has your company's use of strategic partnerships changed? Has your company made…

CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP

Strategic Partnering Objectives & Performance

Key Findings:
Strategic Partnering Objectives and Performance

SPONSOR

- Sponsor objectives for entering into partnerships continue to be economically focused; reducing cost and increasing efficiency.
  - Quality is lower on the list, and has shown decline since 2012.
- Aspects of partnerships that were selected most often as key objectives are slower to be realized and show less favorability in meeting expectations relative to some of the more “functional” attributes (such as global capabilities).
  - An upward trend in perceptions of relationship dimensions was observed, and specifically for the areas that matter most to Sponsors.

Key Findings:
Strategic Partnering Objectives and Performance

PROVIDER

- Providers are similarly focused on business stability and meeting customer needs.
  - Quality is lower on the list, but has moved up since 2012.
- Though Providers express that it takes longer to realize partnership benefits, they show an overall higher level of favorability with respect to their expectations being met, and have the strongest perceptions of their top five business objectives for partnerships.
  - Nearly all relationship attributes showed an increase in meeting expectations since 2012.
- Providers' overall affinity for Strategic Partnerships appears to have carried over into other "bigger picture" areas. They show stronger ratings than Sponsors on perceptions of these relationships having a positive impact on trial execution, development of new technology, and protocol design.

Have Sponsors' Objectives for Entering SPs Changed?

In both 2012 and 2016, Sponsors indicate that '*reduce costs*' and '*improved efficiency in use of internal staff*' are the primary drivers for establishing Strategic Partnerships. Less tangibles benefits, such as gaining expertise and improving quality, have declined as reasons selected for entering into SPs since 2012.

Top Sponsor Objectives for Strategic Partnerships in 2016

% selecting/rank

2016 %	Objective	2012** Rank	2012** %
47%	1. Reduce costs	1	53%
37%	2. Improved internal staff efficiency	3*	43%
30%	3. Operational expertise	4*	**43%**
27%	4.* Improved quality	2*	**43%**
27%	5.* Reduced contracting effort	7	25%

N: Sponsor=105

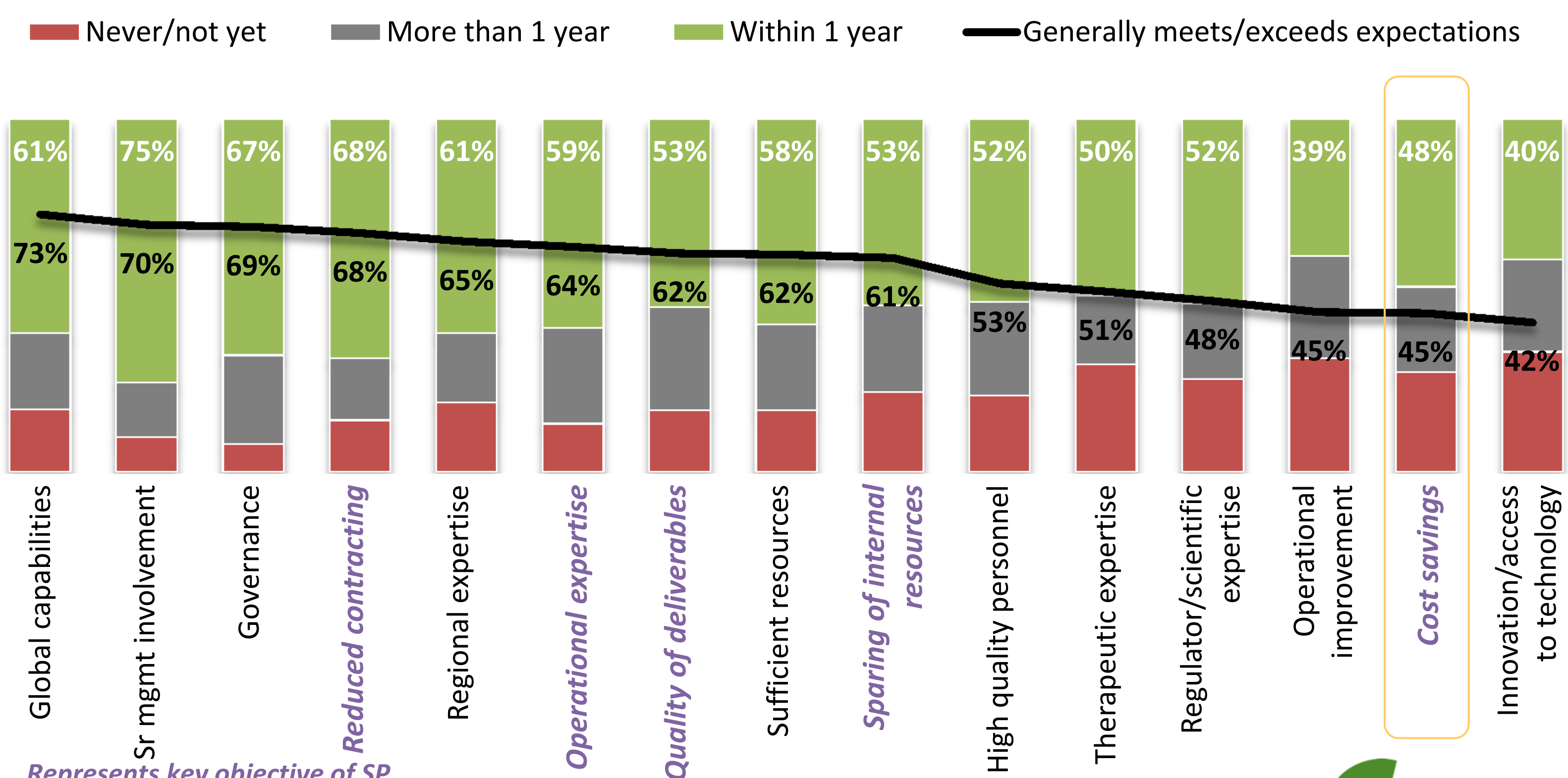
*What were your company's primary objectives in launching this strategic partnership? Please select up to three responses. *Tied in ranking. **Based on analysis of one respondent per company.*

How are SPs Performing Against Objectives?

