

# The 2017 Avoca Industry Report

Evaluating and Managing Risk  
in Clinical Trials



August 2017



# 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.

In this year's industry review, Avoca examined how Sponsors and Providers assess and manage risk in clinical trials. This topic is a continuation of research first conducted in 2013; longitudinal comparisons of key variables are noted, where applicable.

This report summarizes the key findings from our research.

# Usage Guidelines

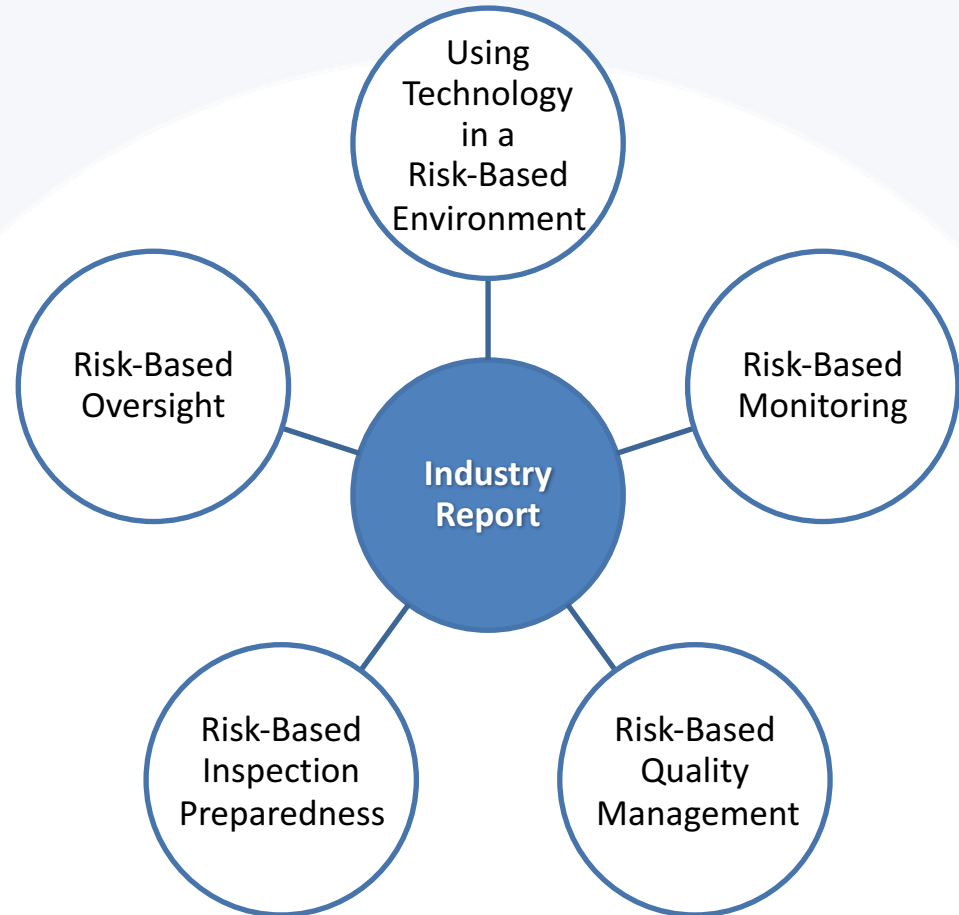


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# 2017 Avoca Industry Report Series

This 2017 Avoca Industry Report represents a summary of the key, high-level findings observed among Sponsors and Providers.

Additionally, Avoca will issue a series of follow-up reports that examine specific areas, such as risk-based quality management and using technology to support risk-based approaches, in greater detail.



# Methodology



- All fieldwork was conducted between March and June of 2017.
- A total of 273 completed surveys were received from respondents representing 94 individual Sponsor organizations.
- A total of 121 completed surveys were collected from respondents representing 49 individual Provider organizations.
- Classification information about respondents and companies they represent can be found in the appendix of this report.



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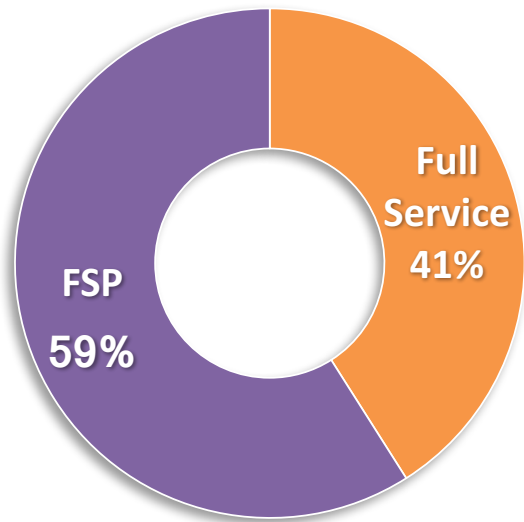
# State of the Industry

*Clinical Outsourcing Spend & Key  
Relationship Health Measures*

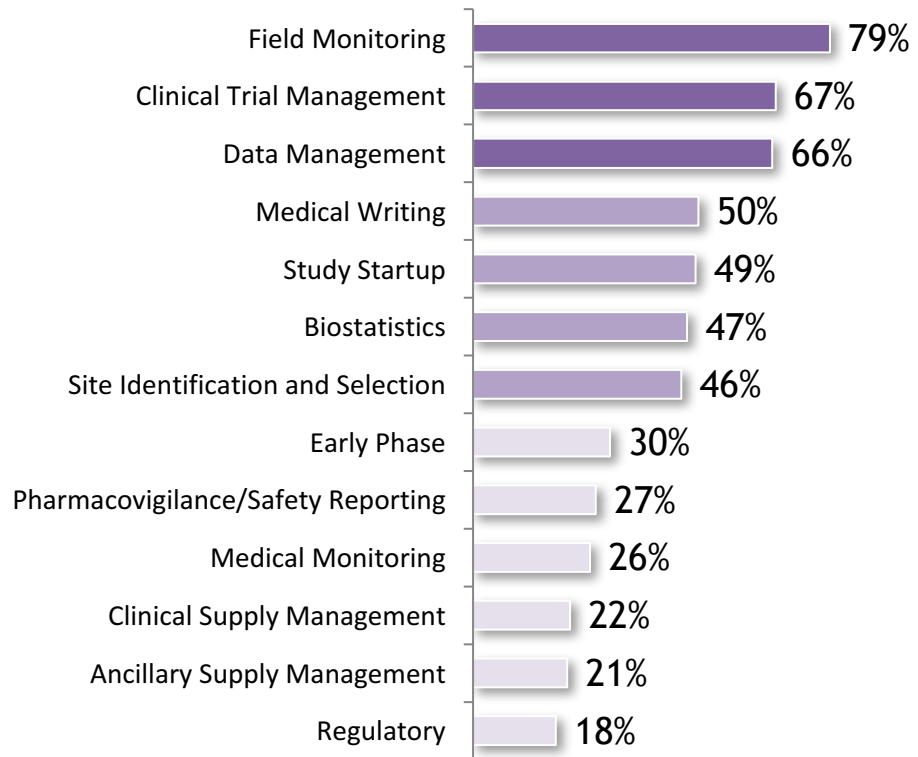
# State of the Industry

Nearly 60% of respondents from Sponsor organizations report primarily using a functional approach to outsourcing – field monitoring, clinical trial management and data management are the most frequently outsourced functions.

## SPONSOR: Outsourcing Model



## SPONSOR: FSP Outsourced Functions



N: SPONSOR=270/158

Q: Please select the outsourcing model that best represents your company's approach to clinical development outsourcing. If both approaches are equally utilized, please select the one that you have the most experience with at your current company.

Q: You indicated that your company uses a functional outsourcing approach. Which functions are outsourced in this way?



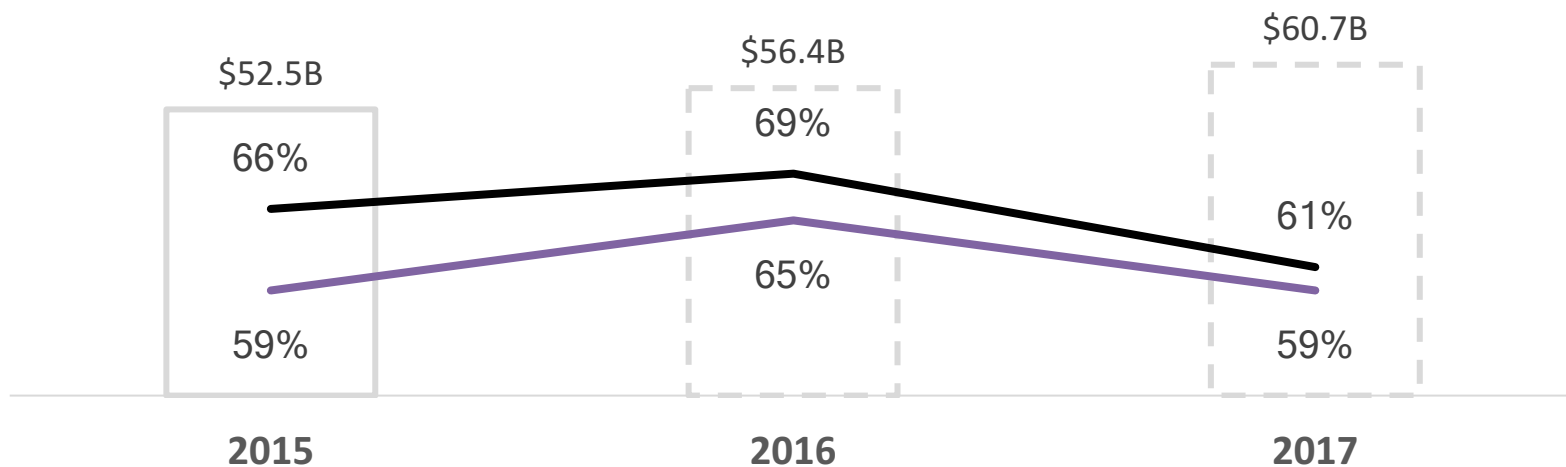
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# State of the Industry

Today, about 60% of clinical development spend is outsourced, which aligns to spend levels observed over recent years. Though respondents have anticipated modest increases in outsourced spending, this has not come to fruition.

