

# The 2017 Avoca Industry Report

Using Risk-Based Approaches to  
Quality Management



September 2017



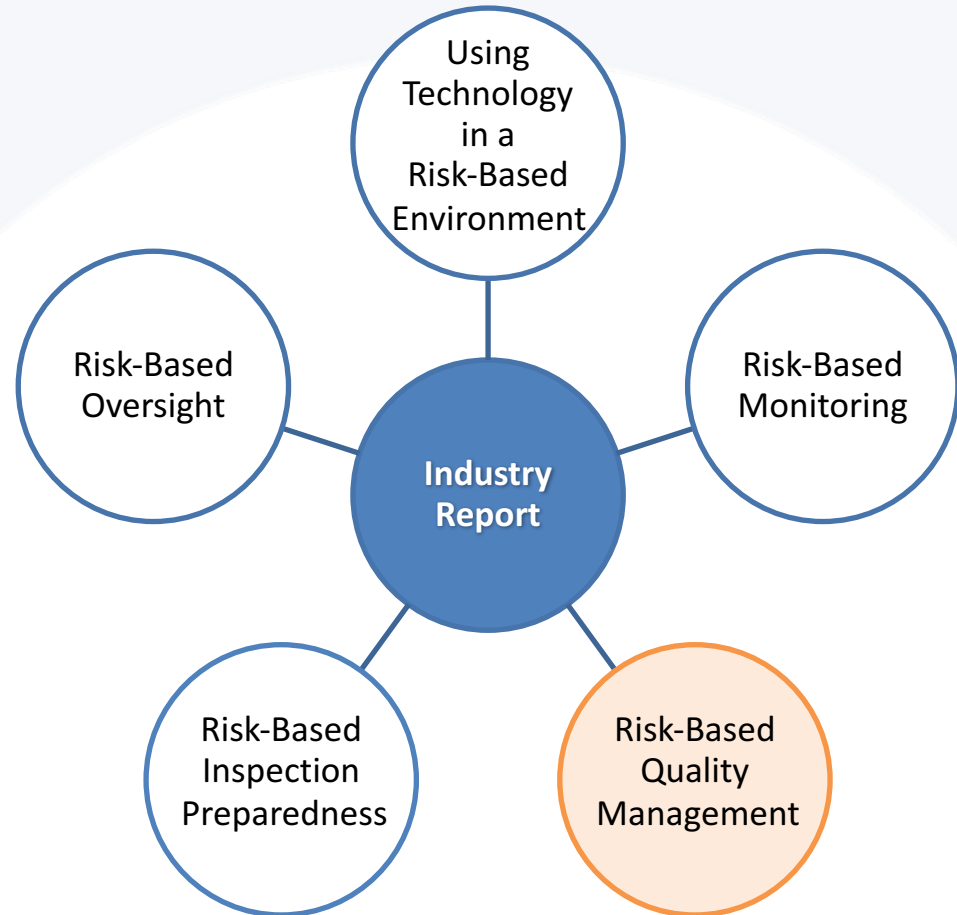
# 2017 Avoca Industry Report Series



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 2017, Avoca issued the Industry Report, which is a high level overview of key results.

In addition, Avoca is issuing a series of follow-up reports that examine specific areas in greater detail, with this being the second in this series.



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# 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.

# Summary of Key Topline Findings: Industry Survey on Risk

- 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.



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# Key Findings

## *Risk-Based Quality Management*

# Risk-Based Quality Management

Though nearly 70% of Sponsor respondents indicate having a “good” or “very good” understanding of best practices in risk-based quality management, this was lower than the nearly 90% of Providers who indicated this level of knowledge.