The more "functional" aspects of SPs (e.g., global capabilities, senior management involvement) are being realized more quickly and show greater satisfaction among Sponsors. Reduced costs, a key objective of SPs, is among the slowest to take hold, and is weakest with respect to meeting expectations.

Sponsor Ratings on Performance on SP Dimensions

Time to meet expectation/% SP has met/exceeded expectations



Represents key objective of SP

N: Sponsor=92-105

For each of the areas listed below, please indicate <u>how long it took</u> before the partnership "generally" met your expectations.

To date, please describe the extent to which this strategic partnership has met your expectations with respect to each of the following.

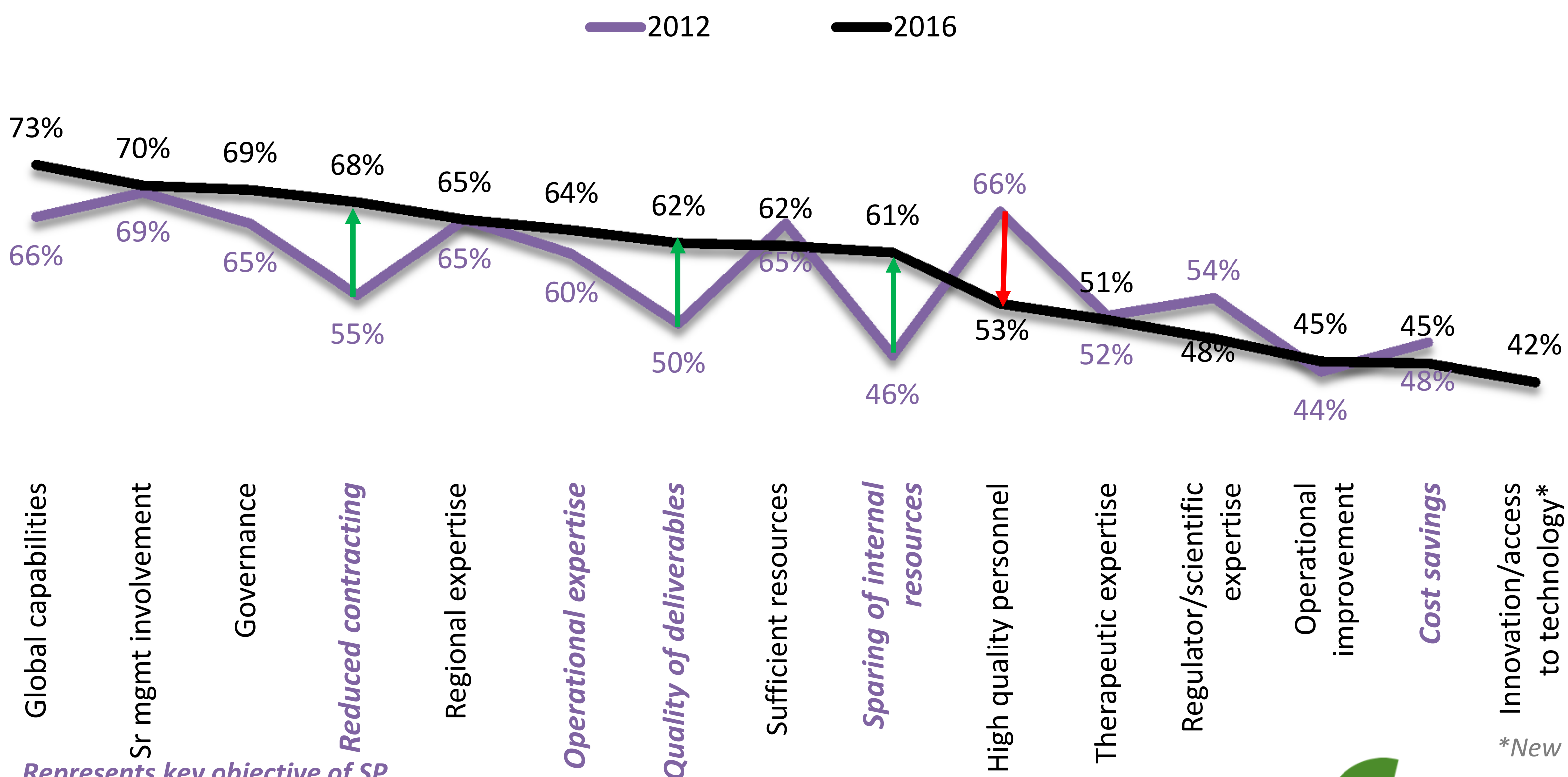
CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP

Strategic Partnership Dimensions Performance Trend

On three out of the five top objectives of SPs – reduced contracting effort, quality and sparing of internal resources - an increase in perceptions of meeting expectations has been observed since 2012. Cost savings, the primary objective of SPs, has remained low and flat relative to 2012. Access to high quality personnel has declined.

Sponsor Ratings on Performance on SP Dimensions

% SP has met/exceeded expectations



*New in 2016

Represents key objective of SP

N: Sponsor=92-105

To date, please describe the extent to which this strategic partnership has met your expectations with respect to each of the following.

CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP

Have Providers' Objectives for Entering SPs Changed?

Providers continue to select *'increased business stability'* as their primary reason for entering into SPs. '*Meeting customer needs*' has increased since 2012, while '*increased profit*' has declined, though it still remains a top five objective for this audience.

