

The 2019 Avoca State of the Industry Report:

Clinical Outsourcing Spend & Key Relationship Measures

April 2020

Introduction

Each year, The Avoca Group surveys industry professionals to understand trends in clinical development, with a particular focus on outsourcing dynamics and relationships between research Sponsors and Providers. This report summarizes key findings with respect to outsourcing trends and key relationship indicators, including analysis of the influence of specific performance attributes on levels of satisfaction.

In this year's industry review, Avoca examined how Sponsors and Providers think about and manage quality in clinical trials. This topic is a continuation of research first conducted in 2011. These data are presented in a separate report, titled *Clinical Quality Management & Provider Oversight*, and includes longitudinal comparisons of key variables are noted, where applicable.

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Methodology

- All fieldwork was conducted between October and December of 2019.
- A total of 98 completed surveys were received from respondents representing Sponsor organizations.
- A total of 99 completed surveys were collected from respondents representing Provider organizations.
- Classification information about respondents and companies they represent can be found in the appendix of this report.

Key Take-Aways

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- Outsourcing rates in 2019 are consistent with those reported in previous years. As expected, smaller Sponsor organizations are outsourcing at a higher rate.
- Though key relationship indicators are favorable, there remains a gap between Sponsors and Providers – that is, Sponsors express weaker satisfaction relative to the ratings Providers give on self-assessments on these same measures.
- Closing this gap will require a greater level of proactivity, effectiveness of oversight, and attention from senior staff – attributes that are closely associated with relationship indicators but have weaker favorability today.
- Generally, FSPs are seen more positively in terms of being able to deliver on the qualities that Sponsors are after, especially as it relates to collaboration and expertise. However, a majority of spend is going to full-service Providers.

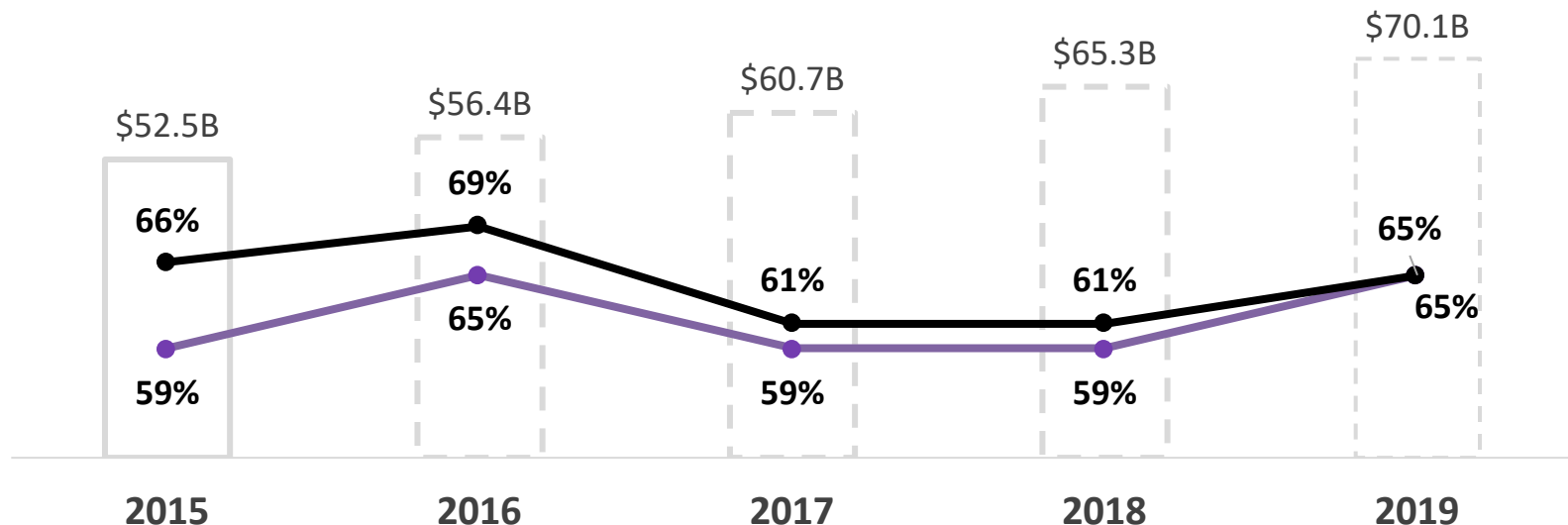
State of the Industry

State of the Industry

Trend in proportion of outsourced clinical development spend – both currently and anticipated in the near future – is on par with what has been reported in recent years.

Sponsor: Proportion of Outsourced Clinical Development Spend

▒ R&D Spend (in billions)* ● Current Outsourced Spend ● Outsourced Spend 3 Years From Now



*Source: William Blair Equity Research (April 2016); 2016-2019 spend estimated based on projected 7-8% CAGR annually.