## 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); 2016/2017 spend estimated based on projected 7-8% CAGR annually.

N: SPONSOR: 2015=123-131, 2016=112-116, 2017=273

Q: Approximately what percentage of your company's spend on clinical development was outsourced in 2016, and what do you expect the percentage will be 3 years from now?



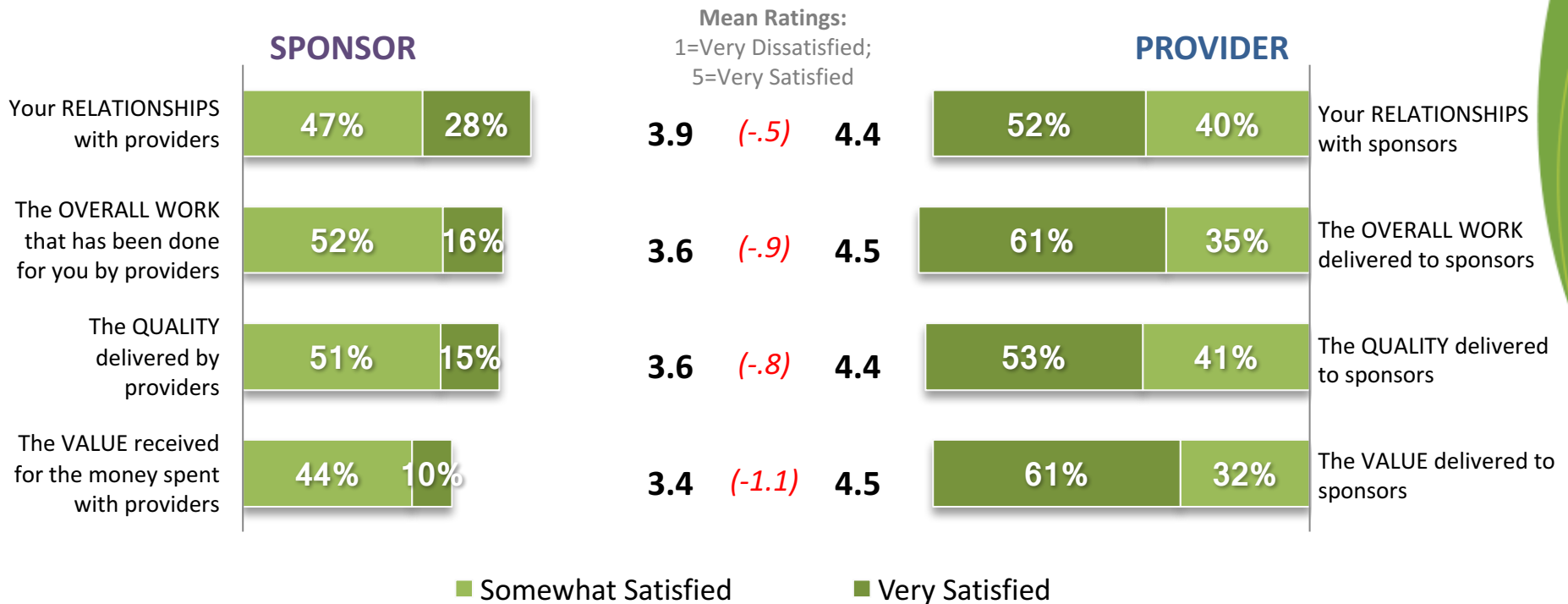
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# State of the Industry

Notable gaps were observed between Sponsors' ratings of satisfaction with key indicators of relationship health relative to those of Providers.

## Overall Assessment of Relationship Health: Sponsors vs. Providers



# State of the Industry

Among Sponsors using different outsourcing models, perceptions of key relationship indicators were comparable.

## Overall Assessment of Relationship Health: Sponsors Using Full-Service vs. FSP Outsourcing Model

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

	All Sponsors	Full-Service	FSP
Your RELATIONSHIPS with providers	3.9	3.9	3.9
The OVERALL WORK that has been done for you by providers	3.6	3.6	3.6
The QUALITY delivered by providers	3.6	3.5	3.6
The VALUE received for the money spent with providers	3.4	3.4	3.3

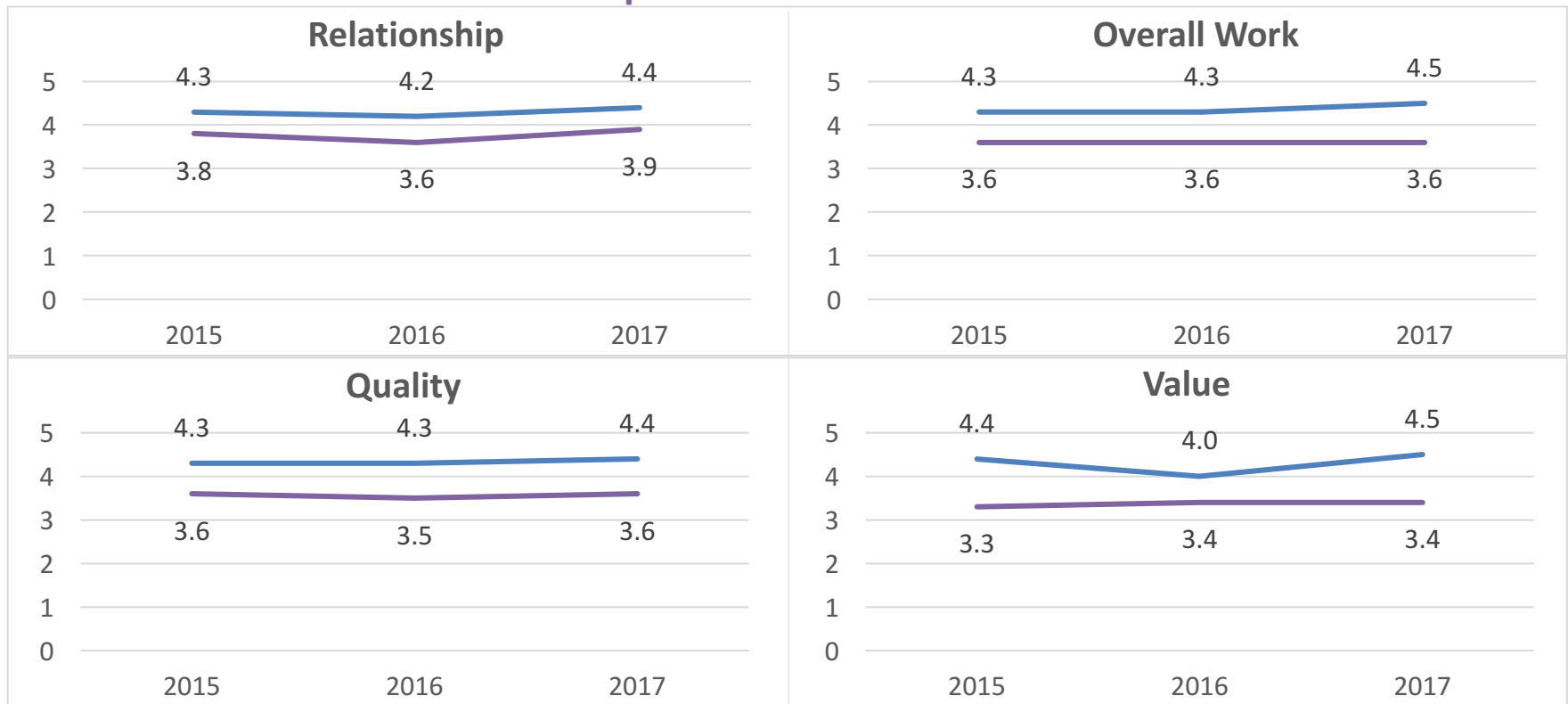


# State of the Industry

These gaps have persisted over time, and do not appear to show signs of narrowing.

## Trend in Overall Assessment of Relationship Health

— Sponsor — Provider



2015 N: SPONSOR=148-152, PROVIDER=88-90; 2016 N: SPONSOR=104-105, PROVIDER=56-60; 2017 N: SPONSOR=255-265; PROVIDER=117-120.

Q: Thinking about your experiences in 2016, how satisfied are you with...



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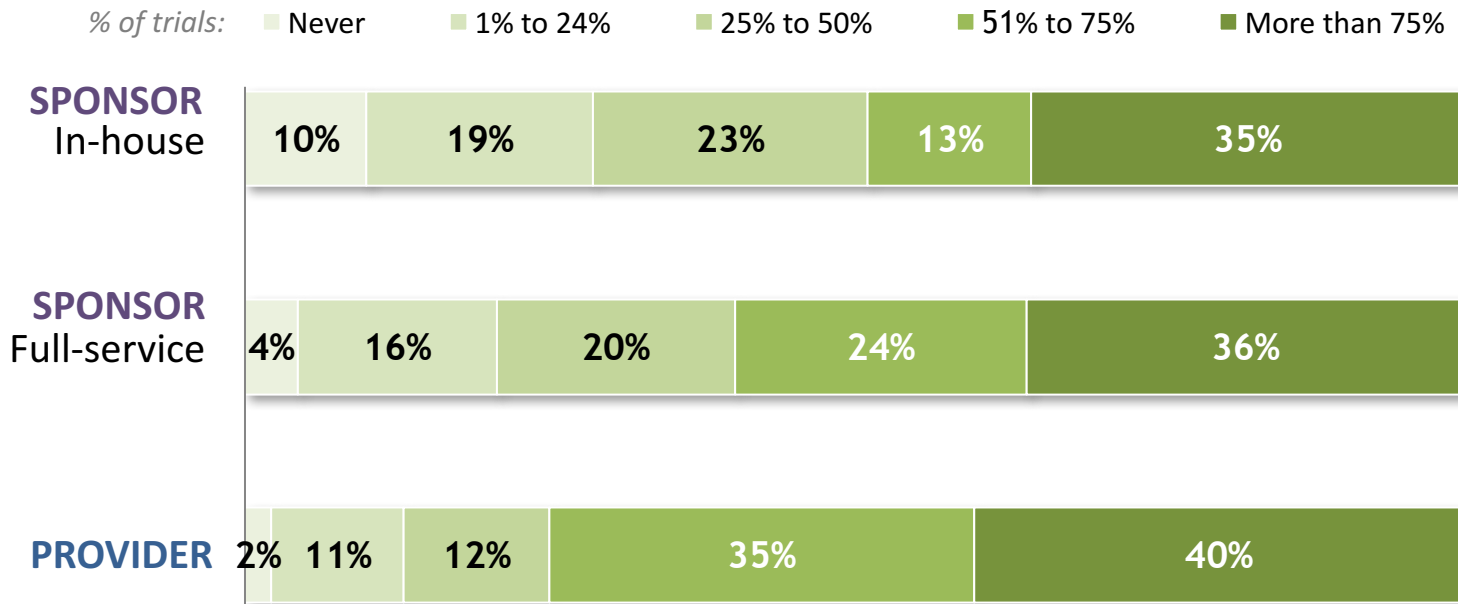
# Risk Assessment