Top Provider Objectives for Strategic Partnerships in 2016

% selecting/rank

% selecting (2016)	Objective (2016 rank)	2012** Rank	2012** %
68%	1. Increased business stability/continuity	1	80%
48%	2. Meet needs/desires of current customer	5	**34%**
38%	3. Improved efficiency in use of staff	2	39%
22%	4.* Increased profit	3	**36%**
22%	5.* Improved quality	9	23%

N: Providers=59

*What were your company's primary objectives in launching this strategic partnership? Please select up to three responses. *Tied in ranking. **Based on analysis of one respondent per company.*

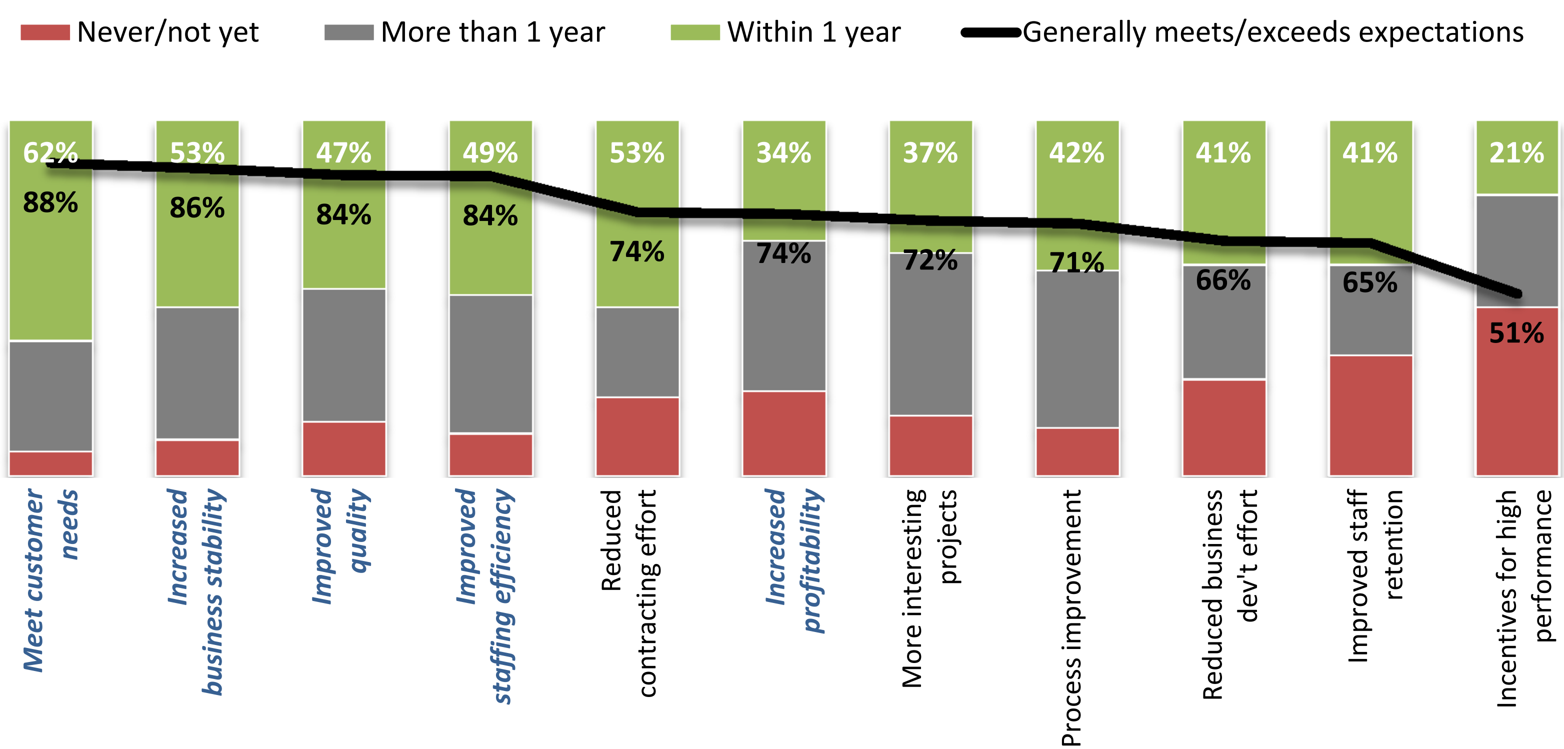
CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP

How are SPs Performing Against Objectives?

Providers are generally taking longer to see results relative to Sponsors; however, they express greater favorability with respect to the relationship meeting expectations. In fact, key Provider objectives for SPs earned among the highest expectation ratings.

