

# The 2017 Avoca Industry Report

Using Risk-Based Approaches to  
Provider Oversight



December 2017



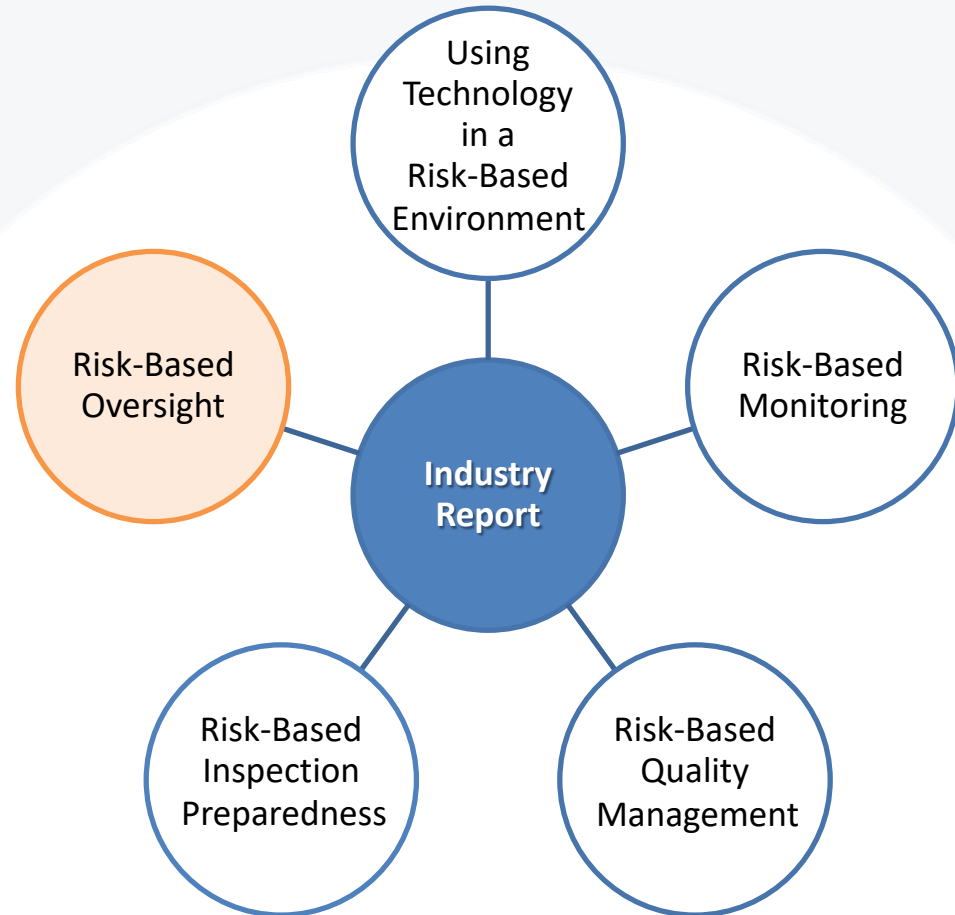
# 2017 Avoca Industry Report Series



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 fourth 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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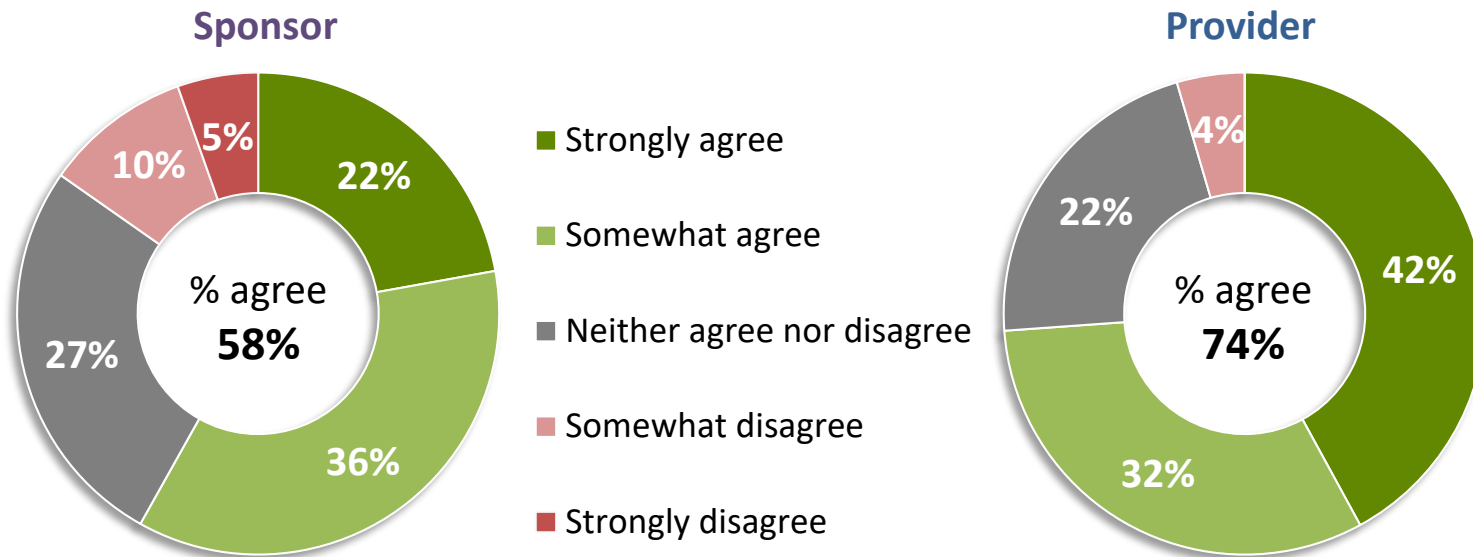
# Key Findings

## *Risk-Based Provider Oversight*

# Risk-Based Provider Oversight

ICH E6 R2 requires Sponsors to ensure oversight of trial-related duties and functions, including third-parties subcontracted by a Sponsor's CROs. While Providers express confidence in their ability to address oversight changes resulting from ICH E6 R2, Sponsors appear to be less prepared.

## Agreement that Company is Prepared to Address Changes to Oversight Resulting from ICH E6 R2



N: SPONSOR=203; PROVIDER=88

Q. Thinking about risk-based approaches to oversight, please indicate your level of agreement with each statement below using a scale of 1 to 5, with 1 indicating "Strongly Disagree" and 5 indicating "Strongly Agree".