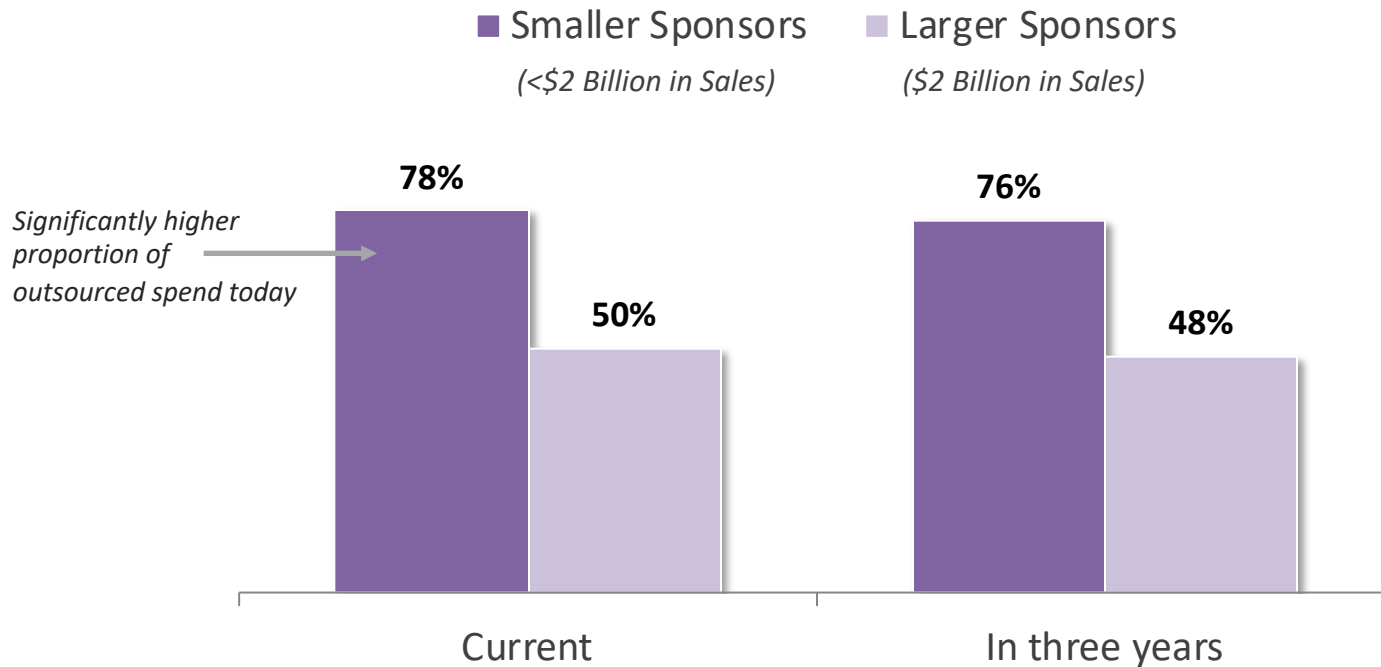
N: Sponsor: 2015=123-131, 2016=112-116, 2017=273, 2018=128, 2019=99

Q: Approximately what percentage of your company's spend on clinical development was outsourced in [YEAR], and what do you expect the percentage will be 3 years from now?

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Another consistent trend is observed with respect to outsourced spend by Sponsor size – smaller Sponsor organizations continue to outsource more of their dollars than do larger Sponsors.

Sponsor: Proportion of Outsourced Spend by Company Size



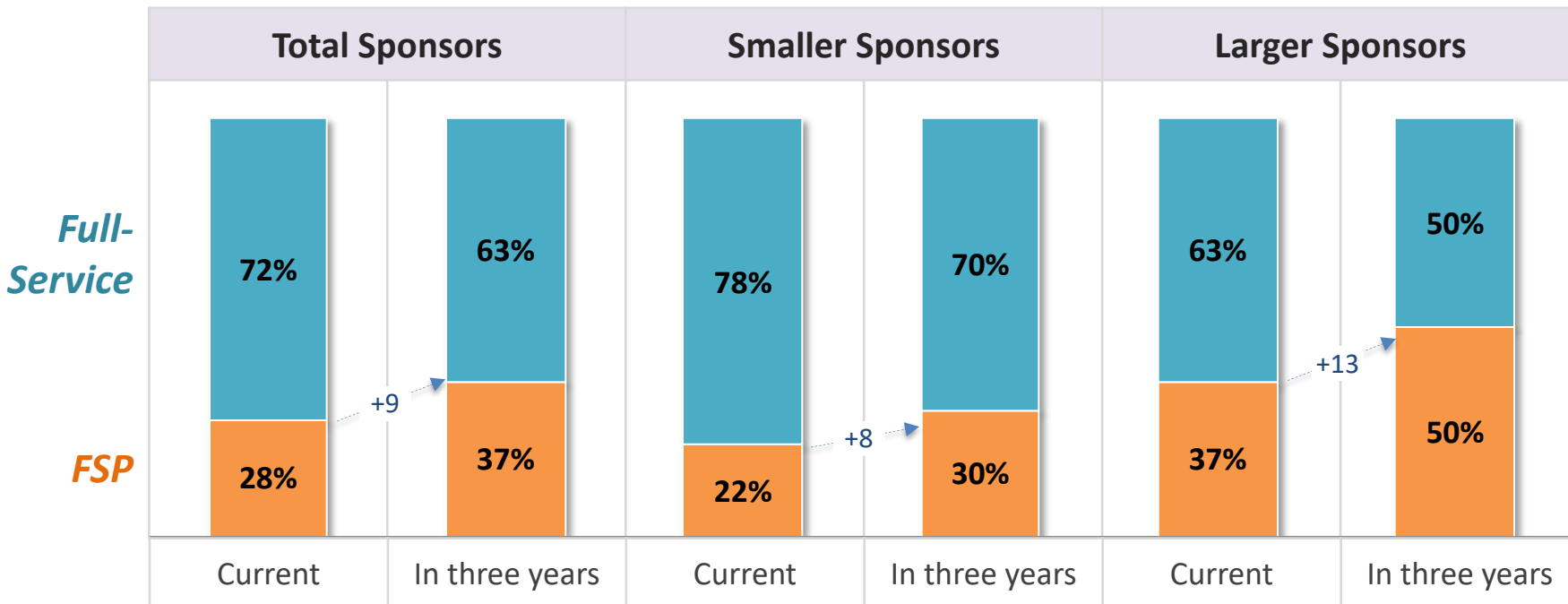
N: Smaller=62, Larger=31

Q: Approximately what percentage of your company's spend on clinical development was outsourced in 2018, and what do you expect the percentage will be 3 years from now?

State of the Industry

A majority of outsourced clinical development spend goes to full-service Providers, though the allocation is expected to shift more-so to functional service Providers in the near future, especially among larger Sponsors.

Sponsor: Proportion of Outsourced Spend Allocated to Provider Type



N: Total Sponsors=77, Smaller Sponsors=50, Larger Sponsors=25

Q: Now, of your company's outsourced spend for clinical development, approximately what percentage was allocated to full-service Providers and/or functional service Providers (FSPs) in 2018, and what do you expect the percentage(s) will be 3 years from now?

State of the Industry

Proportion of trials allocated to each Provider type is commensurate to Sponsor size; larger Sponsor organizations are more likely to utilize large CROs, while smaller Sponsors are more likely to utilize mid-sized CROs.

Sponsor: Proportion of Trials Allocated to Provider Type*

Provider Type	Total Sponsors		Smaller Sponsors		Larger Sponsors	
	Current	In 3 Years	Current	In 3 Years	Current	In 3 Years
Large CRO	49%	47%	37%	40%	73%	62%
Mid-Sized CRO	35%	31%	45%	40%	14%	13%
Small/Specialty CRO	13%	11%	14%	12%	9%	10%
ARO	5%	6%	5%	5%	7%	9%

* Because trials involve varying use of different Provider types, trial allocations were not forced into a 100% allocation; thus, totals represented here do not always sum to 100% across Provider types.

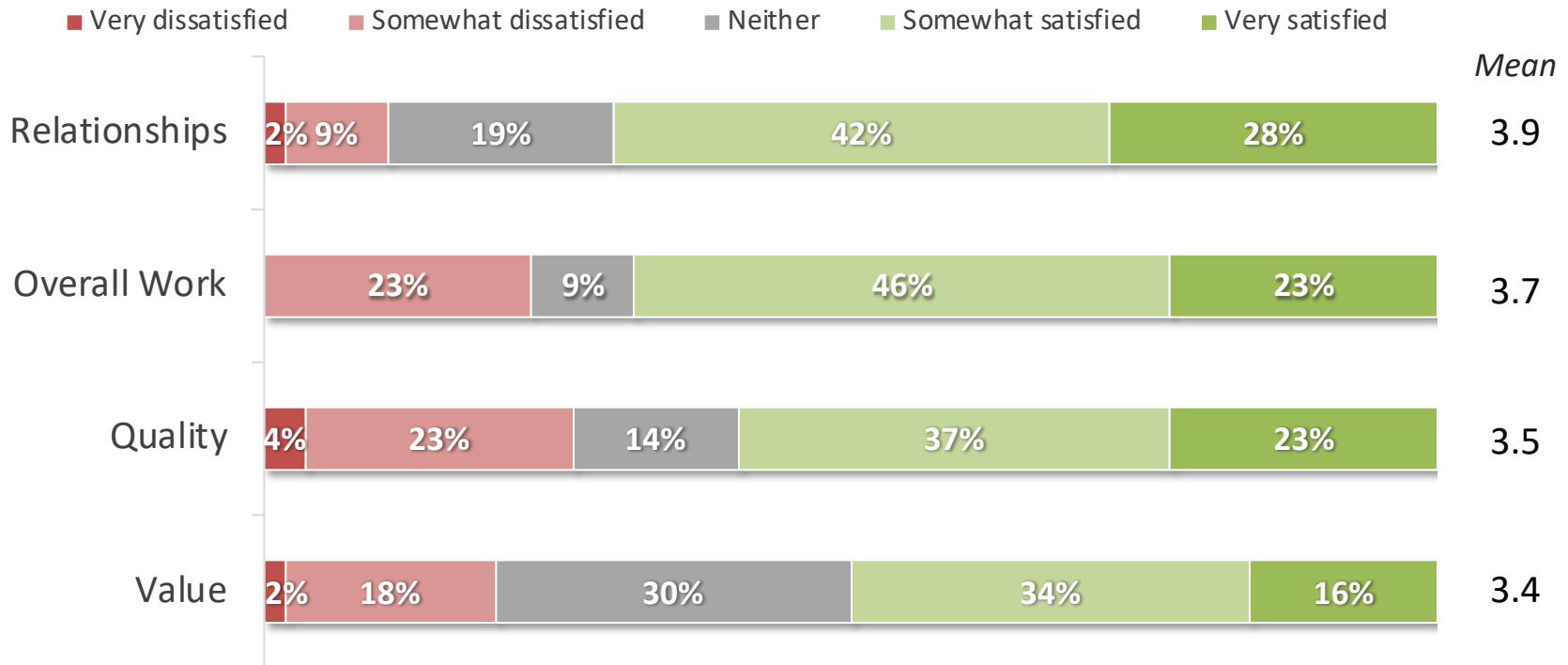
N: Total Sponsors=61, Smaller Sponsors=39, Larger Sponsors=21

Q: Still thinking about your company's outsourced clinical trials, approximately what percentage was allocated to the following providers in 2018, and what do you expect the percentage(s) will be 3 years from now?

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Sponsors generally express some level of satisfaction with respect to key relationship indicator ratings of their interaction with Providers over the past year.

Sponsor: Overall Assessment of Relationship Health



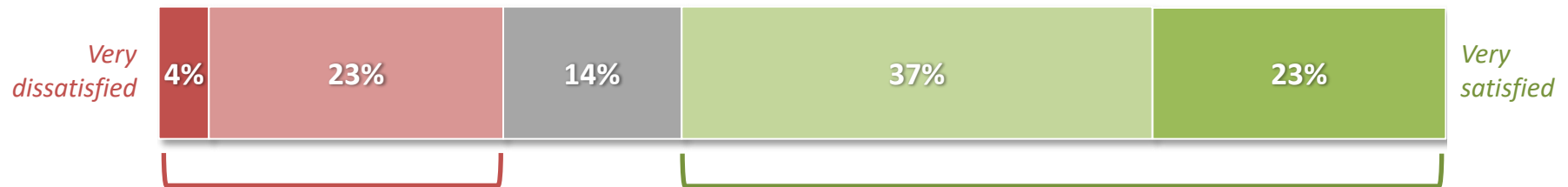
N: Sponsor=56-57

Q: Thinking about your experiences in 2018, how satisfied are you with... (1=Very dissatisfied, 5=Very satisfied)

State of the Industry

Looking at quality ratings, adherence to timelines, communication, deliverables, and commitment are key drivers of satisfaction; turnover, change orders, and issues with deliverables result in weaker satisfaction.

Sponsor: Reasons for Quality Ratings



Themes: Turnover, change orders, requires too much oversight, inability to meet agreed upon deliverables/timelines

- “Multiple change orders, inability to deliver on what they stated they would, constantly shifting timelines.”
- “Especially with large CROs: rigid processes, little flexibility, even standard or routine practices lead to change orders. Staff turnover at CROs, staff quality at CROs.”

Themes: Adherence to timelines, communication, quality of deliverables, established relationship/commitment to success

- “They align their science and client delivery team for long-term understanding of our business.”
- “Timely and efficient communication and workflow; high quality work product.”
- “The niche Providers are able to supply a team with low turnover of key functions, thus leading to a high and consistent study conduct.”
- “Continuity in relationship management and responsiveness to requests.”
- “Worked with us to manage and keep the timelines and quality of the work.”

N: Sponsors=57

Q: You indicated that you were not satisfied with the quality delivered by your Clinical Service Providers in 2018. Why is that?

Q: You indicated that you were satisfied with the quality delivered by your Clinical Service Providers.

What, specifically, led you to provide this rating?

State of the Industry

Many of these same variables appear to influence ratings of perceptions of the value received from clinical service Providers, suggesting a connection between quality and value.

Sponsor: Reasons for Value Ratings



Themes: Change orders, amount of oversight required

- “Change orders are an ongoing problem with CROs. The CRO’s inability to properly forecast enrollment, site selection and targeted countries seem to pass on the costs to the Sponsor.”
- “Many change orders, even for what should be considered standard tasks. Bait and switch. Staff turnover and staff quality, you pay for experience but get relatively inexperienced/junior staff.”

Themes: Adherence to timelines/study specifications, quality of deliverables/staff, quality of communication

- “Timely and efficient communication and workflow; quality of work product; excellent organization and project management.”
- “Financials controlled through governance meetings and good project management/communication with vendors along with written communication plans.”
- “Professional, knowledgeable team. Delivered all that was promised on time.”
- “Respect of timelines, good relationship, nice reporting.”

N: Sponsors=56

Q: You indicated that you were not satisfied with the value delivered by your Clinical Service Providers in 2018. Why is that?

Q: You indicated that you were satisfied with the value delivered by your Clinical Service Providers.

What, specifically, led you to provide this rating?

State of the Industry

In fact, there is a strong relationship between key relationship indicators as evidenced by high correlation coefficients.

Sponsor: Correlation Between Key Relationship Indicators

	Quality	Value	Relationship	Overall Work
Quality	1.00	0.81	0.80	0.84
Value	0.81	1.00	0.79	0.80
Relationship	0.80	0.79	1.00	0.82
Overall Work	0.84	0.80	0.82	1.00

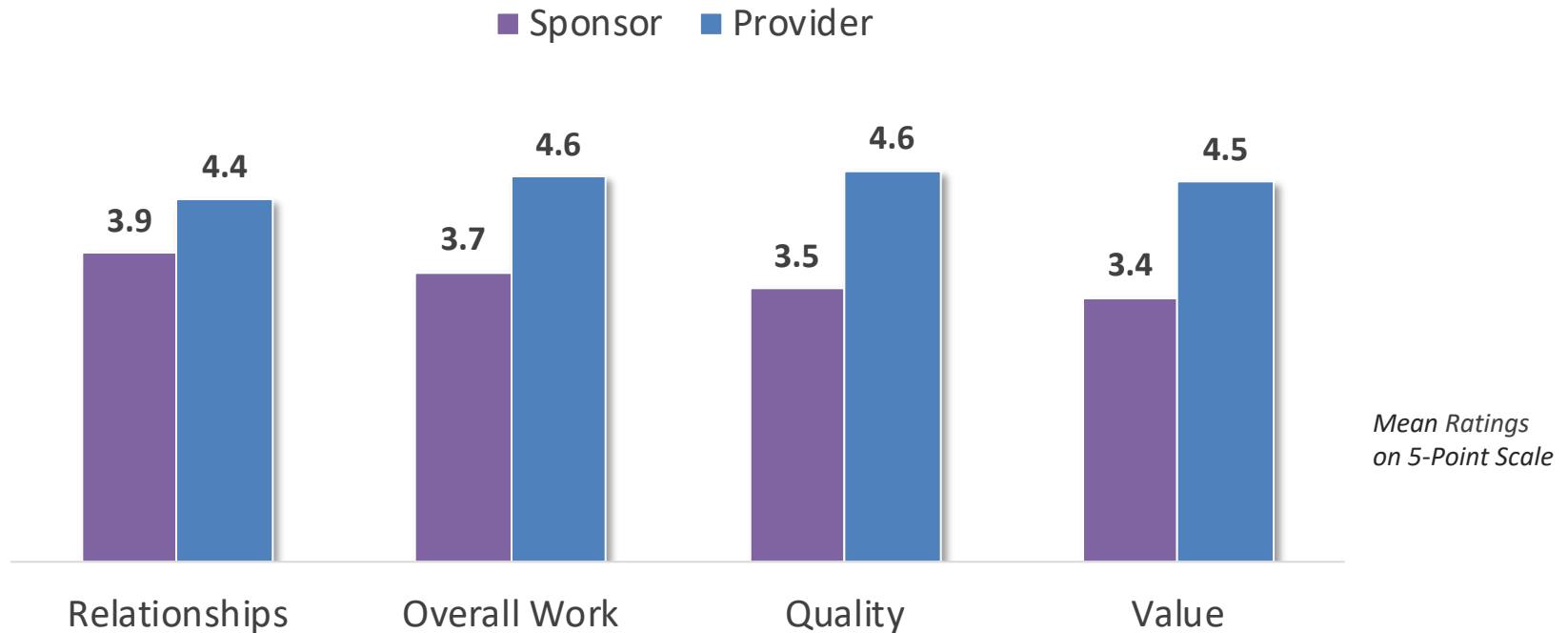
N: Sponsors=55

Q: Thinking about your experiences in 2018, how satisfied are you with... (1=Very dissatisfied, 5=Very satisfied)

State of the Industry

Though Sponsor ratings overall skew positive, relative to Providers, there is a significant lag.

Overall Assessment of Relationship Health



N: Sponsor=56-57, Provider=92-93

Q: Thinking about your experiences in 2018, how satisfied are you with... (1=Very dissatisfied, 5=Very satisfied)

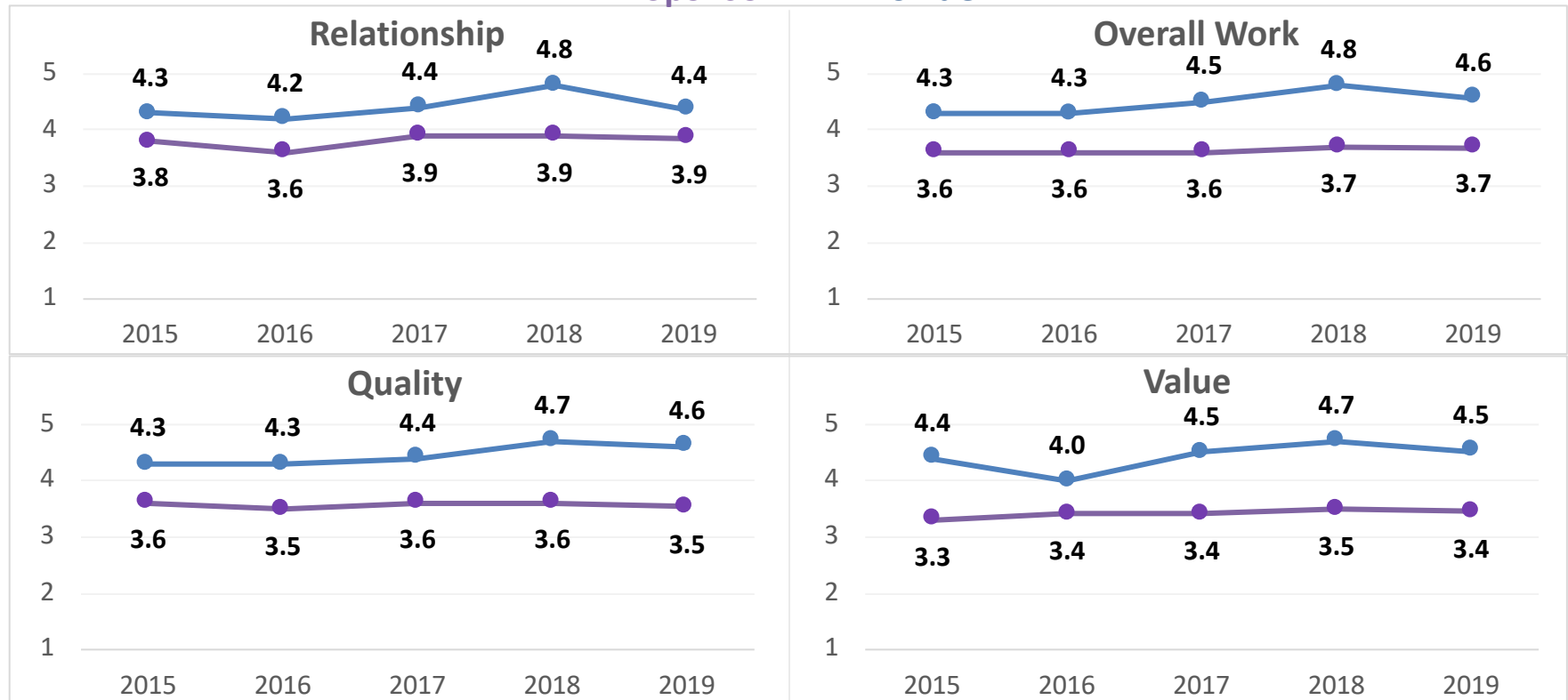
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The observed lag has persisted over time, with mean ratings among Providers outpacing Sponsors by half a point or more across all key relationship indicators.

Trend in Overall Assessment of Relationship Health

— Sponsor — Provider

Mean Ratings
on 5-Point Scale



2015 N: Sponsor=148-152, Provider=88-90; 2016 N: Sponsor=104-105, Provider=56-60; 2017 N: Sponsor=255-265; Provider=117-120; 2018 N: Sponsor=124-125; Provider=151-155; 2019 N: Sponsor=56-57; Provider=92-93

Q: Thinking about your experiences in [YEAR], how satisfied are you with... (1=Very dissatisfied, 5=Very satisfied)

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Today, Sponsors tend to see FSP models delivering more favorably on quality. These types of interactions are thought to provide for stronger communication/collaboration, more expertise, flexibility, and control – it delivers better on the attributes that drive perceptions of quality.

Sponsor: Ratings of Quality Perception by Provider Type



FSP Themes: Stronger relationship/better collaboration, more expertise/ can select best in class, greater flexibility, Sponsor retains control

- “FSP tends to foster greater collaboration than the traditional CRO-Sponsor relationship.”
- “Not all CROs are good in all things or trial designs. therefore, FSP model allows for flexibility to choose the best fit.”
- “You generally are able to operate under your own company's SOPs and staffing tends to be more stable - less turnover - ability to have input into training of personnel.”
- “More flexibility with FSP to make changes if needed to improve quality.”
- “You can control the staff allocated to your project better. Better relationships with allocated staff. In the full outsourcing model, many players are 'hidden' and for sure not dedicated to your study(ies).”

Full-Service Themes: Familiarity with this model; “all in one” approach provides better outcomes/relationship

- “The people on the study get to truly know the study inside and out.”
- “Full-service model is usually more organized and consistent.”
- “All in one service, better communication.”
- “Negotiated rates, familiarity, governance model in place.”

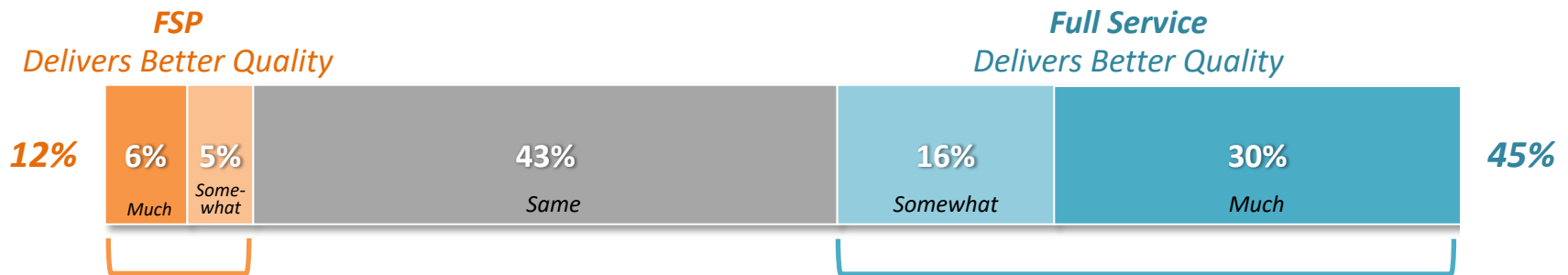
N: Sponsor=81

Q: Regardless of what models you may employ/provide today and based on your experience working with varied sourcing models, please select the statement that best reflects your perspective in terms of the quality that is delivered.

State of the Industry

Interestingly, Providers have the opposite view, and are more likely to indicate that full-service engagements are better able to deliver on quality due to the strength of the relationship, ability to integrate, and efficiencies gained.

Provider: Ratings of Quality Perception by Provider Type



- “FSP is more specialized to deliver on specific requirements.”
- “The more familiar you are with a client the better able you are to predict their needs and how to serve them best.”
- “The difficulty in accurately defining Sponsors’ strategic needs and goals.”

Full-Service Themes: Stronger relationships/ collaboration/integration, allows for big picture/strategic thinking, greater efficiency

- “A deeper team integration seems to allow for better collaboration and improved efforts on both sides.”
- “Better integration with the whole clinical trial life cycle requirements, deliverables and expectations from Sponsor to CRO.”
- “Less issues due to fewer reconciliation of issues and miscommunications.”
- “We tend to have closer/tighter oversight when it's full service.”
- “Because you're not as silo'd and working with the other groups in your same company allows for more knowledge transfer.”

N: Provider=77

Q: Regardless of what models you may employ/provide today and based on your experience working with varied sourcing models, please select the statement that best reflects your perspective in terms of the quality that is delivered.

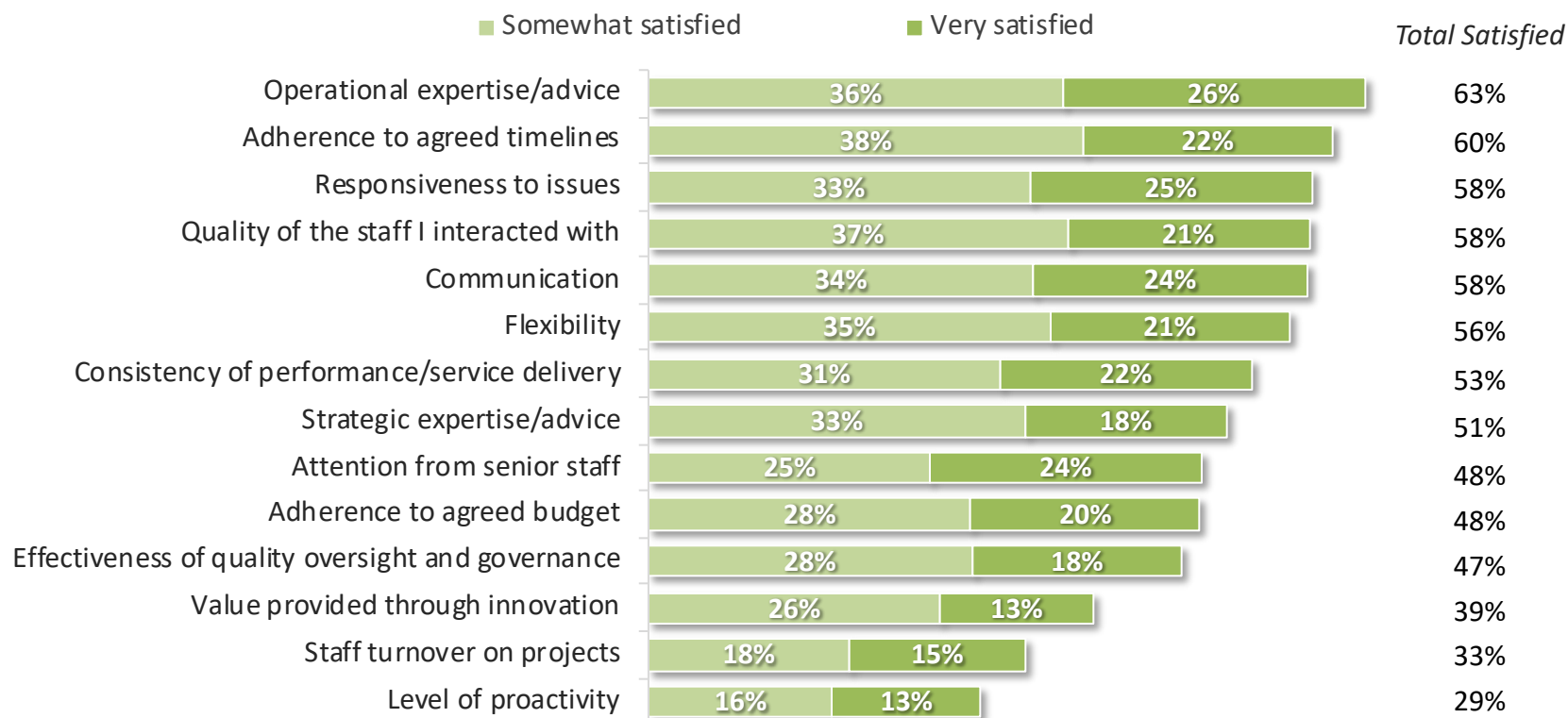
How can we work toward closing the “gap” between Sponsors and Providers?



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Sponsor ratings of satisfaction with various performance dimensions indicate room for improvement, especially in the areas of quality oversight, value provided through innovation, turnover, and proactivity – all have relatively low “top box” and “top 2 box” response.

Sponsor: Satisfaction with Performance Dimensions



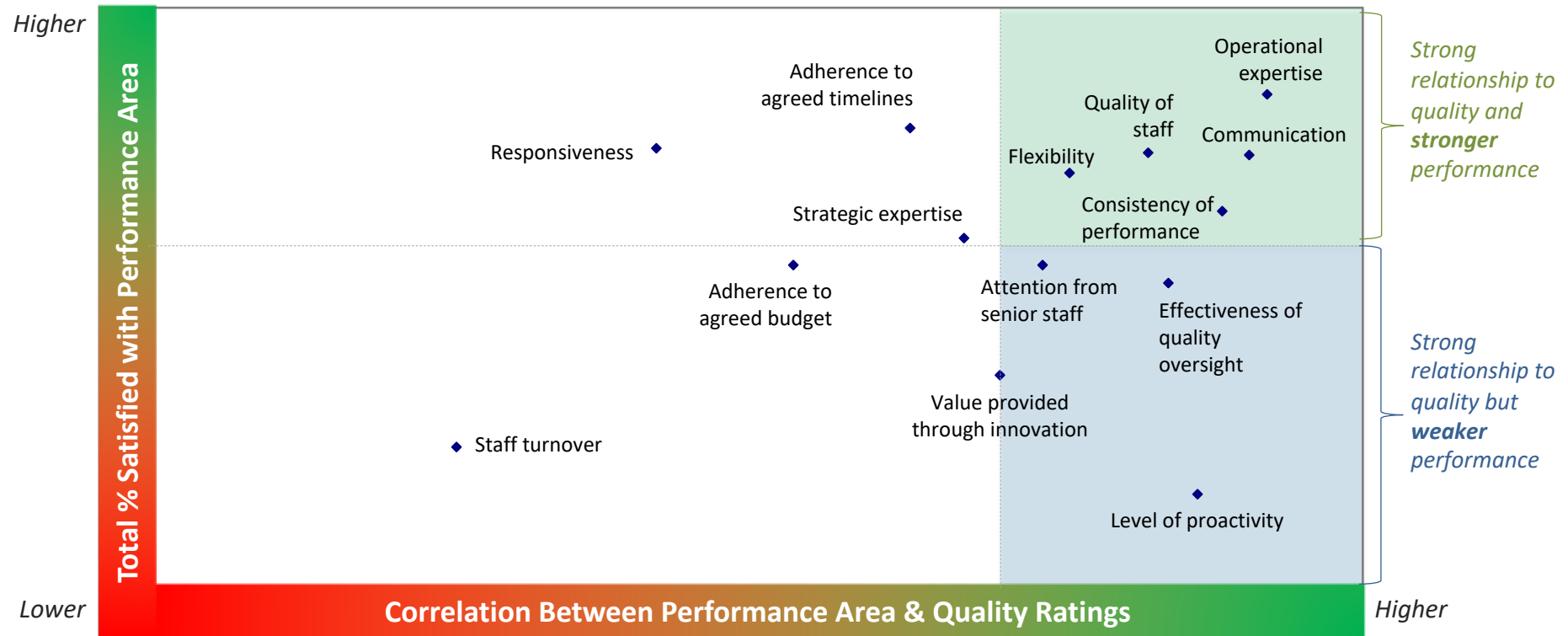
N: Sponsors=85-93

Q: Thinking about the past 12 months and your experience working with Clinical Service Providers, please rate your level of satisfaction with the following areas of Clinical Service Provider performance.

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When performance ratings are mapped against their correlation to overall quality ratings, proactivity, effectiveness of quality oversight, and attention from senior staff are identified as areas where there is an opportunity to improve.

Sponsor: Performance Area Correlations to Quality vs. Satisfaction Ratings



N: Sponsors: Attribute Ratings=85-93, Correlations=55

Q: Thinking about the past 12 months and your experience working with Clinical Service Providers, please rate your level of satisfaction with the following areas of Clinical Service Provider performance.

Q: Thinking about your experiences in 2018, how satisfied are you with... (1=Very dissatisfied, 5=Very satisfied)

Recommendations

In order to improve level of satisfaction across all key relationship indicators, Avoca recommends that Sponsors and Providers:

- Utilize outsourcing relationships as a platform to introduce and mobilize innovative approaches to clinical trial execution
- Collaborate on effective quality oversight frameworks that focus on key risk and quality indicators and outcomes-focused metrics
- Be proactive in sharing information and identifying and taking actions on risks and issues
- Invest in building and maintaining strength in relationships by regularly measuring and discussing relationship health as part of continuous improvement

How Avoca Can Help

For more information and case studies describing how The Avoca Group supports Sponsors and Providers, please contact Dawn.Auerbach@theavocagroup.com

- QMS Gap Assessment and Implementation Support
- Vendor Oversight and Management Framework Design and Improvement
- ICH E6(R2) Compliance
- Mock Inspection and Inspection Preparation Support
- Quality Tolerance Limits and Quality Metrics
- Risk Management and Risk-Based Approaches to Quality
- Sponsor-CRO Bi-directional Relationship Assessments
- Site Feedback Surveys
- Market Perception Assessments
- Client Satisfaction Surveys
- Virtual and Instructor-led Training and Workshops
- Vendor Qualification Assessments

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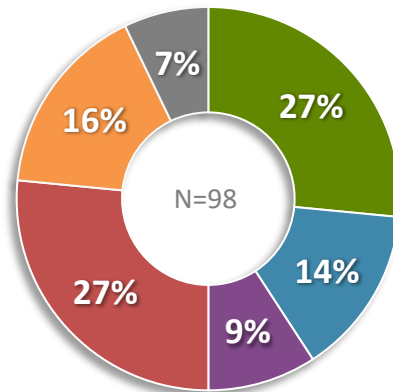


Appendix

Company Characteristics

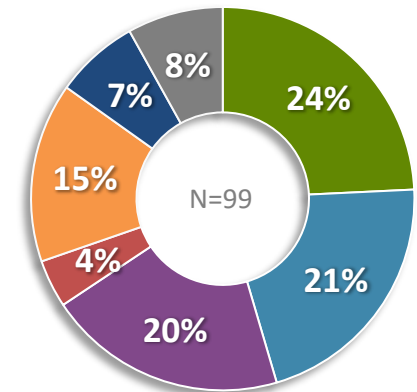
Sponsor: Company Size

- Top 20 Biopharma (\$10+ billion sales)
- Top 50 / Mid-sized Biopharma (\$2.0 - \$9.9 billion sales)
- Other Mid-sized Biopharma (\$500 million - \$1.9 billion sales)
- Small / Specialty Biopharma (<\$500 million sales)
- Pre-Revenue Biopharma (\$0 sales)
- Other



Provider: Company Type

- Large CRO (\$500+ million sales)
- Mid-sized CRO (\$50 - \$500 million sales)
- Small/Specialty CRO (<\$50 million sales)
- Non-CRO Clinical Service Provider
- Academic Research Organization (ARO)
- Consulting Company
- Other



Respondent Characteristics

Sponsor: Tenure in/at...

N=98

Mean Years

Pharmaceutical industry	18.5
Current company	6.6
Current role	4.8

Provider: Tenure in/at...

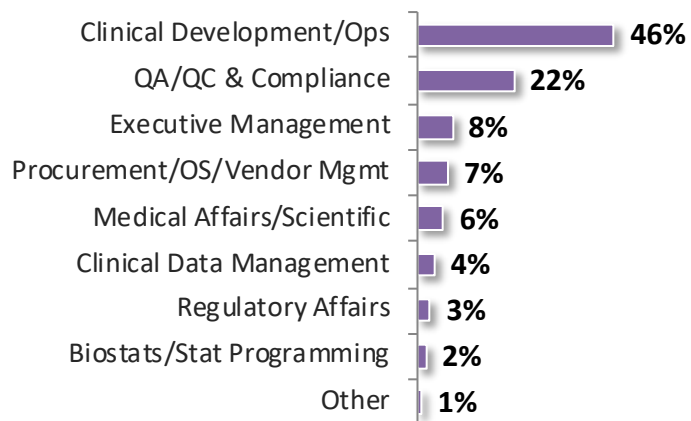
N=99

Mean Years

Pharmaceutical industry	15.9
Current company	6.5
Current role	5.5

Sponsor: Primary Functional Area

N=98



Provider: Primary Functional Area

N=99