Provider Ratings on Performance on SP Dimensions

Time to meet expectation/% SP has met/exceeded expectations



Represents key objective of SP

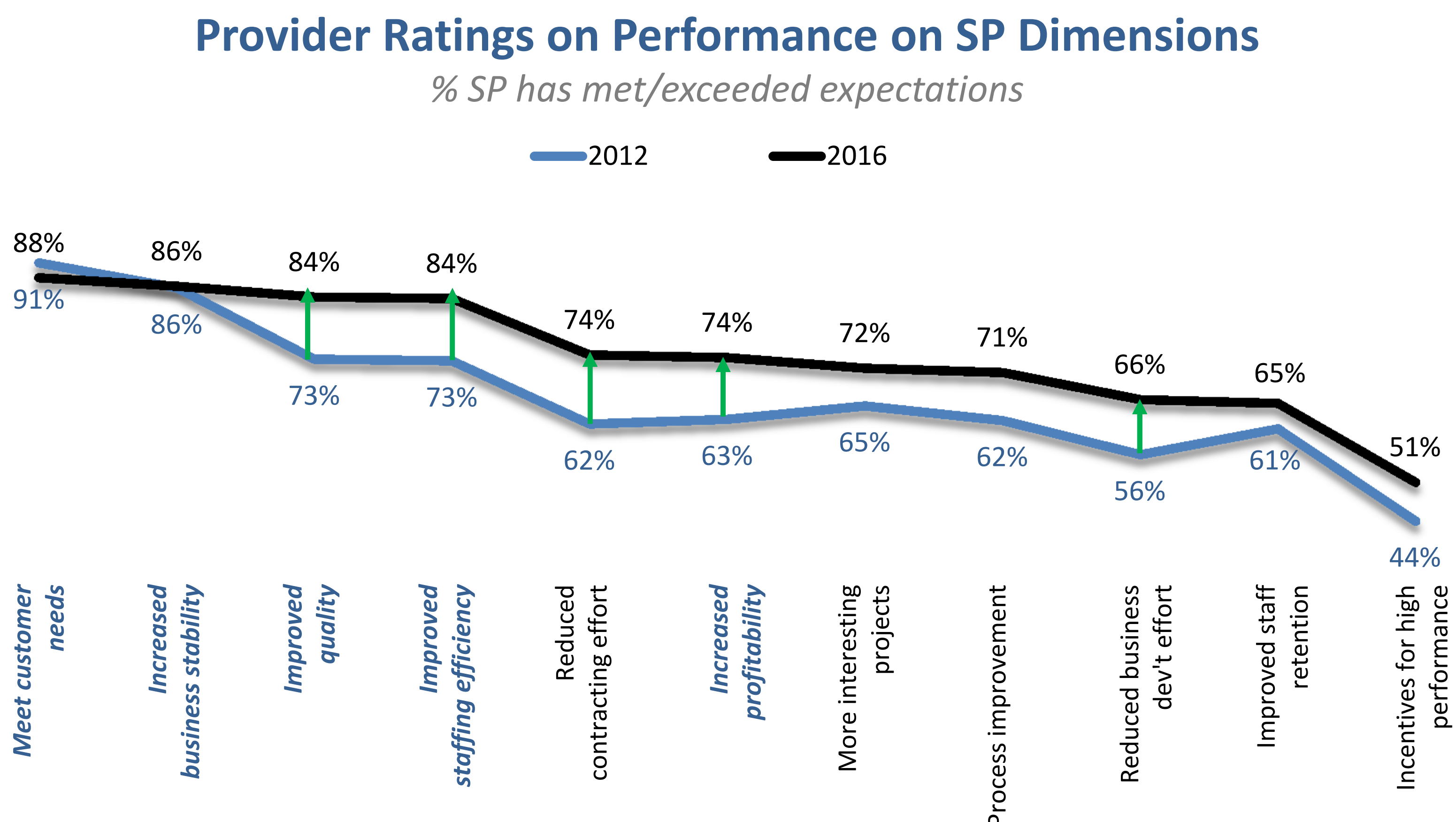
N: Provider=43-59

For each of the areas listed below, please indicate how long it took before the partnership "generally" met your expectations.
To date, please describe the extent to which this strategic partnership has met your expectations with respect to each of the following.

CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP

Strategic Partnership Dimensions Performance Trend

Generally, perceptions of meeting expectations increased across the board among Providers, and especially so for improved quality, improved staffing efficiency, reduced contracting effort, profitability and reduced business development effort.



**New in 2016*

Represents key objective of SP

N: Provider=43-59

To date, please describe the extent to which this strategic partnership has met your expectations with respect to each of the following.

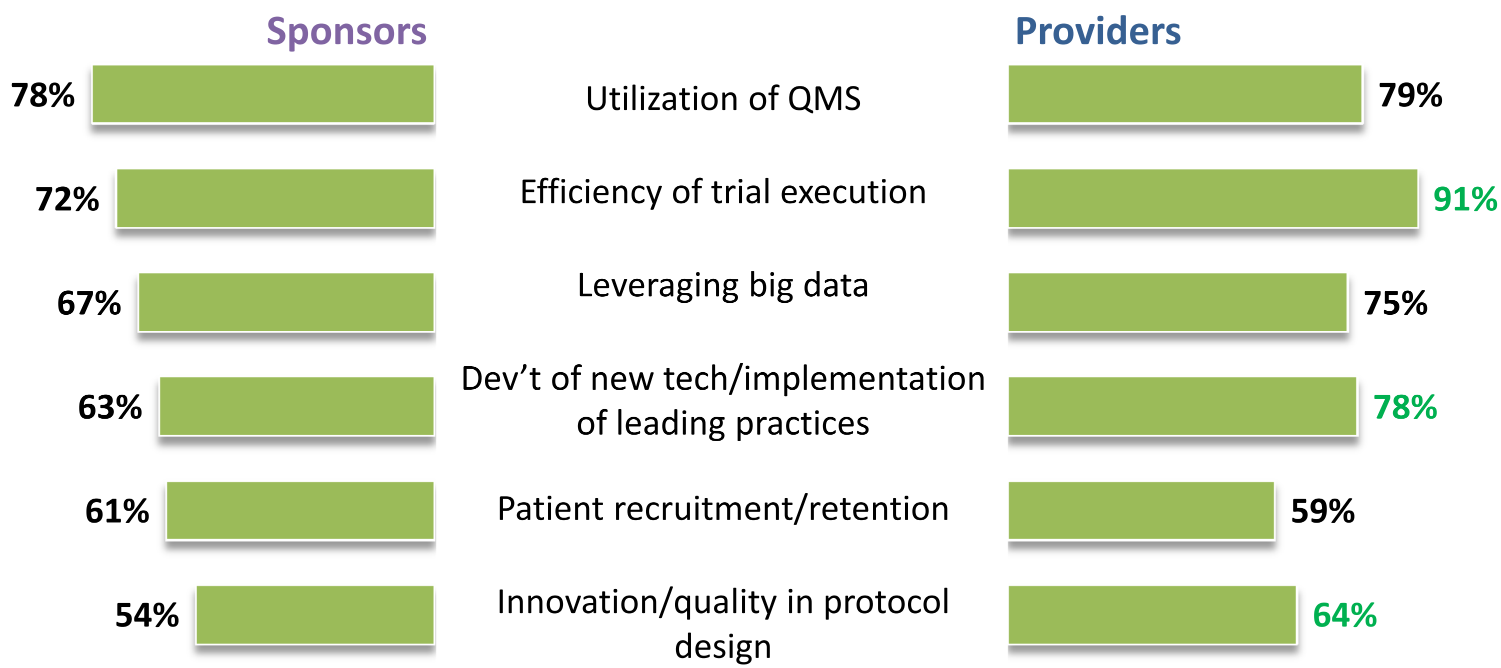
CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP

Impact of SPs on Aspects of Clinical Trial Execution

Both audiences believe that SPs have impact on key aspects of clinical trials, especially so for utilization of quality management systems and efficiency of trial execution. Providers show even greater favorability to the positive impact of SPs.