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# Risk-Based Provider Oversight

About two-thirds of Sponsors and Providers report having a “good” or “very strong” understanding of best practices in risk-based oversight.

## Familiarity with Risk-Based Approaches to Provider Oversight

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





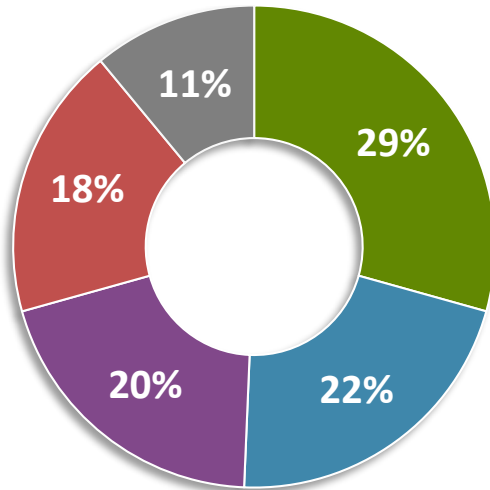
# Risk-Based Provider Oversight

Among Sponsors, approximately half report using a risk-based approach to Provider oversight in more than half of their trials; usage of this approach was slightly less frequent among Providers who oversee other clinical service providers.

## Frequency of Use of Risk-Based Provider Oversight

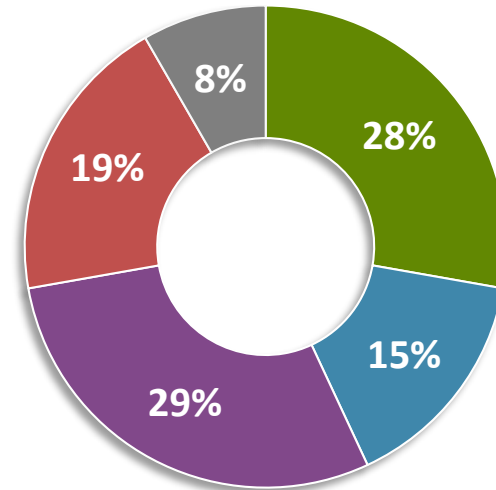
*% of trials utilizing risk-based provider oversight*

### Sponsor



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

### Provider



N: SPONSOR=212; PROVIDER=72

SPONSOR Q: How often do your teams use a risk-based approach to...? (assessment of CROs and other clinical service providers in aggregate) PROVIDER Q: How often does your company use a risk-based approach to...?