## Familiarity with Risk-Based Approaches to Quality Management

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

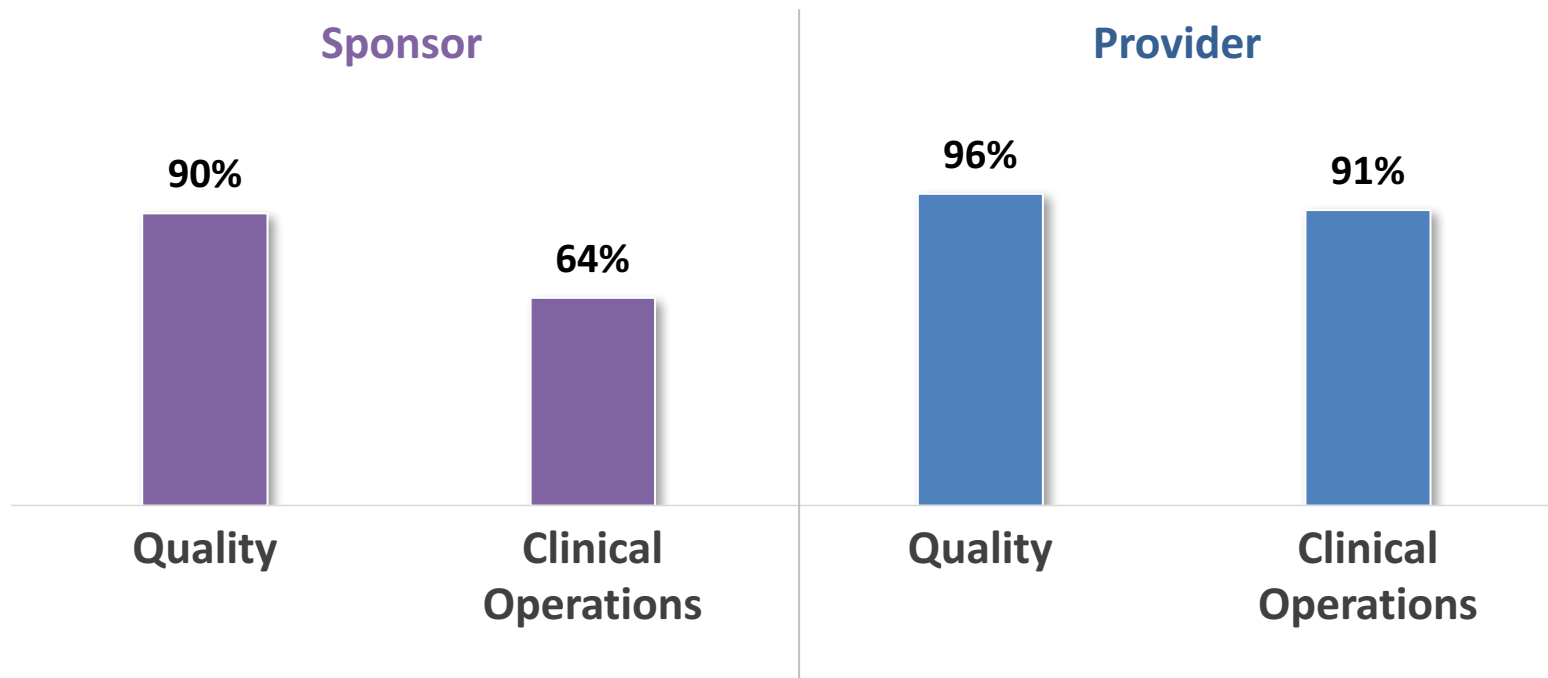


# Risk-Based Quality Management

Among Providers, understanding of risk-based quality management was consistent by function; however, among Sponsors, those in Clinical Operations expressed a substantially lower level of familiarity than did those representing the quality function.

## Familiarity with Risk-Based Approaches to Quality Management by Function

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





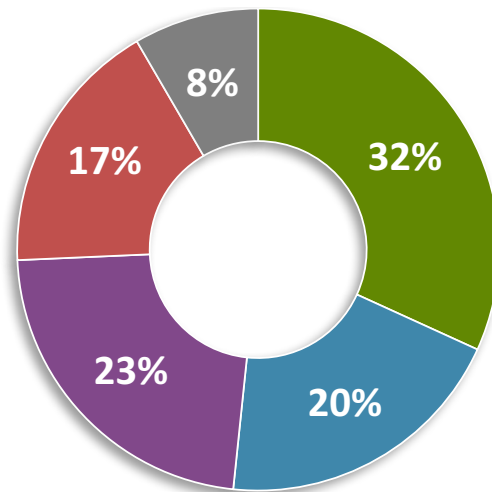
# Risk-Based Quality Management

Approximately 50% - 60% of respondents reported that risk-based quality management is being utilized in at least half of the trials they run.

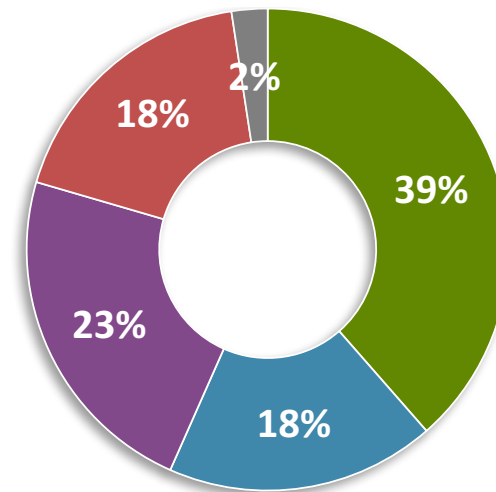
## Frequency of Use of Risk-Based Quality Management

*% of trials utilizing risk-based quality management approach*

### Sponsor



### Provider



- More than 75%
- 51% to 75%
- 25% to 50%
- 1% to 24%
- Never

N: SPONSOR=226; PROVIDER=83

SPONSOR Q: How often do your teams use a risk-based approach to...? PROVIDER Q: How often does your company use a risk-based approach to...?



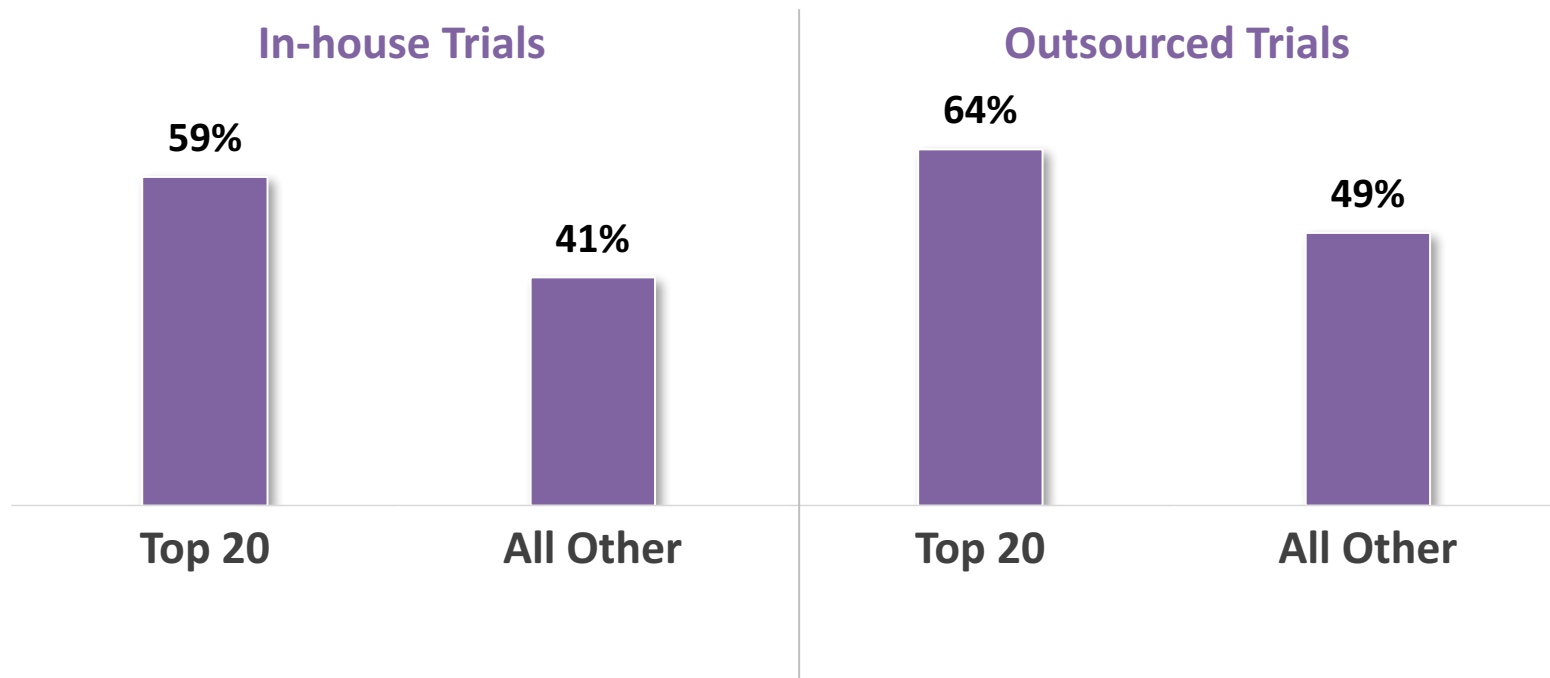
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# Risk-Based Quality Management

Whether in-house or outsourced, respondents from Top 20 Sponsor organizations report greater utilization of risk-based quality management than do those representing smaller organizations.

## Frequency of Use of Risk-Based Quality Management by Sponsor Size

*% indicating that risk-based quality management approach is used in at least half of trials*



N: SPONSOR: In-house: Top 20=71, All other=112; Outsourced: Top 20=81, All Other=129

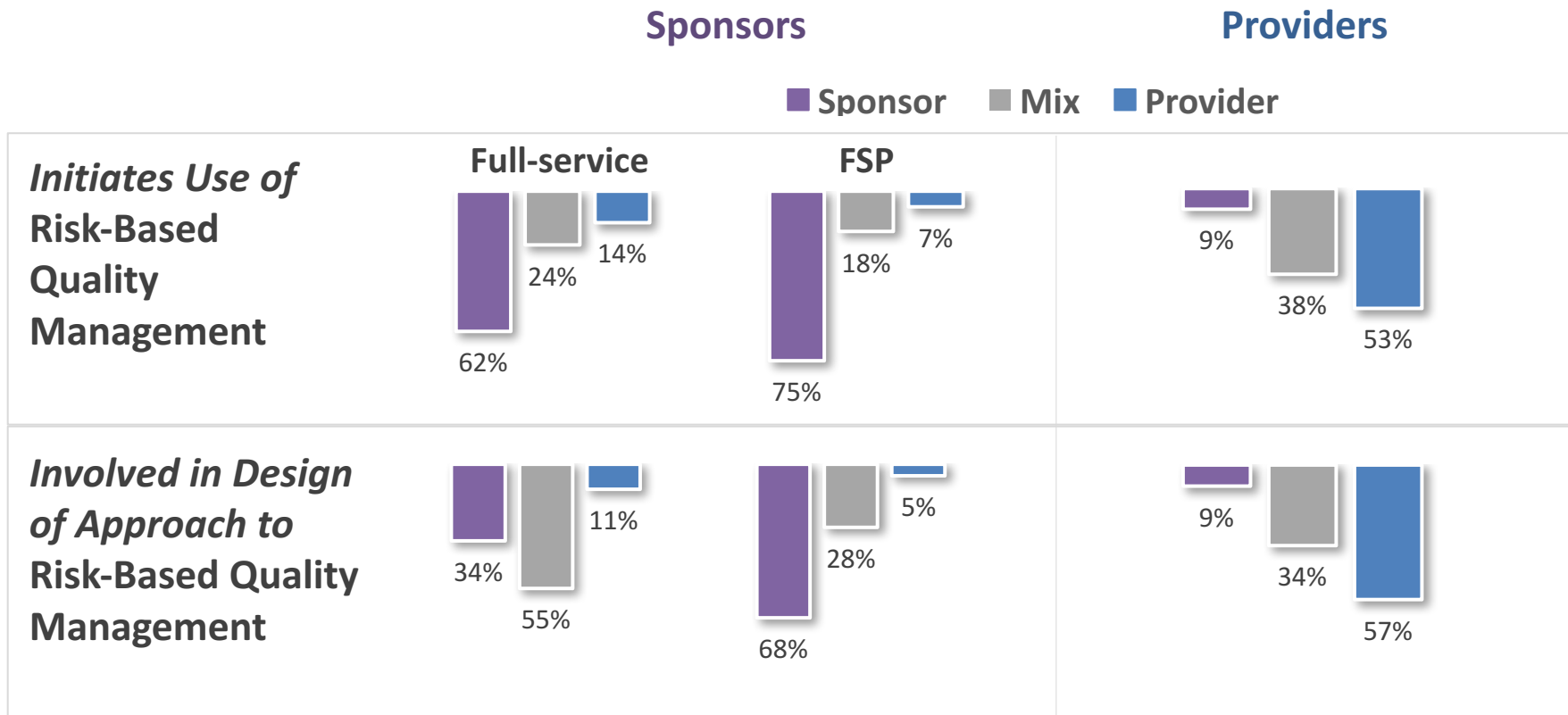
SPONSOR Q: How often do your teams use a risk-based approach to...? SPONSOR Q: How often do you use a risk-based approach to prepare for inspections for clinical trials with functions outsourced to FSPs



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# Risk-Based Quality Management

Regardless of the outsourcing model, Sponsors primarily indicating initiating the use of risk-based quality management. Design of this approach is a more shared responsibility in full-service vs. FSP relationships. Providers are likely to see themselves as driving both initiation and design of quality management.



N: SPONSOR Full-service=82-84; SPONSOR FSP=105-114; PROVIDER=89-91

SPONSOR Q: For fully-outsourced clinical trials, who generally initiates/requests the use of...? Q: For clinical trials utilizing functional service providers, who generally initiates/requests the use of...? For fully-outsourced clinical trials, to what extent is the CRO generally involved in designing the approach to...? For clinical trials utilizing functional service providers, to what extent is the FSP generally involved in designing the approach to...? PROVIDER Q: Who generally initiates/requests the use of...? To what extent is your company generally involved in designing the approach to...?



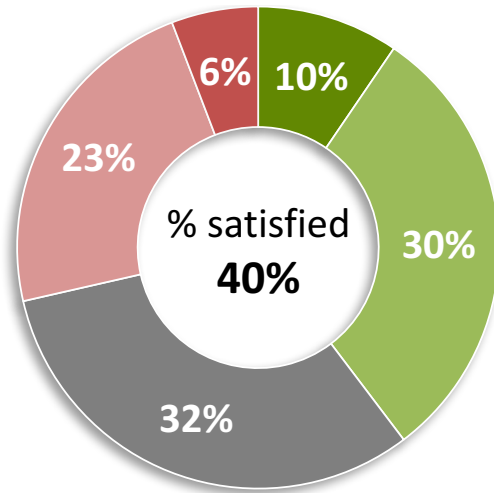
# Risk-Based Quality Management

A large disparity exists in terms of Sponsors' perceptions of Provider performance on applying risk-based approaches to quality management, and Providers' self-assessments in this area.

## Satisfaction with Risk-Based Approach to Quality Management

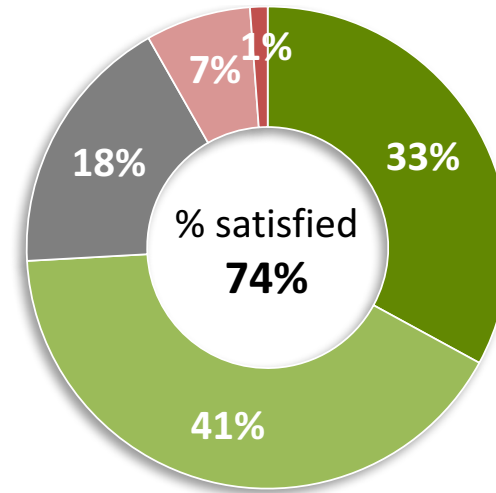
*% selecting response*

### Sponsor Assessment of CROs/FSPs



- Very satisfied
- Somewhat satisfied
- Neither satisfied nor dissatisfied
- Somewhat dissatisfied
- Very dissatisfied

### Provider Self-Assessment



N: SPONSOR=189; PROVIDER=85

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 Quality Management

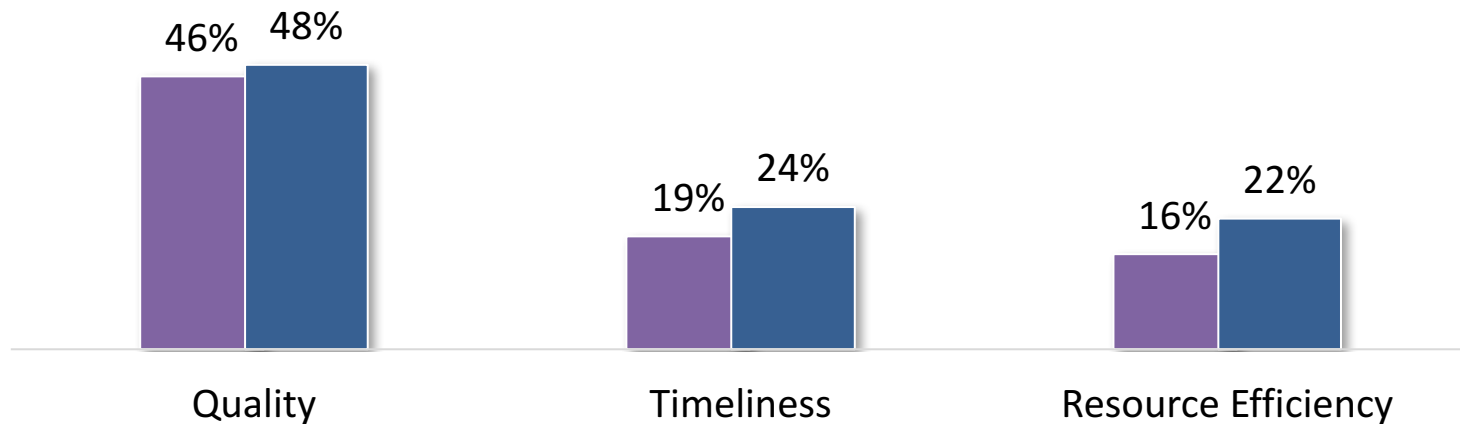
Approximately half of respondents indicate that risk-based quality management has been “very” or “extremely” impactful on increasing quality in trials; fewer feel this is resulting in improvements to efficiency in terms of time or resources. Those in a full-service model express seeing greater impact.

## Impact of Risk-Based Approach to Quality Management on Increasing...

% “extremely” or “very impactful”

**Sponsor**

**Provider**



*Sponsors using:*

<i>Full-service</i>	51%	28%	23%
<i>FSP</i>	42%	13%	11%



# Risk-Based Quality Management

Verbatim commentary on the use of risk-based quality management suggests that it can positively influence awareness, communication and strategy, but that challenges remain in gaining alignment on rationale, process and measurement.

## Positive Impacts

## Risk-Based Quality Management

## Challenges

*"Planning has opened communication amongst team.."*

*"Increased awareness of threats to quality of study."*

*"Our teams are constantly meeting and reassessing to make sure that the potential risks and actual risks are being pointed out and dealt with."*

*"Early proactive risk-based strategizing. Examine all possibilities and potential to decrease risks Before making decisions. Usually, risks are decreased, money is saved, and efficiency is increased."*



*"Sometimes interpreting the data for meaningful conclusions is difficult. Also, the lack of understanding by most on how to use the data."*

*"Understanding what QRM is, understanding why we are doing it, understanding thresholds around KRIs."*

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

# Key Take-Aways for Risk-Based Quality Management

- Overall, Sponsors and Providers report a fairly good understanding of best practices in risk-based quality management; however, among Sponsors this knowledge primarily “lives” among those in the Quality function.
- Sponsors report primarily initiating quality management approaches in outsourced trials, but the design of this approach is more of a shared responsibility within full-service sourcing. Providers generally see this as a joint effort.
- There is a notable discrepancy between Sponsors and Providers in terms of Provider performance on applying risk-based quality management approaches.
- Risk-based quality management is seen as having the greatest impact on quality, and much less impact on efficiency. Those using full-service sourcing approaches appear to be realizing somewhat greater benefits than those using functional sourcing models.



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**Thank you**

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**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





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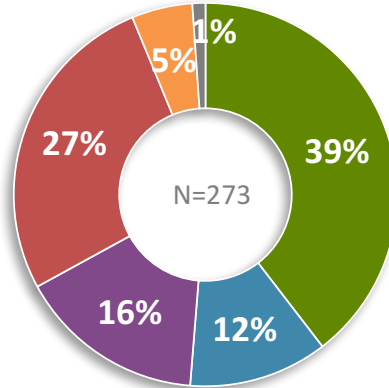
# Appendix

## *Demographics*

# Company Characteristics

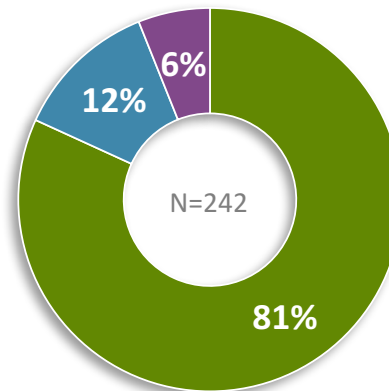
## SPONSOR: Company Size

- 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



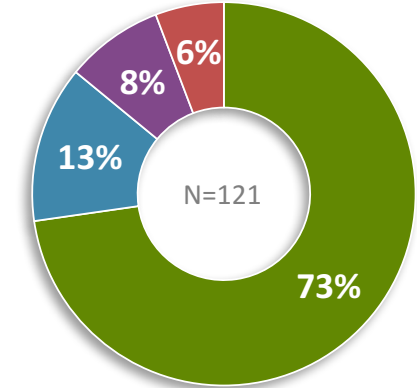
## SPONSOR: Company Headquarters

- United States
- Western Europe
- Other



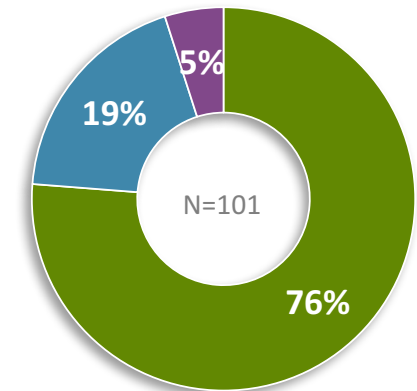
## PROVIDER: Company Type

- CRO
- Clinical Service Provider
- Consulting Company
- Other



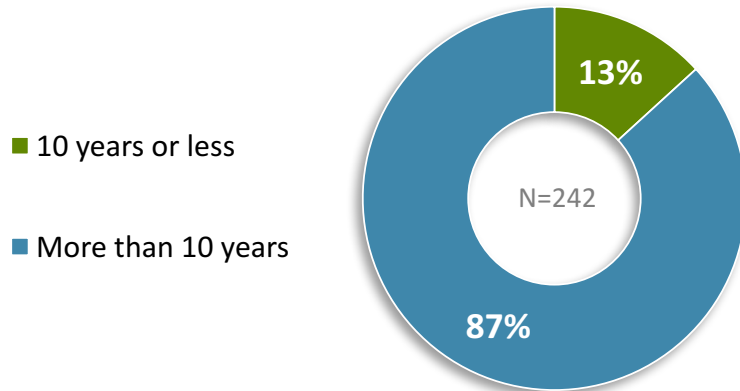
## PROVIDER: Company Headquarters

- United States
- Western Europe
- Other

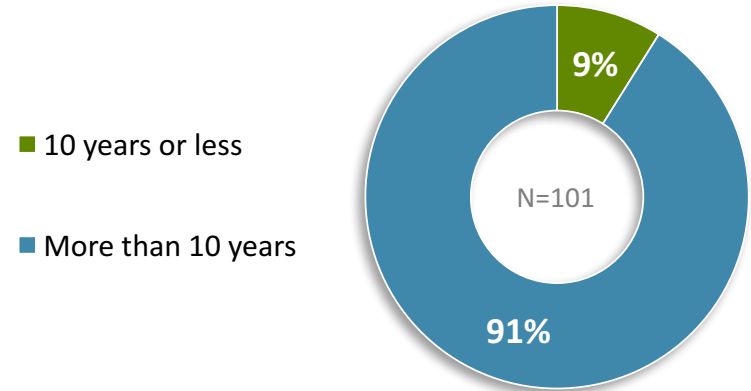


# Respondent Characteristics

## SPONSOR: Time in Industry

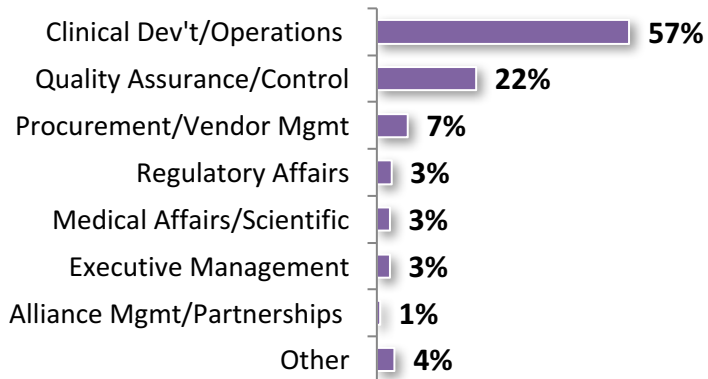


## PROVIDER: Time in Industry



## SPONSOR: Primary Functional Area

N=273



## PROVIDER: Primary Functional Area

N=121