*Prevalence and Practice of Risk  
Assessment in Clinical Research*

# Risk Assessment

Systematic risk assessments are being utilized similarly by Sponsors for in-house and fully outsourced trials - between 50% and 60% say they are doing this in at least half of their trials. Providers show even greater utilization.

## Frequency of Risk Assessment



N: SPONSOR In-house=231/Full-service=92; PROVIDER=92

SPONSOR Q: How often do your company's project/program teams use a systematic risk assessment process for trials managed and conducted by in-house teams? SPONSOR Q: How often do the project/program teams with which you work (including the CRO partners) use a systematic risk assessment process for outsourced clinical trials? PROVIDER Q: Approximately how often is a systematic risk assessment process employed for clinical trials conducted by your company?

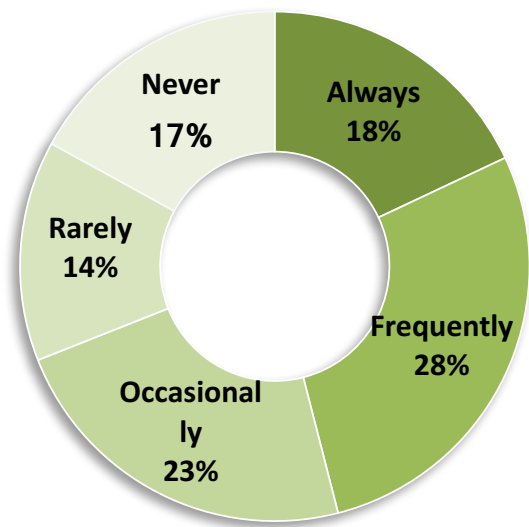


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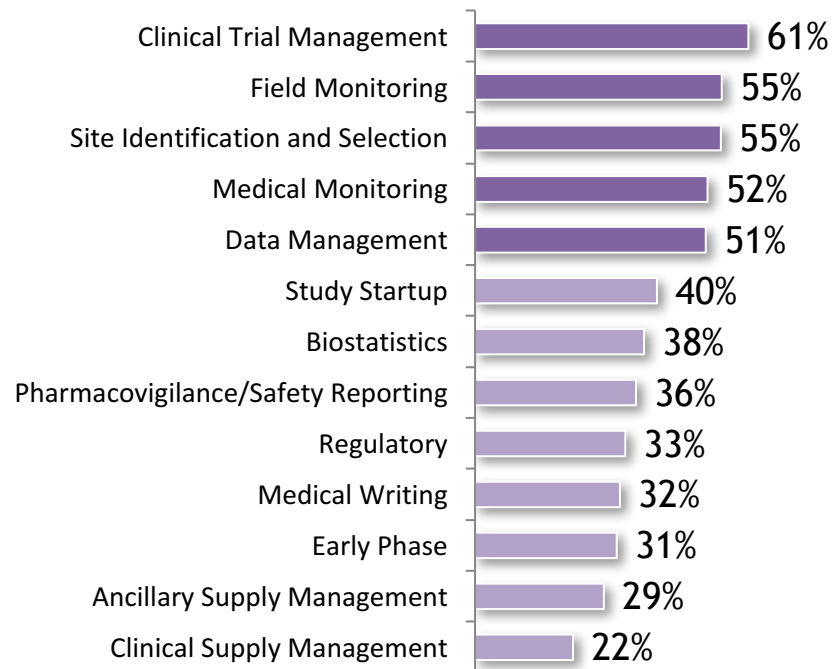
# Risk Assessment

Among Sponsors utilizing a functional outsourcing model, 46% report that they “always” or “frequently” perform risk assessments. Assessments are used most often within the outsourced functions of clinical trial management, field monitoring and site identification and selection.

## Sponsor FSP Model Risk Assessment Utilization



## Sponsor FSP Model % “always” or “frequently” using risk assessment



N: SPONSOR FSP (all functions aggregated)=158; FSP Functions=21-104

SPONSOR Q: You indicated that your company uses a functional outsourcing model. How often do the following outsourced functions participate in a systematic risk assessment process for your trials?



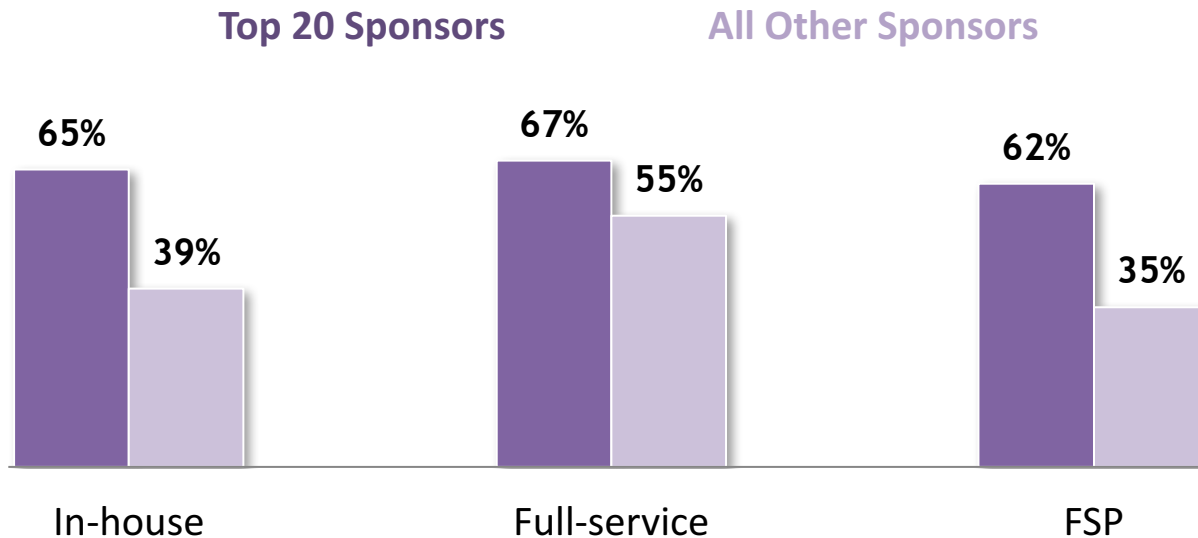
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# Risk Assessment

Regardless of outsourcing model, Top 20 Sponsor organizations are using risk assessments more frequently than are those in smaller organizations. This trend has held true since Avoca's initial assessment of risk behavior in 2013.\*

## Frequency of Risk Assessment

*% using assessment in more than half of trials (for in-house and full-service)  
% using "always" or "frequently" (for FSP)*



\*The 2013 Avoca Industry Report can be found here: [http://theavocagroup.com/wp-content/uploads/2016/01/The\\_2013\\_Avoca\\_Report.pdf](http://theavocagroup.com/wp-content/uploads/2016/01/The_2013_Avoca_Report.pdf)

N: SPONSOR In-house: Top 20=89, Other=142; Full-service: Top 20=36, Other=56; FSP (all functions aggregated); Top 20=61, Other=82