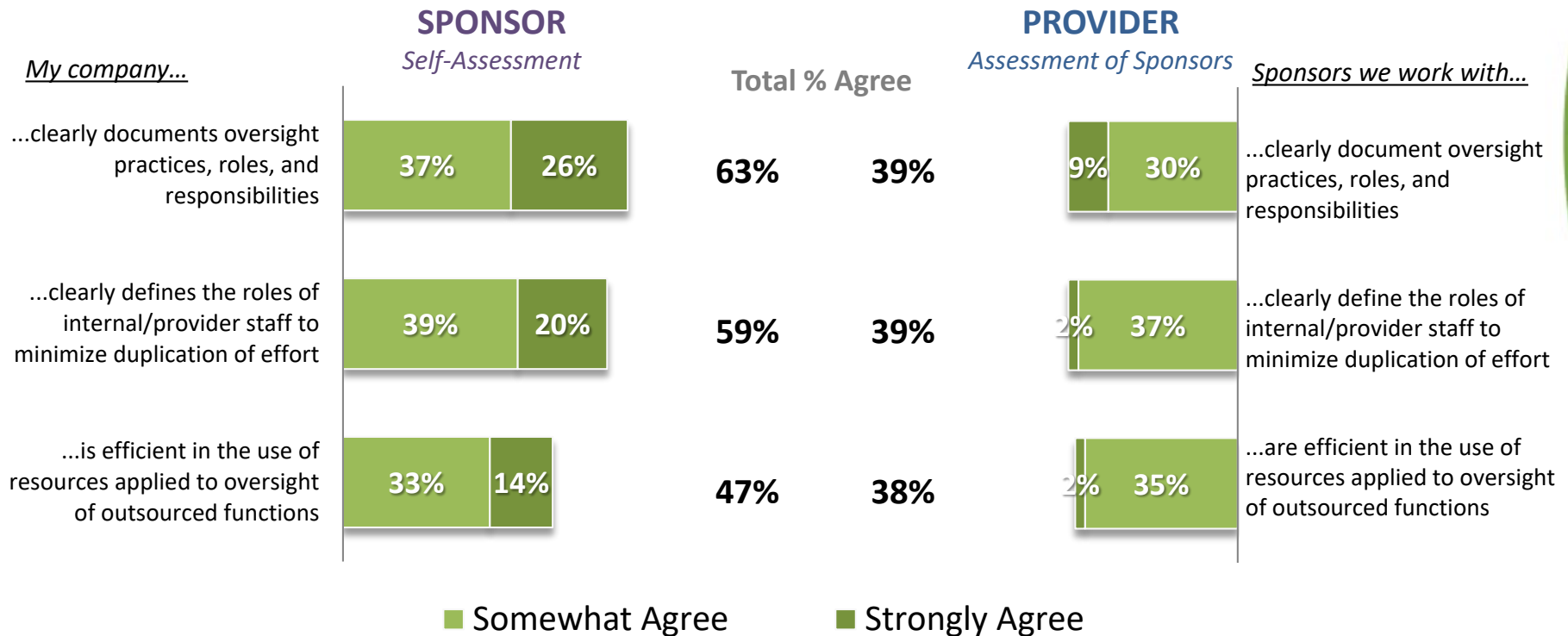


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# Risk-Based Provider Oversight

Sponsors expressed more favorable assessments of themselves than did Providers with respect to the documentation, definition and application of resources dedicated to oversight.

## Agreement with Statements About Oversight Practices



N: SPONSOR=227-231; PROVIDER=87-88

Q. Thinking about risk-based approaches to oversight, please indicate your level of agreement with each statement below using a scale of 1 to 5, with 1 indicating "Strongly Disagree" and 5 indicating "Strongly Agree".