Perceptions of Impact of Strategic Partnerships on…

% somewhat/very positive impact



N: Sponsor=116-126, Provider=69-80

Based on your knowledge and experience, what impact, if any, do you believe strategic partnerships have on the following aspects of the pharmaceutical industry?

CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP

Clinical Outsourcing Relationship Health

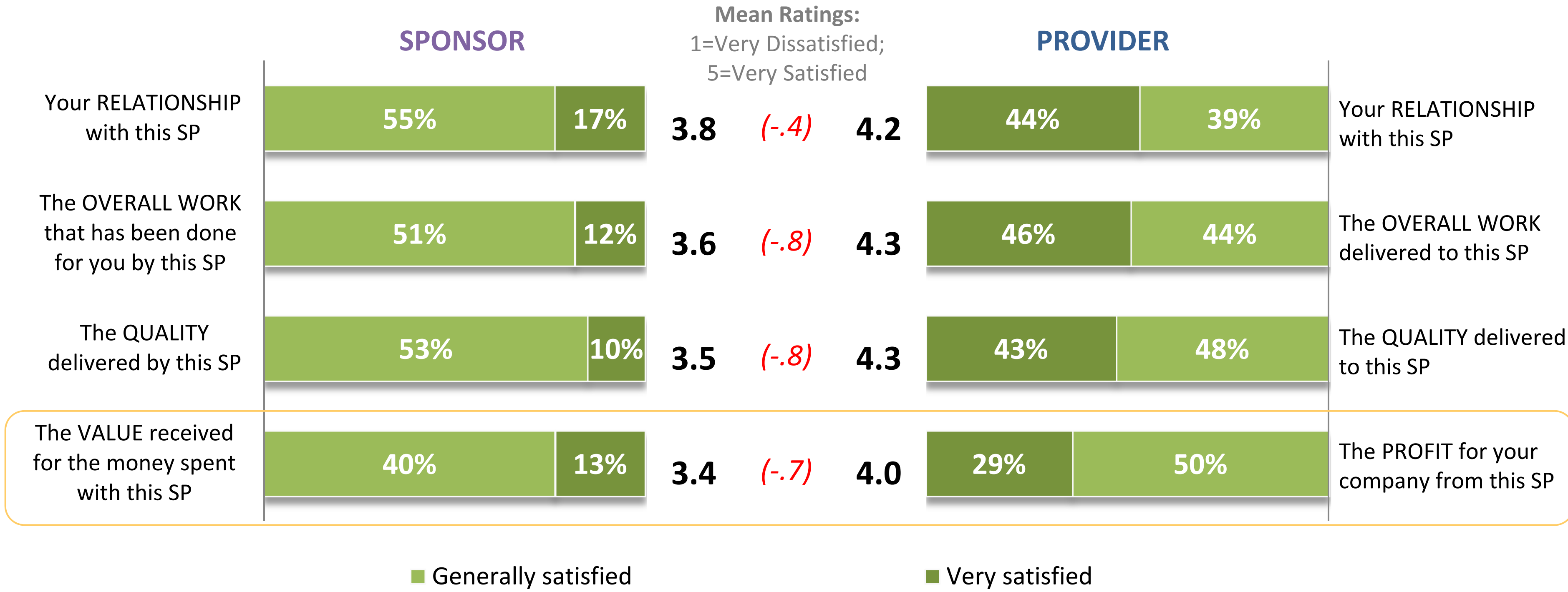
Key Findings:
Clinical Outsourcing Relationship Health

- Disparities persist between Sponsors and Providers on satisfaction with key quality and relationship health indicators.
- Strategic partnerships appear to aid in reducing, but do not eliminate, the gap in satisfaction.
- Length of SP relationship appears related to levels of overall satisfaction, with those in more mature relationships expressing higher satisfaction with the relationship, overall work and value.
  - Quality is flat regardless of time in relationship.
- Both audiences are anticipating increases in the use of strategic partnering, though more so among Providers.
  - Data suggests that Sponsors who are finding more value in the relationship overall are more likely to expect increased use of partnerships in the near future.

Satisfaction with Key Relationship Indicators

Overall, Sponsors and Providers report disparity in satisfaction with service delivery across key quality and relationship health attributes. 'Value for Money,' a key driver of entering into SPs for Sponsors, received the weakest satisfaction rating among Sponsors.

2016 Overall Assessment of Strategic Partnerships



N: Sponsor=104-105, Provider=56-60

Thinking about this strategic partnership overall, how satisfied have you been/were you with…

CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP

Trend in Key Relationship Indicators

This gap is one that has persisted over time, with very similar mean ratings observed in 2012 for both Sponsors and Providers rating Strategic Partners.

N: Sponsor=101-108, Provider=64-67

Thinking about this strategic partnership overall, how satisfied have you been/were you with…

**Showing the three indicators that were asked consistently in both the 2012 and 2016 Industry Surveys*

Relationship Indicators: All Relationships vs. Strategic Partnerships

Compared to all relationships, Strategic Partnerships appear to help narrow the gap in perceptions of relationship health.

2016 Relationship Indicators*: All Relationships vs. Strategic Partnerships

Mean Ratings: 1=Very Dissatisfied; 5=Very Satisfied

	All Relationships			Strategic Partnerships		
	Sponsor	Provider	Difference	Sponsor	Provider	Difference
Relationship	3.6	4.2	*(-.6)*	3.8	4.2	*(-.4)*
Overall Work Delivered	3.5	4.4	*(-.9)*	3.6	4.3	*(-.8)*
Quality Delivered	3.4	4.4	*(-1.0)*	3.5	4.3	*(-.8)*