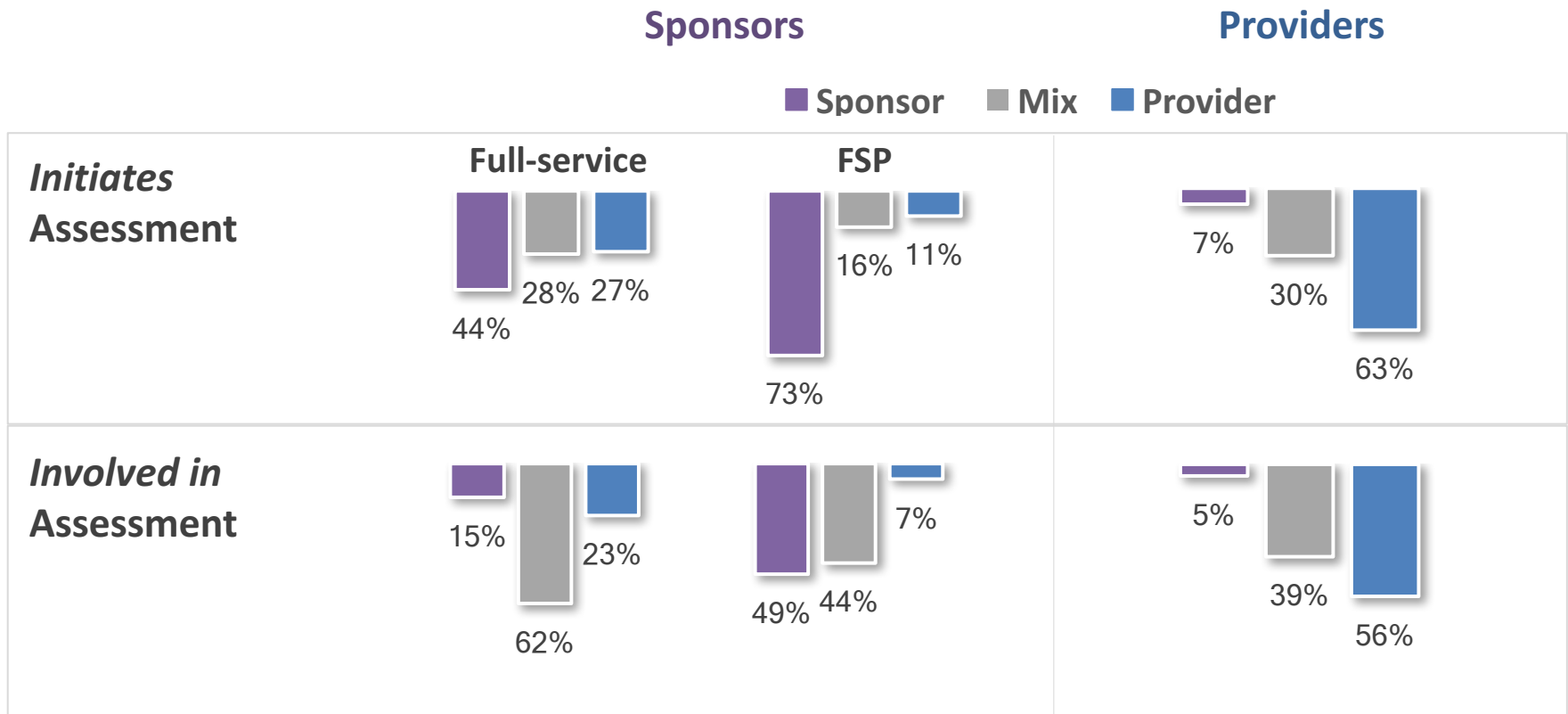
SPONSOR Q: How often do your company's project/program teams use a systematic risk assessment process for trials managed and conducted by in-house teams? SPONSOR Q: How often do the project/program teams with which you work (including the CRO partners) use a systematic risk assessment process for outsourced clinical trials? SPONSOR Q: You indicated that your company uses a functional outsourcing model. How often do the following outsourced functions participate in a systematic risk assessment process for your trials?



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# Risk Assessment

Sponsors are most likely to report that they *initiate* risk assessments, especially within an FSP model; however, the CRO or FSP is at least equally likely to be *involved* in the process. From the Provider point of view, respondents report that their organizations are typically initiating *and* engaging in this process.



N: SPONSOR Full Service=95/95; SPONSOR FSP=124/123; PROVIDER=108/93

SPONSOR Q: For fully-outsourced clinical trials/For trials utilizing functional service providers, who most often initiates/requests a systematic risk assessment? SPONSOR Q: For fully-outsourced clinical trials/For clinical trials utilizing functional service providers, to what extent is the CRO/FSP generally involved in the systematic risk assessment? PROVIDER Q: Who generally initiates/requests a systematic risk assessment? PROVIDER Q: To what extent is your company generally involved in the systematic risk assessment?



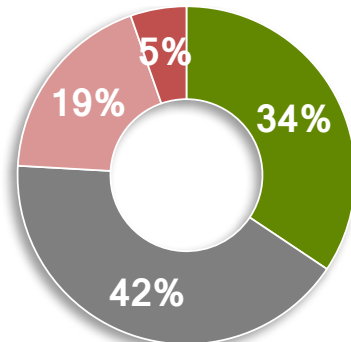


# Risk Assessment

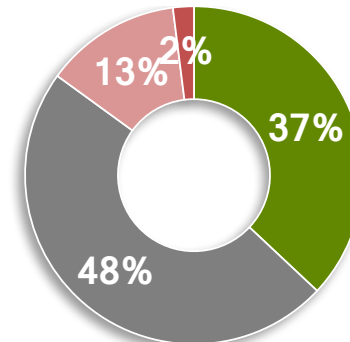
Only about one-third of respondents indicate that gaining alignment on risk is “easy” from an internal perspective. Even fewer say this is the case when attempting to gain alignment with external parties.

## Difficulty Gaining Alignment on Risk...

### SPONSOR: Internally

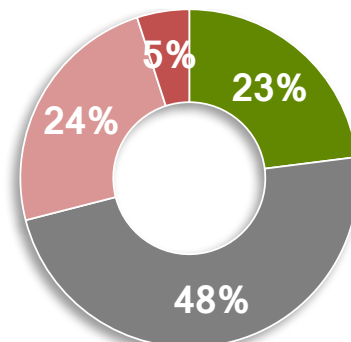


### PROVIDER: Internally

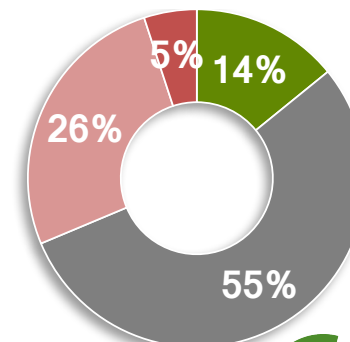


- Easy
- Slightly Difficult
- Somewhat Difficult
- Very Difficult

### SPONSOR: With Providers



### PROVIDER: With Sponsors



- Easy
- Slightly Difficult
- Somewhat Difficult
- Very Difficult

N: SPONSOR=224/210; PROVIDER=98/92

Q: In general, how difficult is it to gain agreement about the probability and importance of the various risks associated with clinical trial conduct...?



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# Risk Assessment

Despite noted gaps in how the two audiences align on risk, Sponsors and Providers are generally in sync regarding *when* they are performing risk assessments. Two-thirds are doing so prior to trial start, approximately half are doing so during start-up and three-quarters are doing so throughout the trial.



# Risk Assessment

Both audiences are also well aligned on the “nature” of risk assessments – approximately half are using a hybrid approach of quantitative and qualitative methods, while most others primarily approach qualitatively.

## How Risk is Assessed



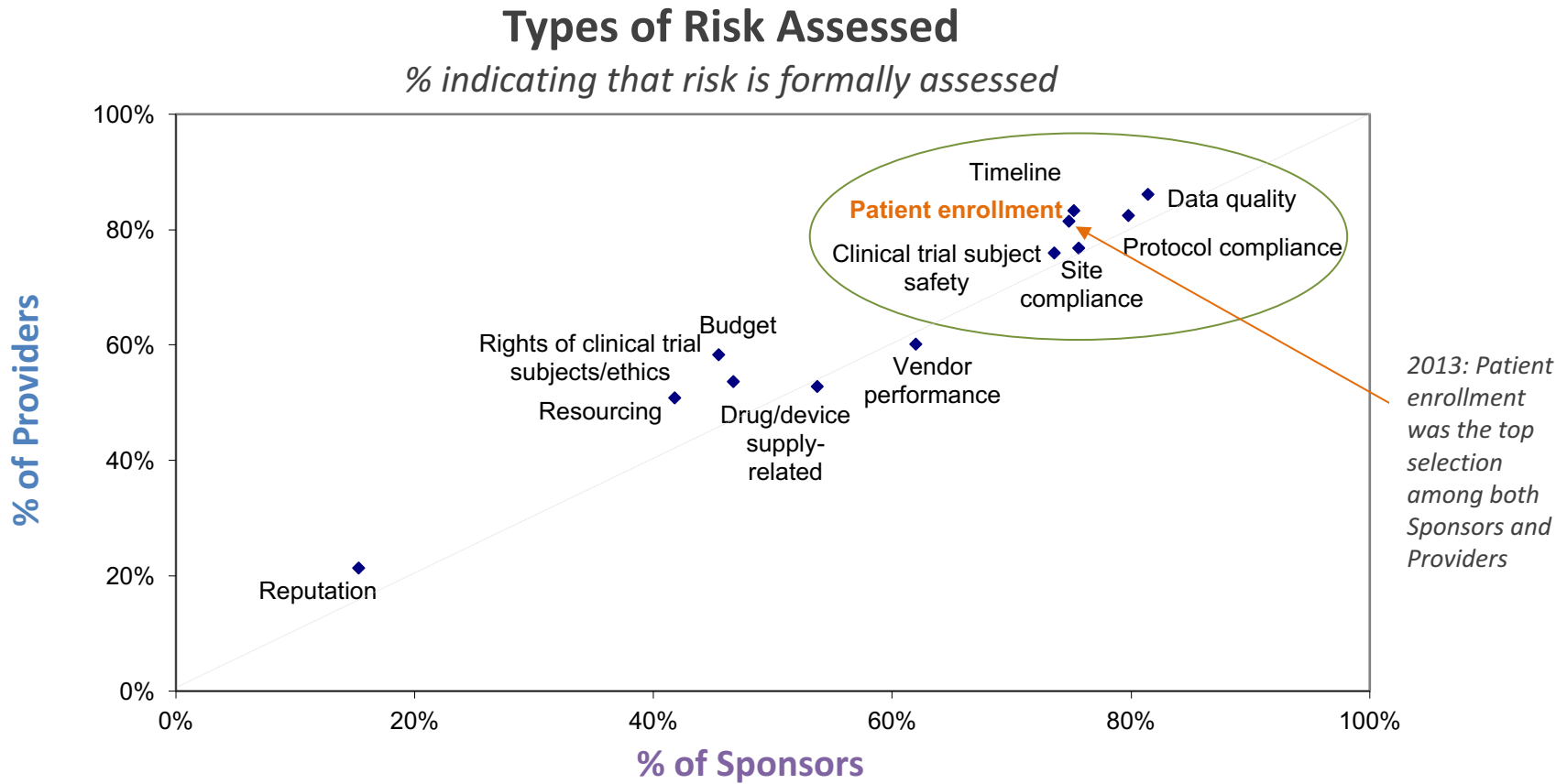
N: SPONSOR=240; PROVIDER=107

Q: Is the risk assessment process primarily qualitative (e.g., risks identified and discussed), or quantitative (e.g., probabilities and consequences of specific risks estimated quantitatively)?