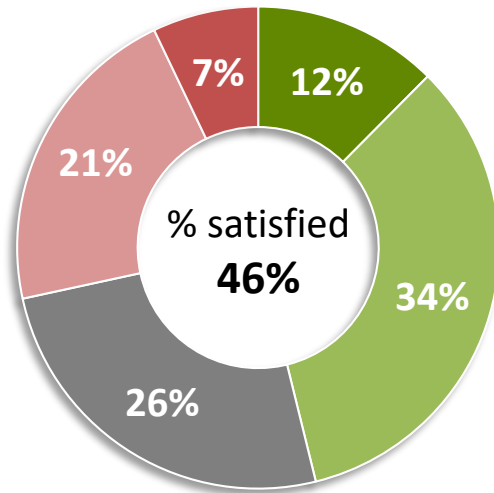
# Risk-Based Provider Oversight

Just under half of Sponsors express satisfaction with their Providers' ability to support them in the use of risk-based approaches to oversight, while nearly two-thirds of Providers indicate satisfaction with their "service" in this area.

## Satisfaction with Risk-Based Approach to Provider Oversight

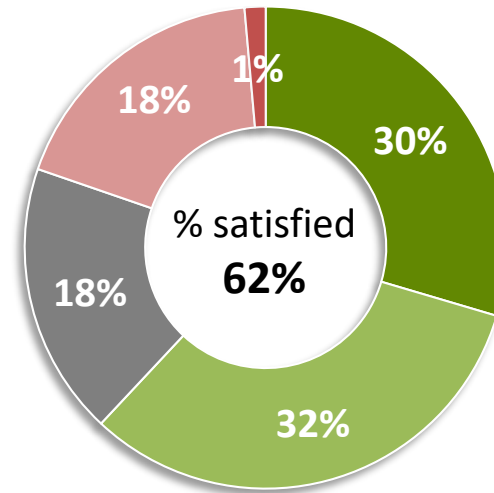
*% selecting response*

### Sponsor Assessment of CROs/FSPs Overseeing Other Clinical Service Providers



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

### Provider Self-Assessment



N: SPONSOR=169; PROVIDER=71

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 Provider Oversight

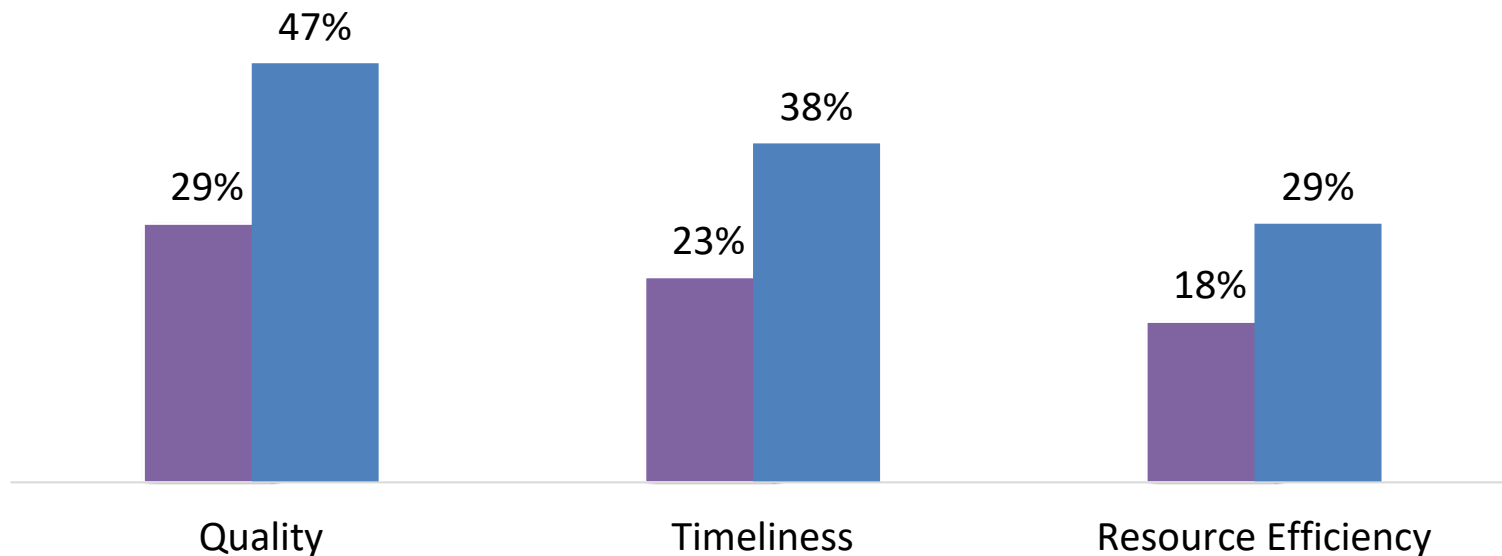
Sponsors see risk-based oversight as being most impactful on quality; however, impact appears to be weak overall. Providers are more favorable in their assessment of impact relative to Sponsors.

## Impact of Risk-Based Provider Oversight on Increasing...

*% "extremely" or "very impactful"*

**Sponsors**

**Providers**



# Risk-Based Provider Oversight

Verbatim commentary on the use of risk-based oversight suggests that those who have successfully implemented such an approach are realizing greater focus; however, alignment on the level of oversight can be a challenge.

## Positive Impacts

## Risk-Based Provider Oversight

## Challenges

*"Identification of "low risk" vendors and activities allowing shift of resources and concentration to higher risk areas. Effective prioritization of issues and gaps to be addressed."*

*"Focused, data driven approach to management of studies and CROs."*

*"Alignment and agreement on clinical trial site oversight requirements."*

*"Striking correct balance of oversight to avoid micro-management and utilize resources most effectively."*

*"Micromanagement of FSP and waste of internal resources."*

*"As a very small Sponsor maintaining oversight of all CROs/vendors involved in a study is challenging. Has led to misunderstanding on deliverables, timelines, etc."*



Q: Considering your company's use of risk-based approaches to clinical trial conduct, what aspect of these has made the greatest positive impact? Q: Considering your company's use of risk-based approaches to clinical trial conduct, what aspect of these has been the most challenging?



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# Key Take-Aways for Risk-Based Provider Oversight

- Overall, a majority of Sponsors and Providers agree they are prepared to address changes to provider oversight stipulated by ICH E6 R2, and report a fairly good understanding of best practices in this area.
- However, there is a notable discrepancy between how Sponsors assess their performance on oversight practices and how Providers perceive performance of Sponsors on these same measures.
- Differences were also noted in terms of assessments of how well Providers oversee other clinical service providers, with Providers giving more favorable self-assessments.
- Though Providers expressed more favorable views, overall, the perceived impact of risk-based oversight on quality and efficiency is not seen as being significant today.



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# Thank you

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# ABOUT US

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As a developer of progressive solutions to challenges faced in clinical research, Avoca makes a tangible difference to the operations of pharmaceutical companies and clinical service providers.



# ABOUT YOU

You want a broader perspective on clinical outsourcing and leading practices in quality.

You want to enable your teams to deliver rapid, breakthrough innovation and the highest standard of quality. You want to develop strong relationships with partners and decision makers who can help your team and your business succeed.

**Insight. Perspective. Solutions.**





**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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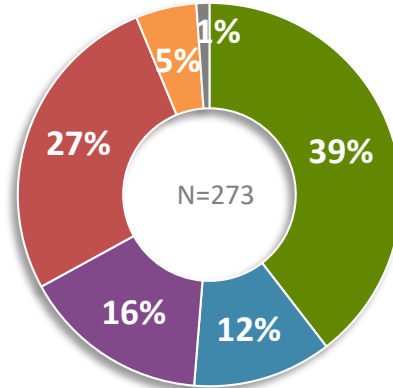
# Appendix

## *Demographics*

# Company Characteristics

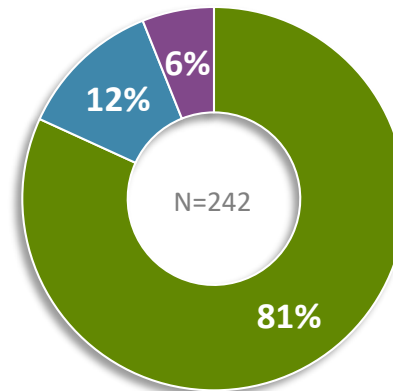
## SPONSOR: Company Size

- 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



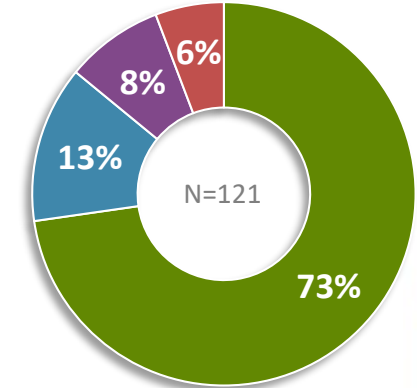
## SPONSOR: Company Headquarters

- United States
- Western Europe
- Other



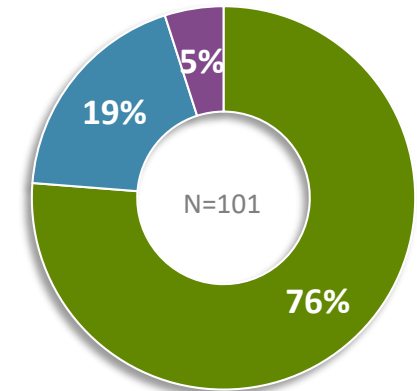
## PROVIDER: Company Type

- CRO
- Clinical Service Provider
- Consulting Company
- Other



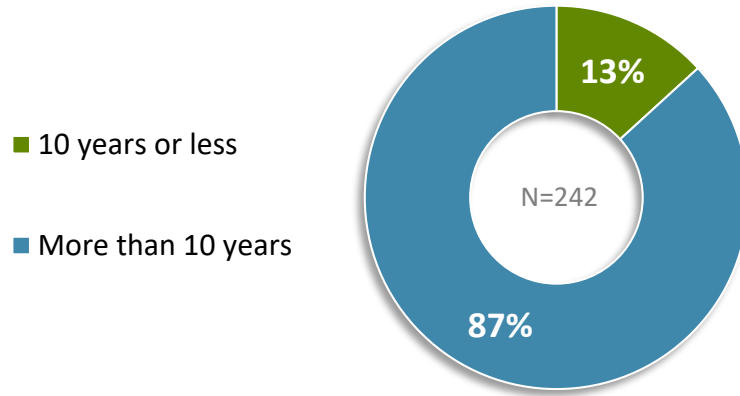
## PROVIDER: Company Headquarters

- United States
- Western Europe
- Other

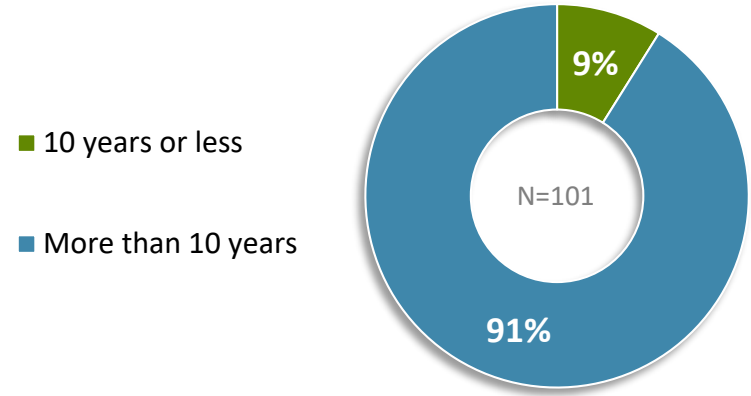


# Respondent Characteristics

## SPONSOR: Time in Industry

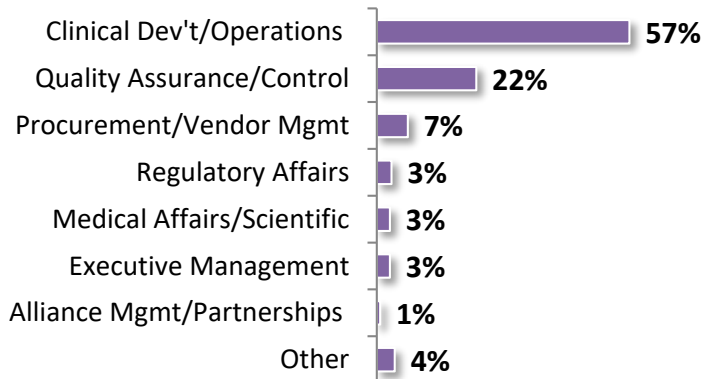


## PROVIDER: Time in Industry



## SPONSOR: Primary Functional Area

N=273



## PROVIDER: Primary Functional Area

N=121