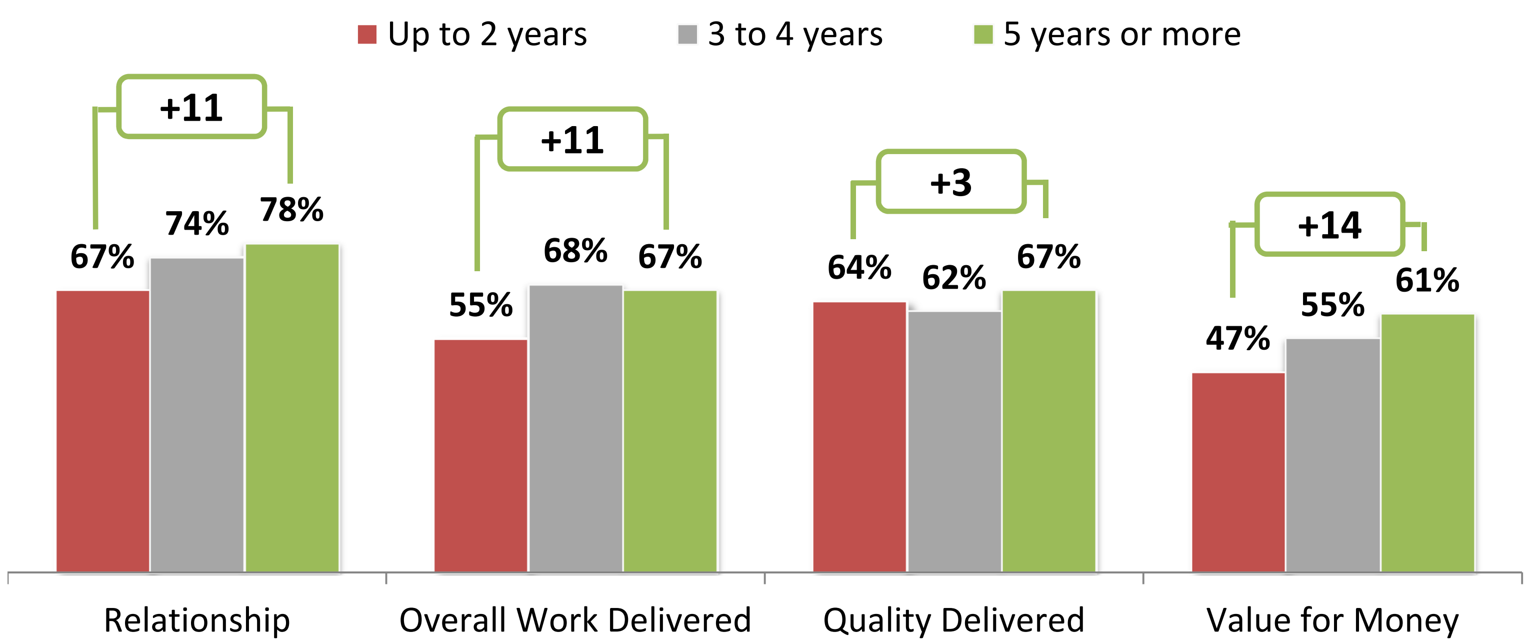
N: Sponsor=126-127, Provider=83-84 [All Clinical Service Providers]
N: Sponsor=104-105, Provider=56-60 [Strategic Partner]
Thinking about your experiences in 2015, how satisfied are you with…? [All Clinical Service Providers]
Thinking about this strategic partnership overall, how satisfied have you been/were you with…? [Strategic Partner]
**Showing measures where comparable measurements were taken for all CSPs and SPs ("Value" not able to be compared)*

Satisfaction by Maturity of Strategic Partnership

Further, longer tenure in the strategic partnership appears to positively impact perceptions of relationships, overall work and value for money. Perceptions of quality remain relatively flat regardless of length of relationship.

Sponsor Satisfaction with Relationship Indicators by Length of SP

% generally/very satisfied



N: Sponsor: Up to 2 years=38-39, 3 to 4 years=47, 5 years or more=18

Thinking about this strategic partnership overall, how satisfied have you been/were you with…?

Future Outlook on Strategic Partnering

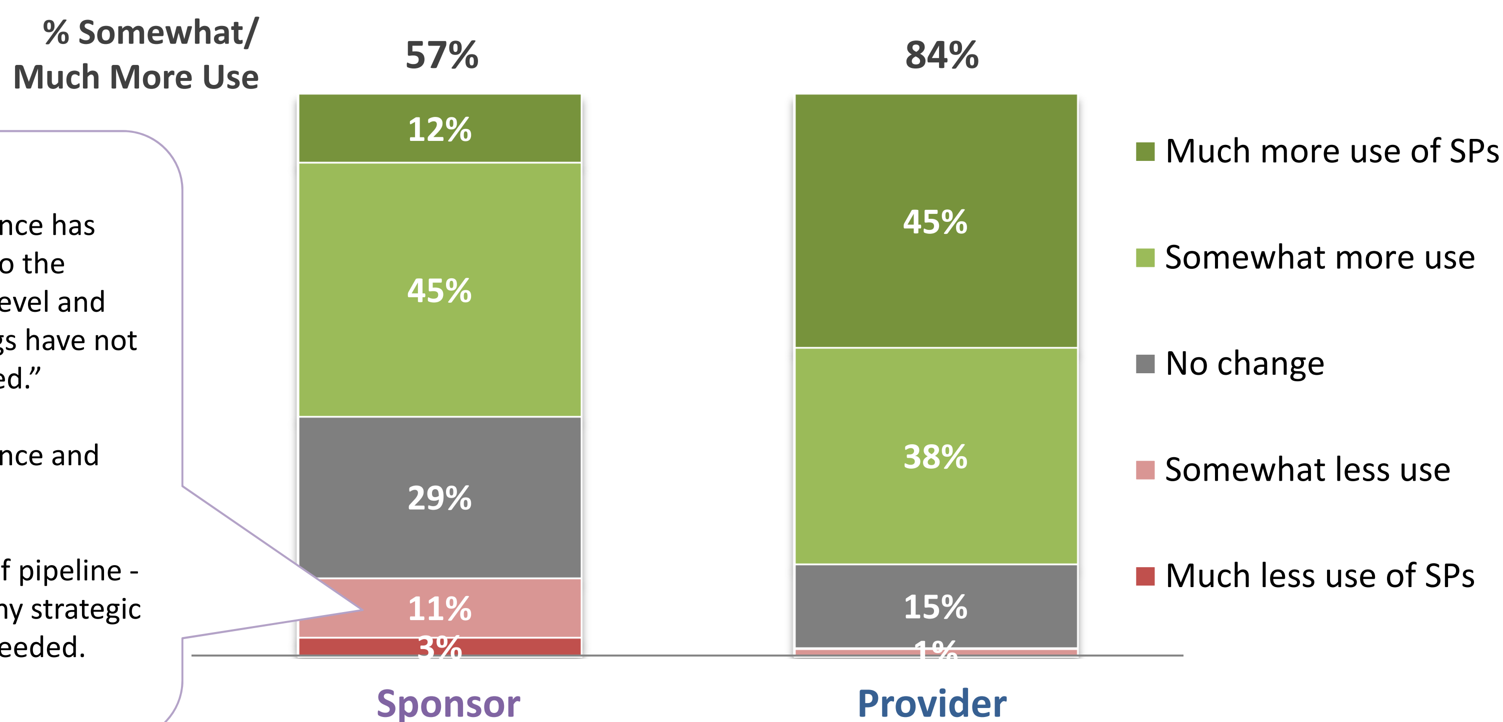
Just over half of Sponsors who were surveyed said they anticipate greater usage of SPs in the near future; 84% of Providers reported the same. Among Sponsors who anticipate less usage, pipeline volume and performance were cited as key reasons.