# Risk Assessment

Risks to data quality, protocol and site compliance, enrollment and safety and timelines are most prevalent in formal risk assessments by both Sponsors and Providers.



N: SPONSOR=242; PROVIDER=108

SPONSOR Q: When a systematic risk assessment is performed for your company's projects, which of the following risks are typically formally assessed? Risks to...

PROVIDER Q: When a systematic risk assessment is performed for projects conducted by your company, which of the following risks are typically formally assessed? Risks to...

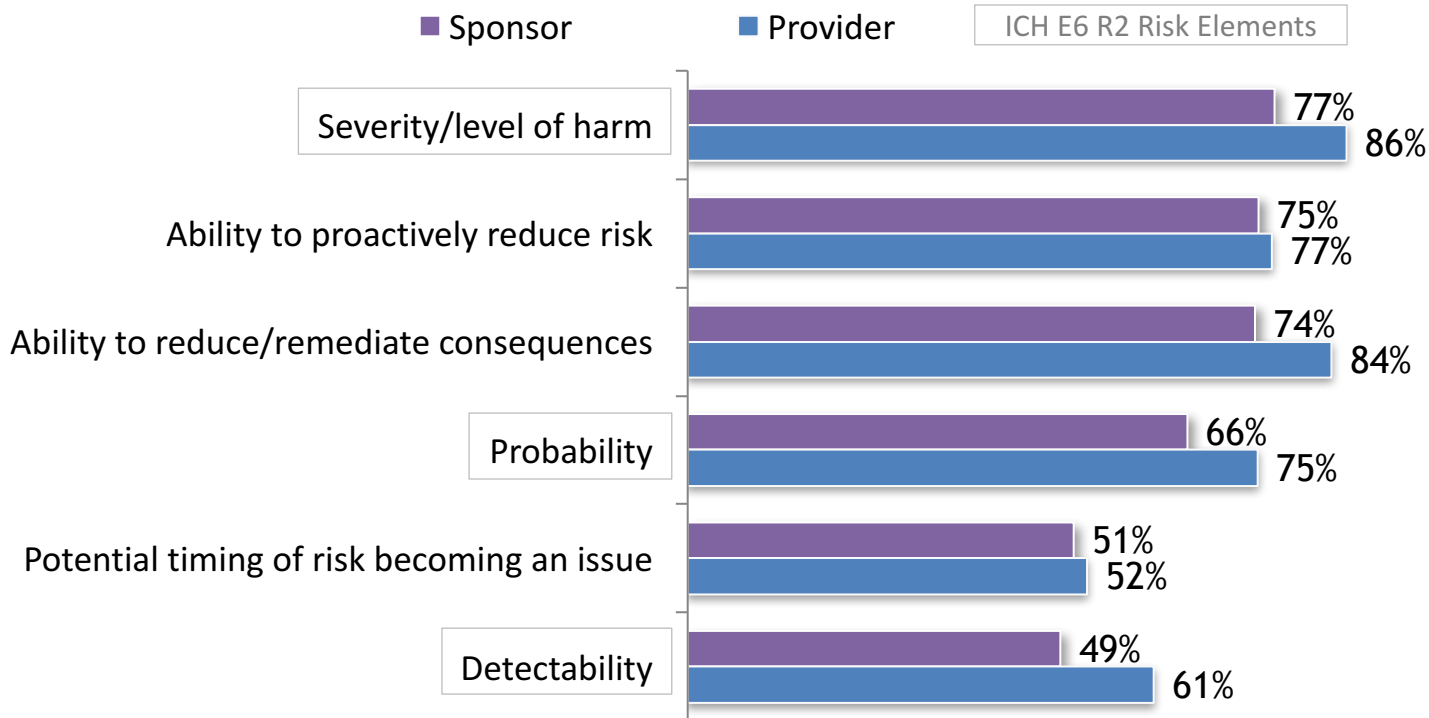


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# Risk Assessment

Today, probability, timing and detectability are less frequently assessed relative to severity and ability to proactively reduce risk and consequences.

## Features of Risk Assessed



N: SPONSOR=235; PROVIDER=101

SPONSOR Q: When a systematic risk assessment is performed for your company's projects, what features of each risk are generally assessed? PROVIDER Q: During risk assessments, what features of risk are generally assessed?

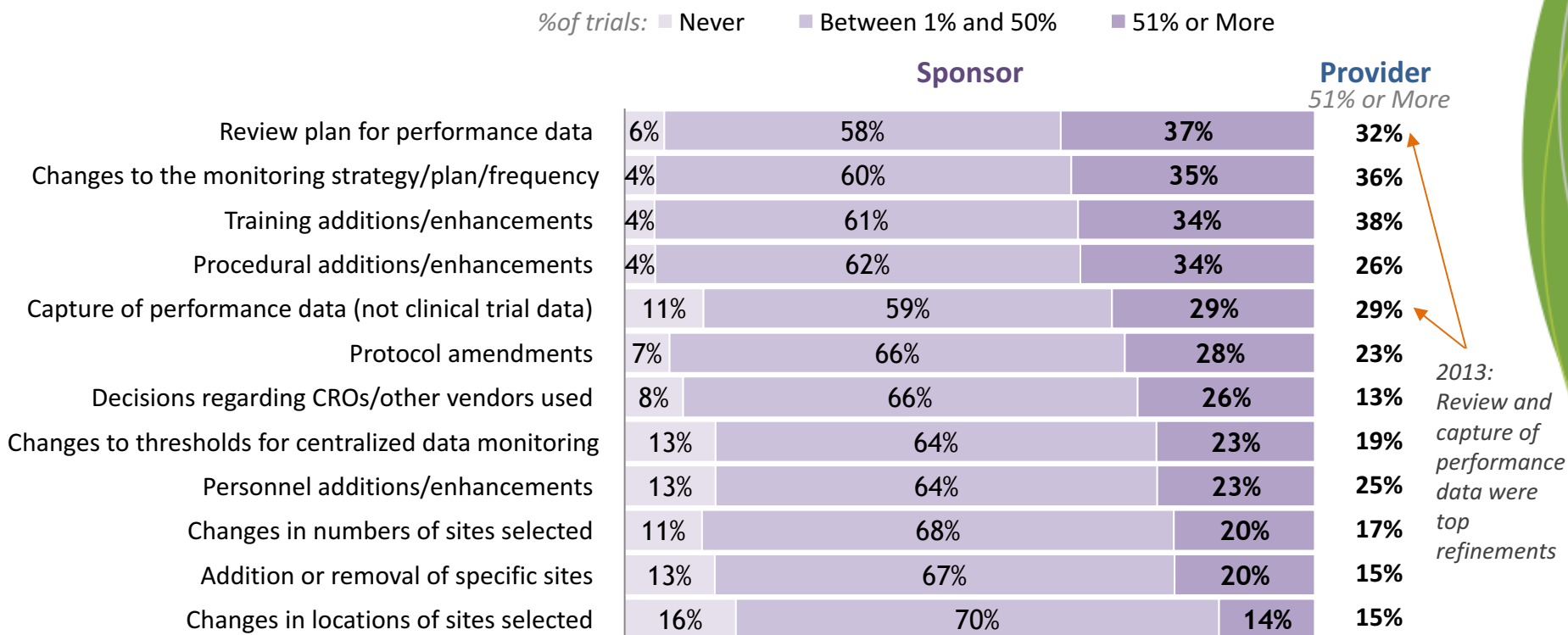


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# Risk Assessment

Risk assessments are reported to have the greatest impact on the refinement of review of performance data, changes to the monitoring plan and training – these were the top three most frequently cited refinements among Sponsors and Providers alike.

## Types of Refinements Made Based on Risk Assessment



N: SPONSOR=174-207; PROVIDER=63-81

Q: How often does your risk assessment process lead to the introduction or refinement of each of the following proactive measures designed to reduce risk?



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# Risk Assessment

There is a disconnect between Sponsors' reported satisfaction with how CROs address risk activities relative to how Providers see themselves as performing. Similar gaps were identified in 2013, suggesting the dynamic has shown little change over time.\*

## Satisfaction with Risk Activities

*% very or somewhat satisfied*

	<b>SPONSOR</b> <i>Assessment of CROs</i>	<b>PROVIDER</b> <i>Self-Assessment</i>
Proactive identification of potential risks	46%	73%
Appropriateness of measures suggested/taken in reaction to risk info	46%	70%
Overall performance on risk assessment and management activities	43%	71%
Ownership over risk assessment and management related activities	43%	69%
Compilation of risk-related trial information during a trial	41%	64%
Communications regarding risk-related trial information	41%	70%
Frequency of review of risk-related trial information	39%	61%
Proactive risk analysis and evaluation	37%	65%
Rigor of review of risk-related trial information	36%	63%

\*The 2013 Avoca Industry Report can be found here: [http://theavocagroup.com/wp-content/uploads/2016/01/The\\_2013\\_Avoca\\_Report.pdf](http://theavocagroup.com/wp-content/uploads/2016/01/The_2013_Avoca_Report.pdf)

N: SPONSOR=187-194; PROVIDER=104-112

SPONSOR Q: In general, how satisfied are you with the performance of each of your in-house teams, CROs and other clinical service providers you work with, with respect to each of the following?

PROVIDER Q: In general, how satisfied are you with your company's teams with respect to each of the following?

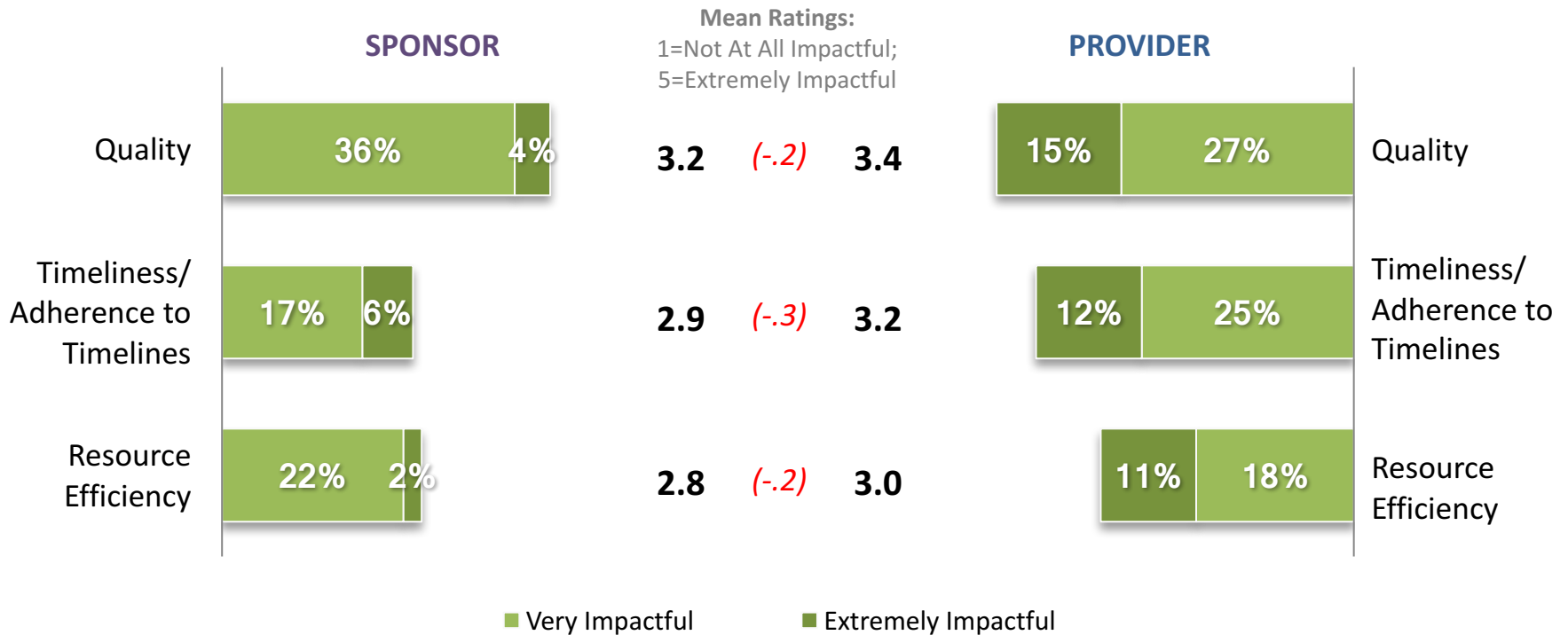


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# Risk Assessment

Moderate mean ratings were observed in terms of the perceived impact of risk assessment and management approaches on quality, timeliness and resource efficiency. Providers were somewhat more favorable in their response.

## Impact of Risk Assessment on Increasing...



N: SPONSOR=219-227; PROVIDER=97-103

Q: How impactful have your risk assessment and management approaches been in terms of increasing...?





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# Risk-Based Approaches

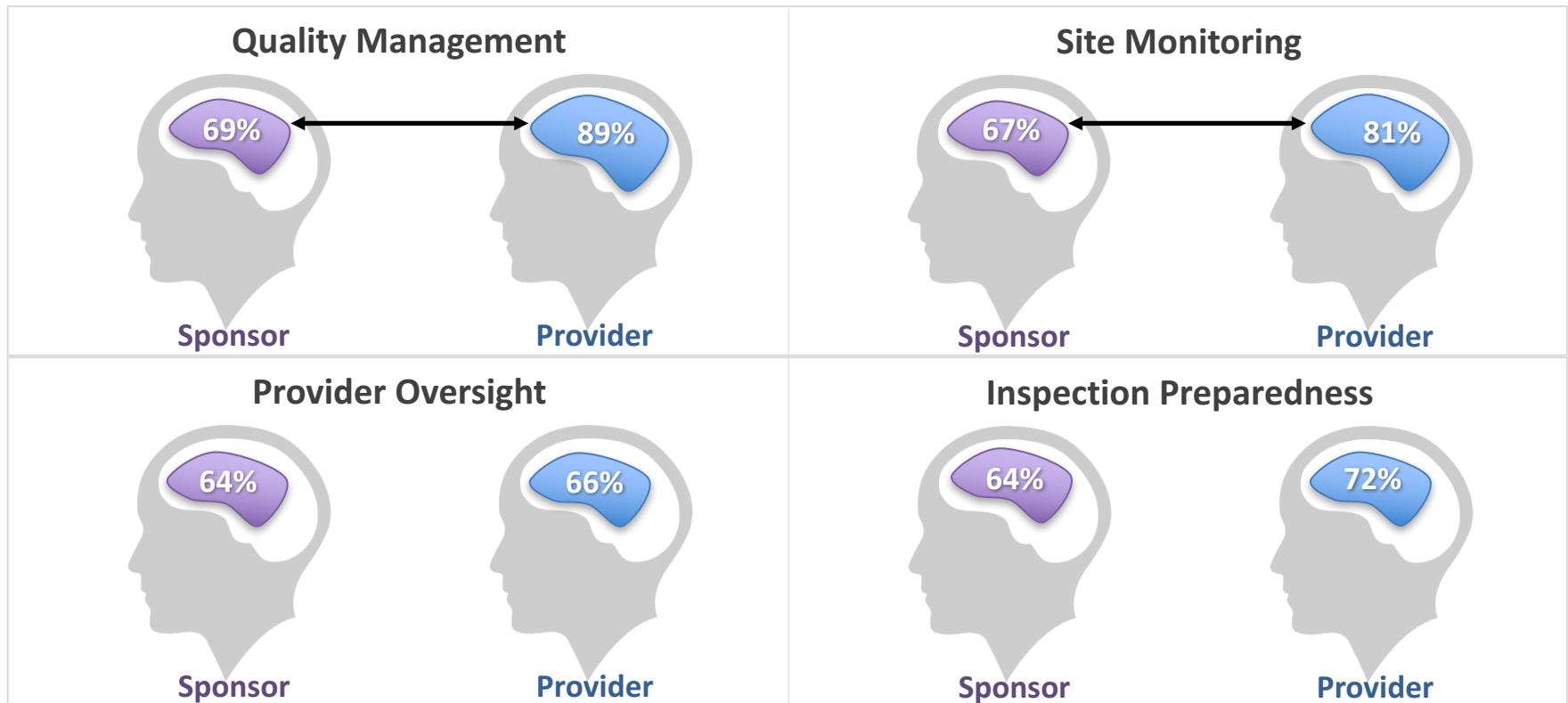
*Utilization and Challenges of Risk-  
Based Approaches*

# Risk-Based Approaches

Approximately two-thirds of Sponsors and Providers report familiarity with best practices in risk-based provider oversight and inspection preparedness. With respect to risk-based quality management and site monitoring, Providers are more likely to express having a “good” or “very good” understanding.

## Familiarity with Risk-Based Approaches

*% having a “good” or “very strong” understanding of best practices*



N: SPONSOR=270-272; PROVIDER=117-118

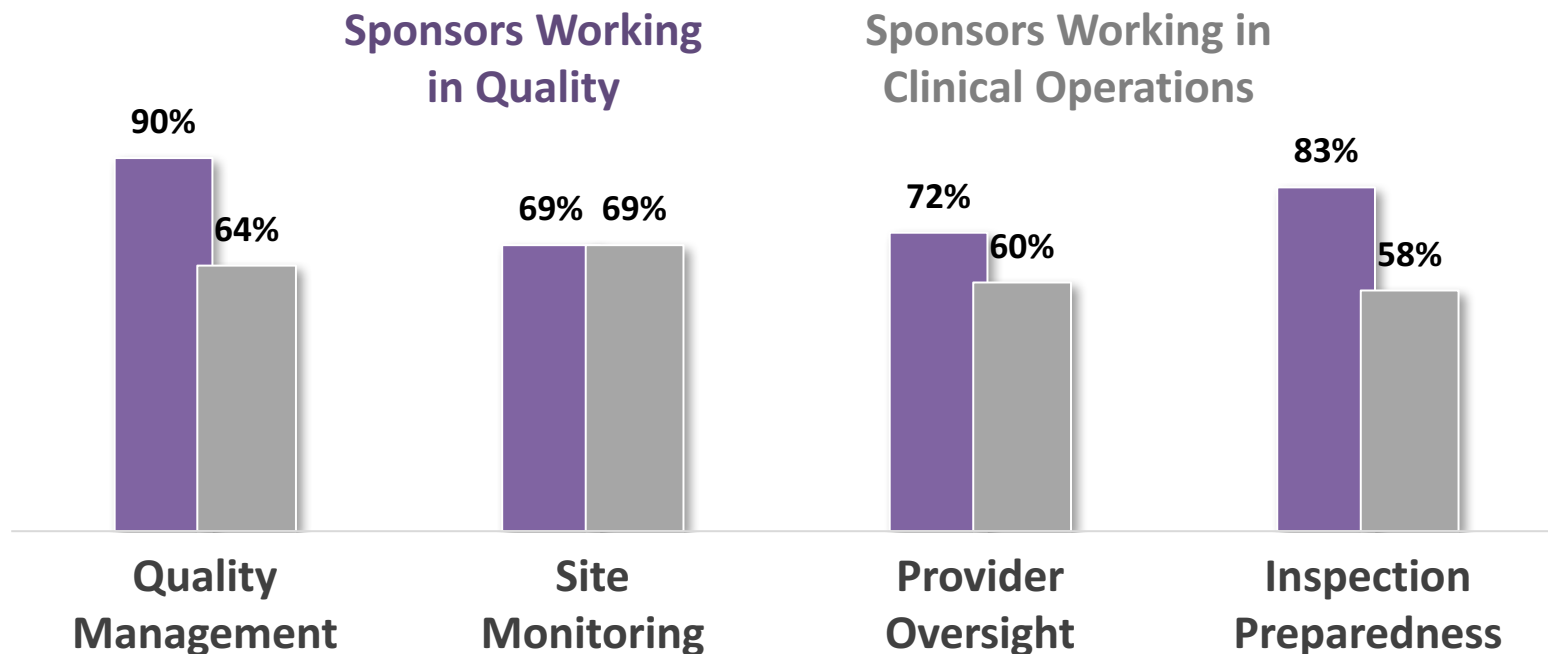
Q: How would you rate your understanding of best practices in...?

# Risk-Based Approaches

By function, notable differences are observed with respect to the level of familiarity with best practices in risk-based quality management and inspection preparedness – those working in quality express a higher level of knowledge than do those in clinical operations.

## Familiarity with Risk-Based Approaches by Sponsor Role

*% having a “good” or “very strong” understanding of best practices*

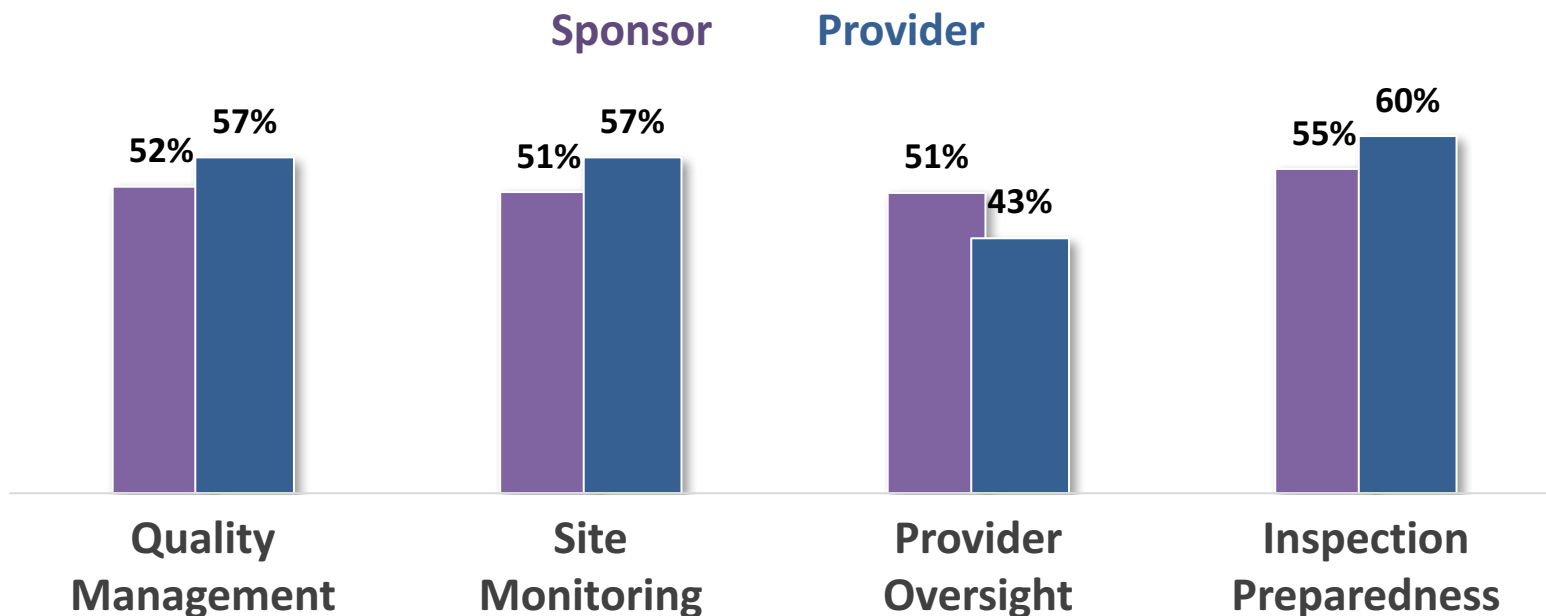


# Risk-Based Approaches

Despite notable differences in reported behavior and perceptions regarding risk, Sponsors and Providers are well aligned regarding the utilization of risk-based approaches to various aspects of trial management – approximately half are using these methods in 50% or more of their trials today.

## Use of Risk-Based Approaches to...

*% using in more than half of trials*



N: SPONSOR=224-230; PROVIDER=72-83

SPONSOR Q: How often do your teams use a risk-based approach to...? SPONSOR Q: How often do you use a risk-based approach to determine the level and/or type of Sponsor oversight employed for FSP providers you work with, with respect to the following outsourced functions? SPONSOR Q: How often do you use a risk-based approach to prepare for inspections for clinical trials with functions outsourced to FSPs? PROVIDER Q: How often does your company use a risk-based approach to...?



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# Risk-Based Approaches

Sponsors and Providers alike report that aligning people and organizational thinking, as well as the structure, systems and processes in place to assess and manage risk are the most significant challenges that are faced in the use of risk-based approaches.

## Aligning People & Thinking

*“Mind shift - understanding that implementing QRM and RBM is not about saving money. Teams still report issues, not risks and the risks identified are mainly focusing on timeline and budget, not on quality.”*

*“Adaptation of such an approach and the buy-in from all functional parties. They don't understand it well enough to adopt and allow the needed resources to be applied in order to get it off the ground.”*

## Challenges Regarding Use of Risk-Based Approaches



## Aligning Systems & Processes

*“We've had challenges in bringing together disparate data sources into one RBM view point. We've also been applying RBM approaches to legacy studies where the study setup has not been conducive to data integration.”*

# Risk-Based Approaches

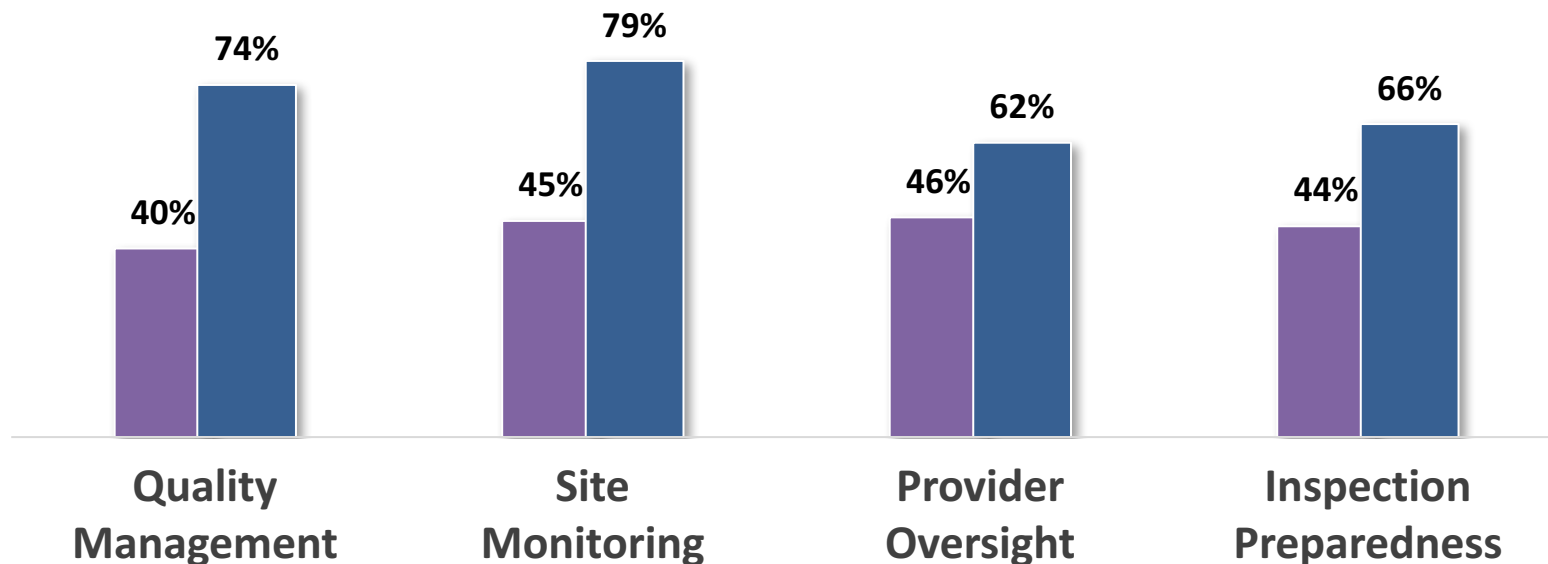
There is lack of alignment on satisfaction levels associated with various risk activities – while a majority of Providers are satisfied with what their organizations are providing in these respects, less than half of Sponsors say the same.

## Satisfaction with Risk Activities

*% very or somewhat satisfied*

### Sponsor Assessment of CROs/FSPs

### Provider Self-Assessment



N: SPONSOR=169-189; PROVIDER=71-86

SPONSOR Q: Overall, how satisfied have you been with the CROs/FSPs you work with in terms of their ...?

PROVIDER Q: Overall, how satisfied have you been with your company in terms of the...?



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# Risk-Based Approaches

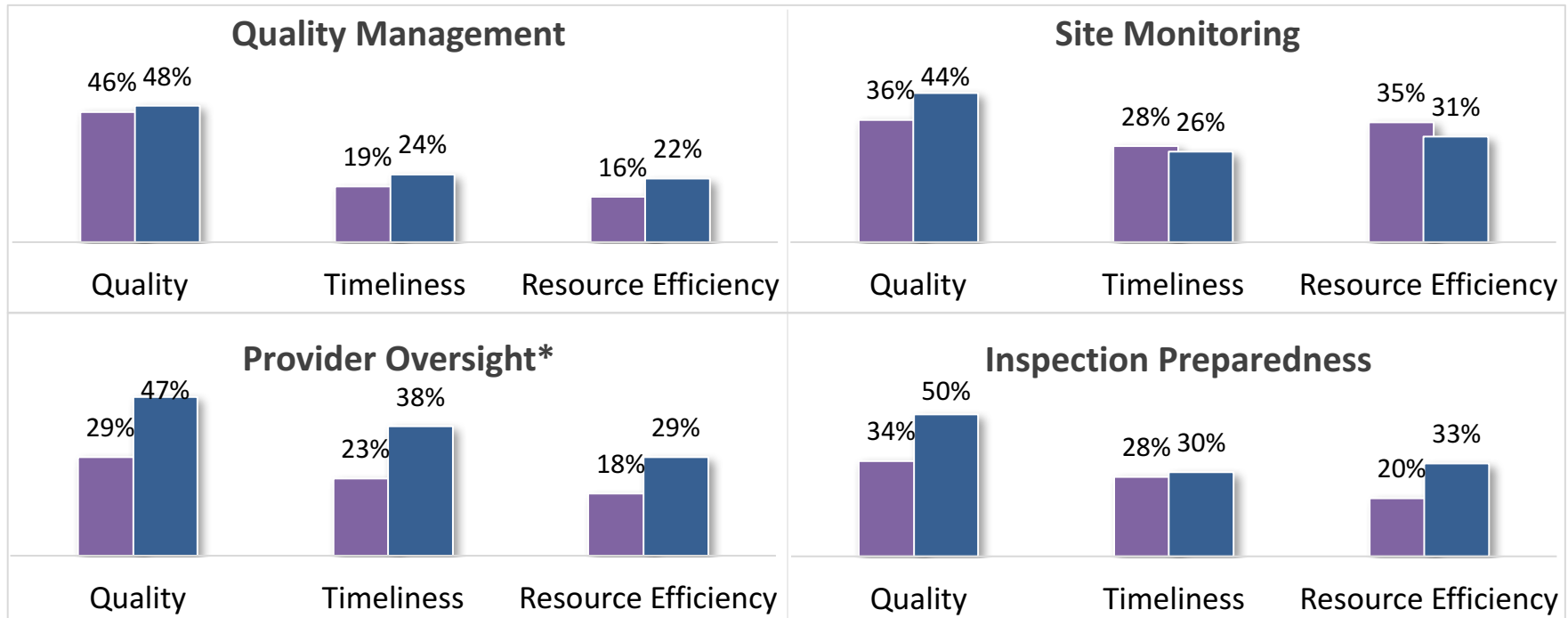
Across all risk-based approaches, only 50% or less feel that the measures taken are having a significant impact on quality, timeliness and resource efficiency.

## Impact of Risk-Based Approaches on Increasing...

% "extremely" or "very impactful"

**Sponsor**

**Provider**



N: SPONSOR=125-165; PROVIDER=38-71

Q: How impactful have the following risk-based approaches been in terms of increasing ...? \*Represents Sponsors rating oversight of CROs/FSPs (depending on outsourcing model) and Providers rating oversight of other clinical service providers.



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# Key Take-Aways



## Key Take-Aways

- Despite marked shifts in the landscape and in regulatory requirements, these data suggest that **little has changed with respect to how the Industry is approaching and managing risk assessment.**
- The **alignment of people and processes appears to be a significant barrier** in more widespread adoption of risk-based techniques to clinical trial management.
- **Large gaps continue to exist** between how Sponsors perceive their environment, and specifically their relationships with Providers, and how Providers perceive their own performance.





**Avoca Integrated Consulting and Research delivers a fresh perspective — a clear, and neutral take on how to increase efficiency, improve quality, and mitigate risk in clinical trial execution and management.**

**Avoca pairs best-in-class research capabilities with a team that understands what trends mean for the industry and how they affect your day-to-day business.**



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# Avoca Client List

## Pharmaceutical/Biotech



## Service Providers





The Avoca Quality Consortium brings together quality, outsourcing and operational professionals from member pharma, biotech, niche clinical service providers, and CRO organizations to accelerate and streamline clinical trial execution and improve quality through industry collaboration.



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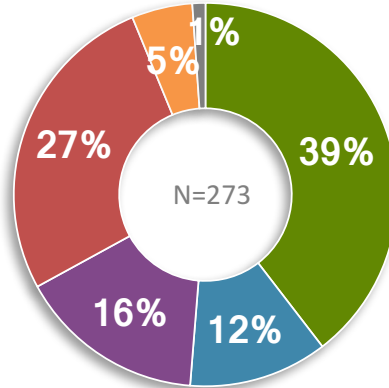
# Appendix

## *Demographics*

# Company Characteristics

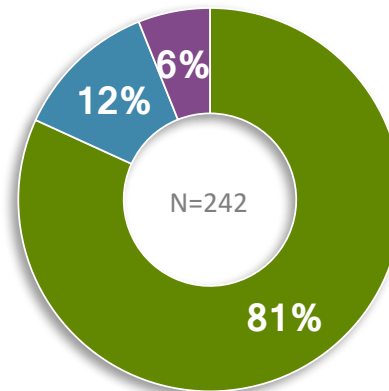
## SPONSOR: Company Size

- 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)
- Medical Device company
- Other



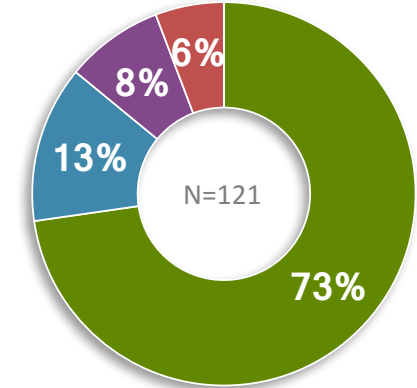
## SPONSOR: Company Headquarters

- United States
- Western Europe
- Other



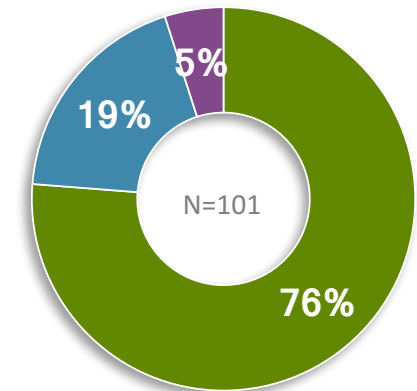
## PROVIDER: Company Type

- CRO
- Clinical Service Provider
- Consulting Company
- Other



## PROVIDER: Company Headquarters

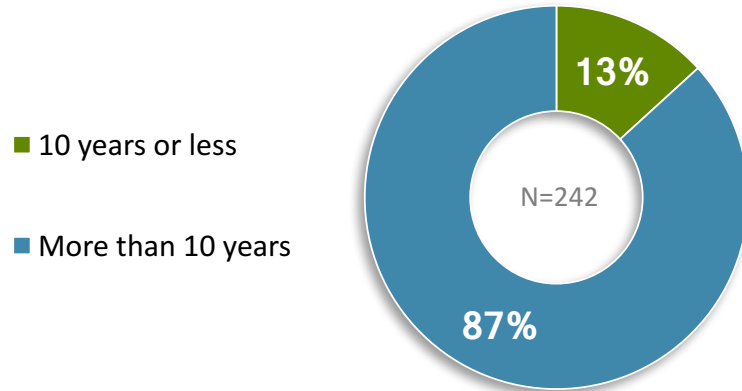
- United States
- Western Europe
- Other



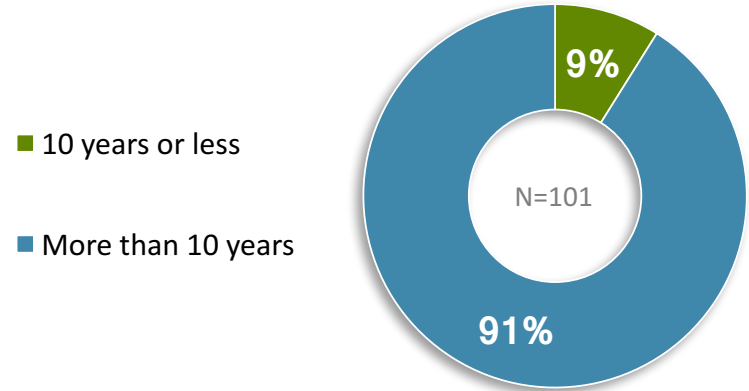


# Respondent Characteristics

## SPONSOR: Time in Industry

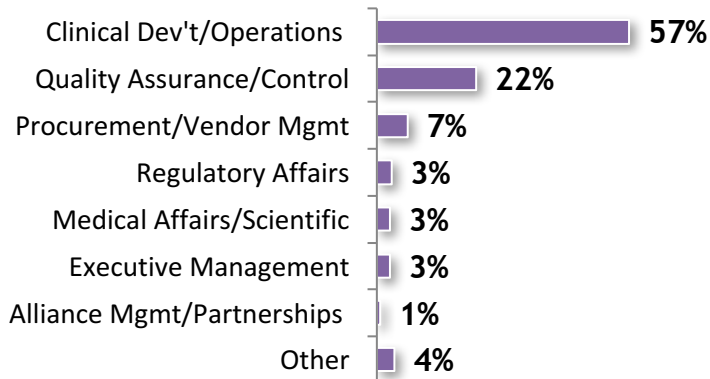


## PROVIDER: Time in Industry



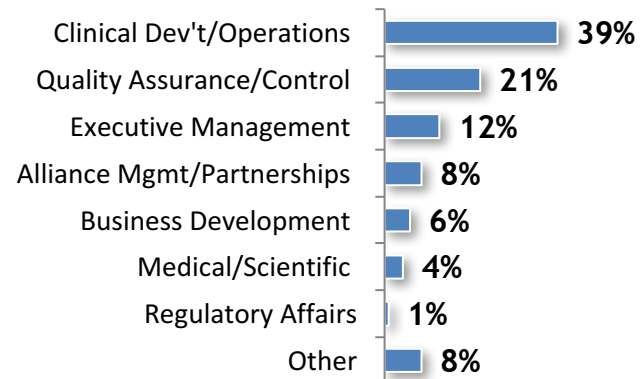
## SPONSOR: Primary Functional Area

N=273



## PROVIDER: Primary Functional Area

N=121







**CONSULTING AND  
RESEARCH SERVICES**

THE AVOCA GROUP

# Thank you

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