Anticipated Use of Strategic Partnerships in Next 5 Years

“Performance has not been to the expected level and cost savings have not materialized.”

“Performance and volume.”

“Volume of pipeline - not so many strategic partners needed.



N: Sponsor=122, Provider=73

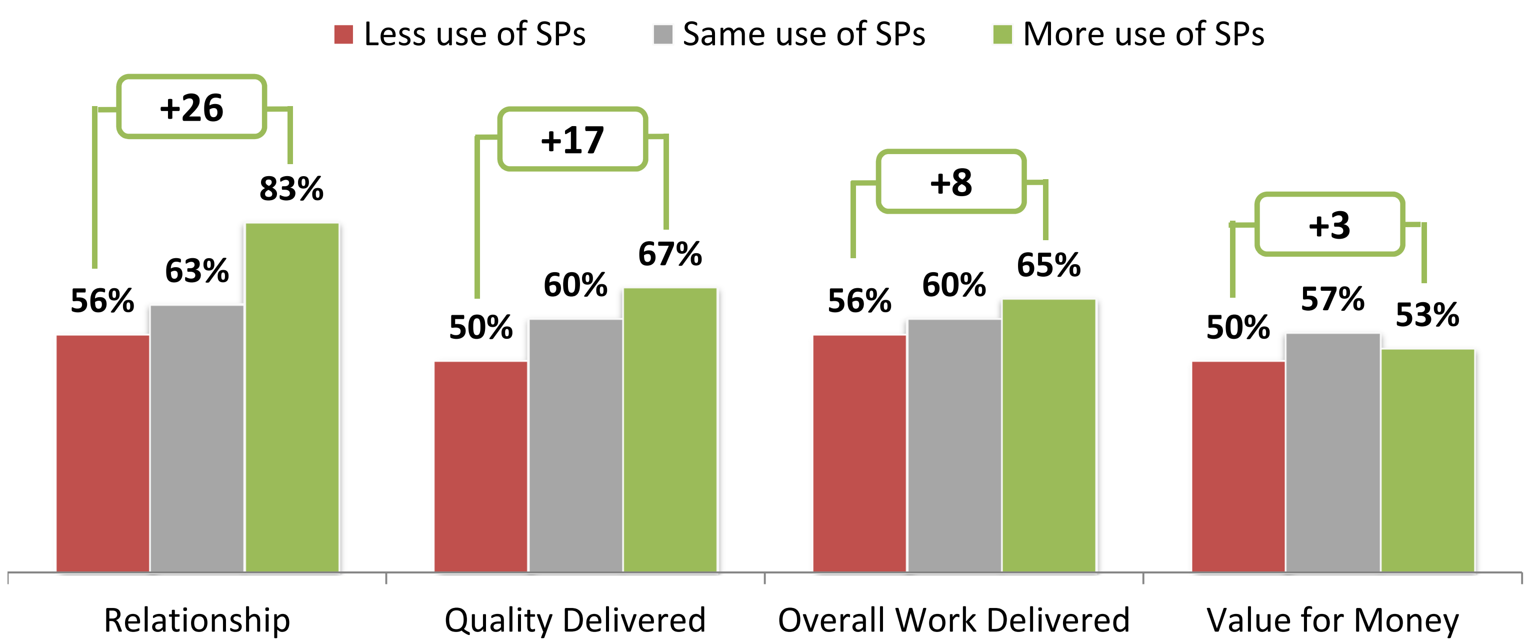
Thinking ahead to the next five years, how do you anticipate your company’s use of strategic partnerships will change? Will your company make…

Drivers of Future Strategic Partnering

Data suggests that though cost savings is an objective, and perhaps expected, of entering SPs, Sponsors want more from the relationship. Those who are more likely to utilize SPs in the future also report notably stronger satisfaction with the relationship and with quality.

Sponsor Drivers of Future Strategic Partnering by Anticipated Use of SPs

% generally/very satisfied



N: Sponsor: Less use of SP=16, Same use of SP=30, More use of SP=51-52

Thinking about this strategic partnership overall, how satisfied have you been/were you with…?

CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP

CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP

Thank you

Contact Avoca at:
(609) 252-9020
www.theavocagroup.com
info@theavocagroup.com

179 Nassau Street, Suite 3A
Princeton, NJ 08542

CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP

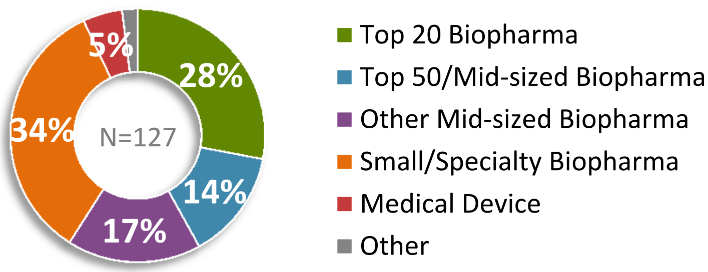
Appendix:

Respondent Demographics

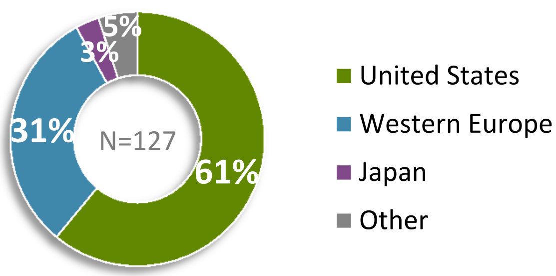
Respondent Demographics: Sponsor

130 professionals from **79** individual **Sponsor** companies participated in the 2016 Industry Survey.
84% with greater than 10 years of biopharmaceutical industry experience.

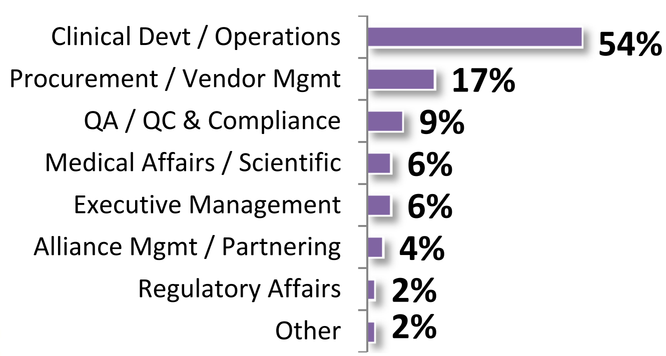
Company Type



Sponsor Company Headquarters



Functional Area



Companies Represented

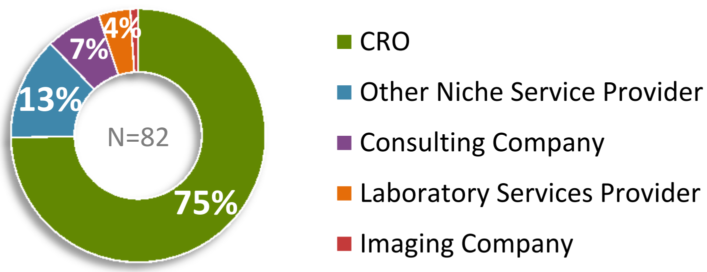
Achaogen
Achillion
Agensys
Alder
Alexion
Alnylam
Amgen
Arbor
Arno
ASLAN
Astellas
AstraZeneca
Baxter
Bayer
BD
BioMarin
Boehringer Ingelheim
Braintree
Breckenridge
Bristol-Myers Squibb
CDG
Celgene
Celldex
ContraVir
DRL
Eisai
EMD Serono
Emergent
Endo
Endocyte
Ferring
FORUM
Gilead
Grünenthal
GS
Horizon
HRS
Ignyta
ImaginAb
Immunocore
Indi
Infinity
Inst. of Clinical Research
Ionis
IRIS
Knopp Biosciences
LEO Pharma
Medrobotics
Menarini
Merck
Merrimack
Meta-IQ
Neuralstem
NeuroHealing
Novartis
Noven
Novo Nordisk
Otsuka
PF Labs
Pfizer
Philips
Procyrion
Recordati
Regeneron
Roche
RP Ltd
Sanofi Genzyme
Seattle Genetics
Shire
SOLTI
Stelis
Sucampo
Synageva
Takeda
TetraLogic
TP Therapeutics
UCB
Vectura
ViaCyte

CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP

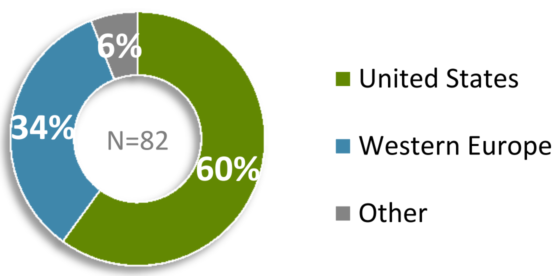
Respondent Demographics: Provider

84 professionals from **41** individual **Provider** companies participated in the 2016 Industry Survey.
73% with greater than 10 years of biopharmaceutical industry experience.

Company Type

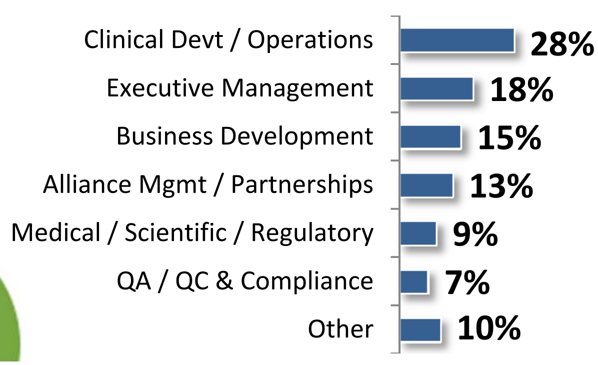


Provider Company Headquarters



Functional Area

N=82



Companies Represented

ACM Global Central Laboratory
Acurian
Advanced Clinical
Almac Clinical Technologies
AMC Health
Baystate
BioPharma Resources
Biotrial
Cato Research
Certara Strategic Consulting
Chiltern
Clinical Excellence Group
CompleWare
Drexel University
Emergent Clinical Consulting
ERT
ExecuPharm
Finell Clinical
Genelex
Higginbotham Group
ICON
INC Research
inSeption Group
Intrinsic Imaging
inVentiv Health
Julius Clinical
Longboat
PAREXEL
Pharm-Olam
PK Consulting
PPD Central Laboratory
PRA
Premier Research
PSI CRO
Quintiles
RH Bouchard & Associates
Spaulding Clinical Research
TFS
The Clinical Resource Network
Vantage BioTrials
Zifo Technologies

CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP