The 2017 Avoca Industry Report

Using Risk-Based Approaches to Inspection Preparedness

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August 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 first in this series.

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Usage Guidelines

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

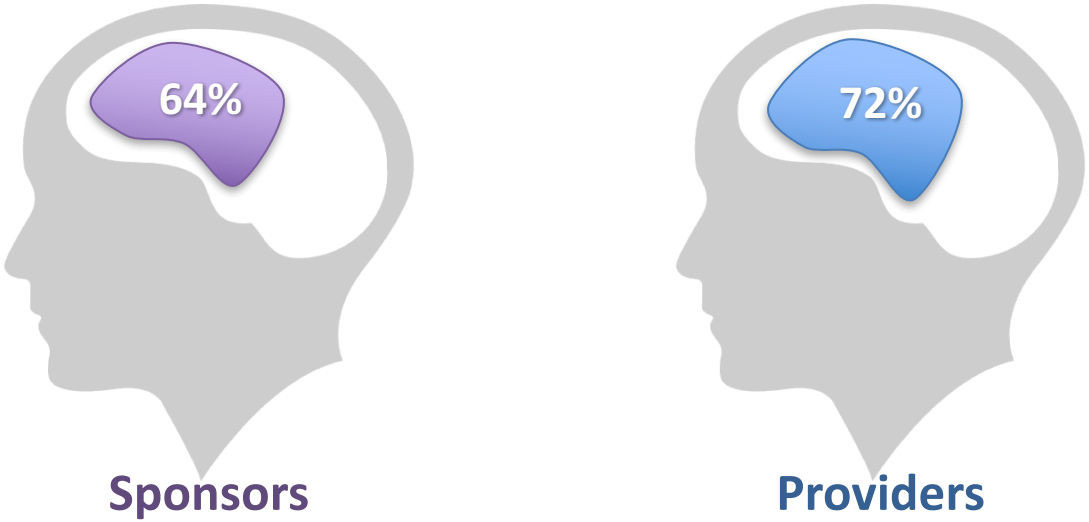
Risk-Based Inspection Preparedness

Inspection Preparedness

About two-thirds of Sponsors and three-quarters of Providers report having a "good" or "very strong" understanding of best practices in risk-based inspection preparedness.

Familiarity with Risk-Based Approaches to Inspection Preparedness

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



N: SPONSOR: Total=272; PROVIDER: Total=117

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

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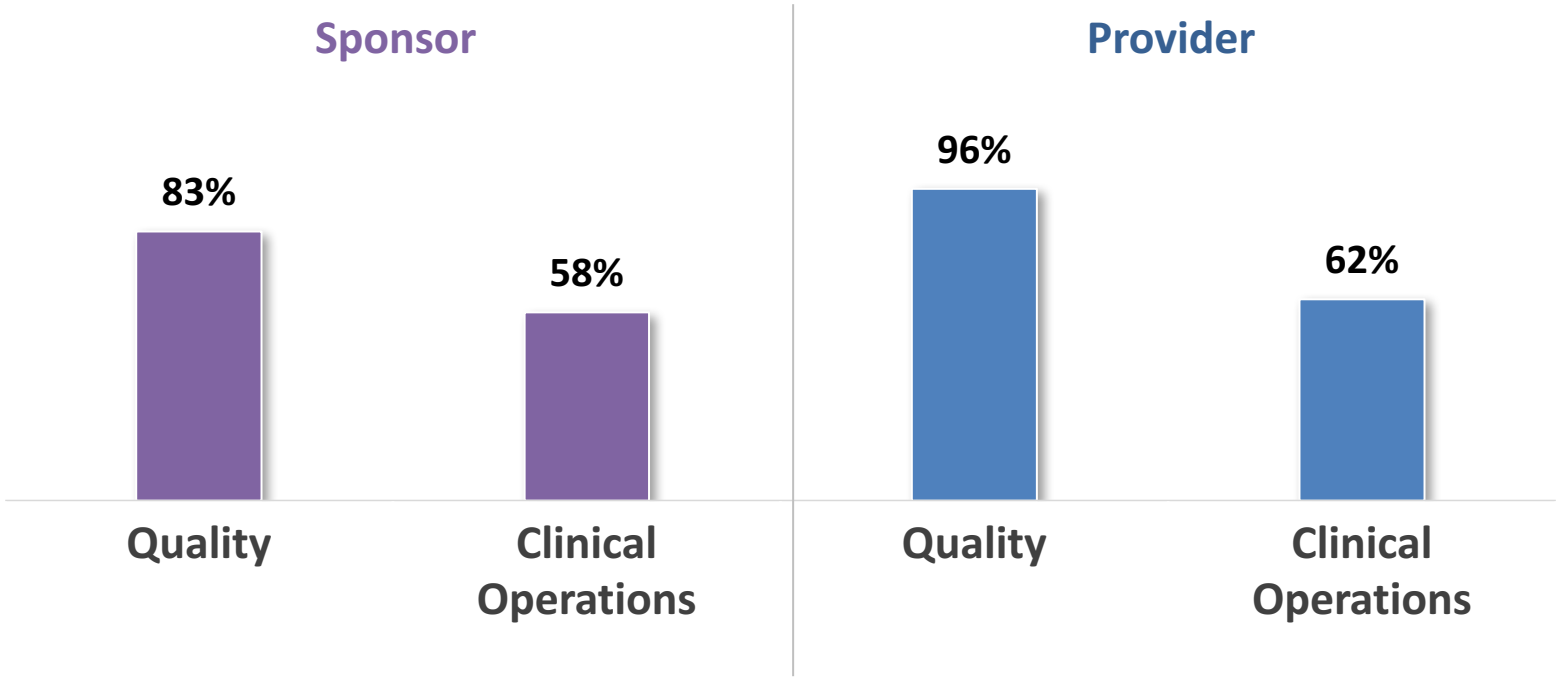
Inspection Preparedness

Notable differences are observed by function, with those working in quality expressing a higher level of knowledge about risk-based inspection preparedness relative to those in clinical operations.

Familiarity with Risk-Based Approaches to Inspection Preparedness

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



N: SPONSOR: Quality=60,Clinical Operations=154; PROVIDER: Quality=26, Clinical Operations=45

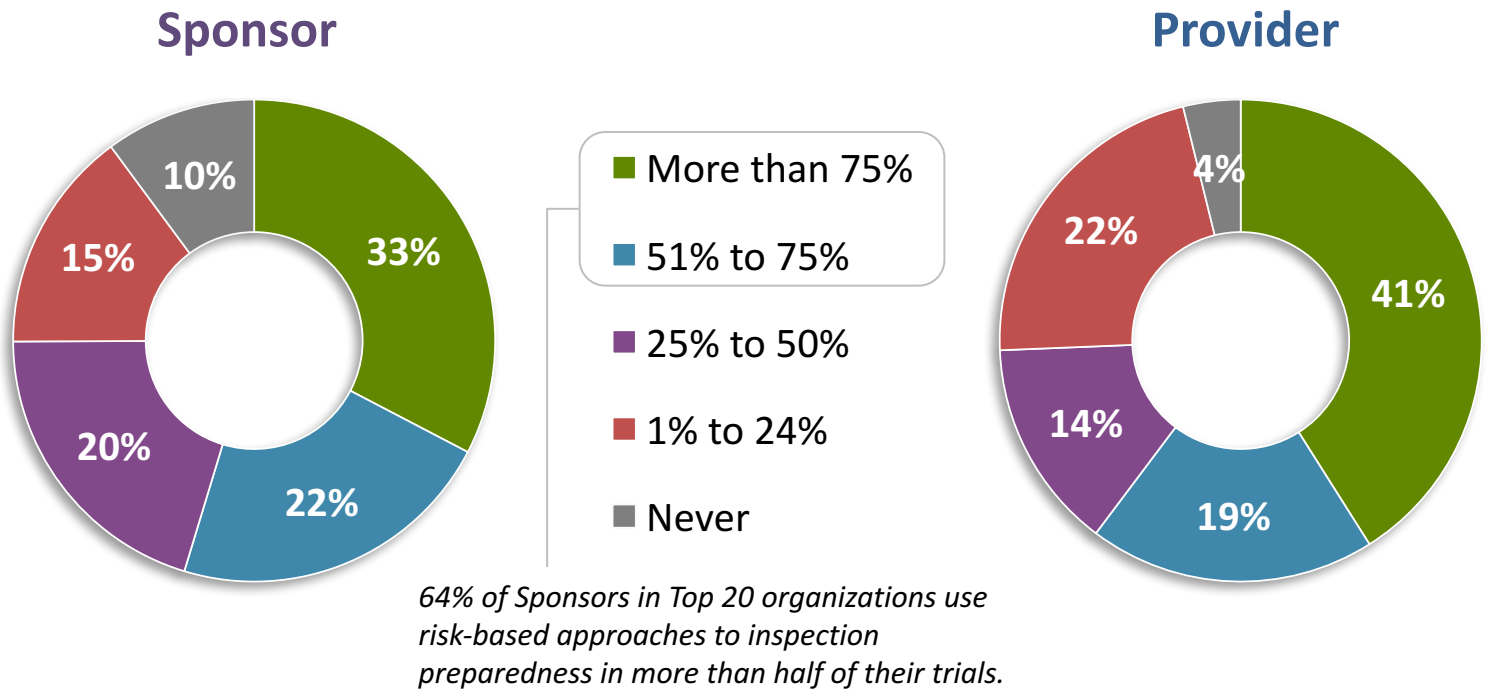
Q: How would you rate your understanding of best practices in…?

Inspection Preparedness

Among Sponsors, 55% report using a risk-based approach to inspection preparedness in more than half of their trials; this goes up to 60% among Providers.

Frequency of Use of Risk-Based Inspection Preparedness

% of trials utilizing risk-based inspection preparedness approach



64% of Sponsors in Top 20 organizations use risk-based approaches to inspection preparedness in more than half of their trials.

N: SPONSOR=224; PROVIDER=78

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? PROVIDER Q: How often does your company use a risk-based approach to…?

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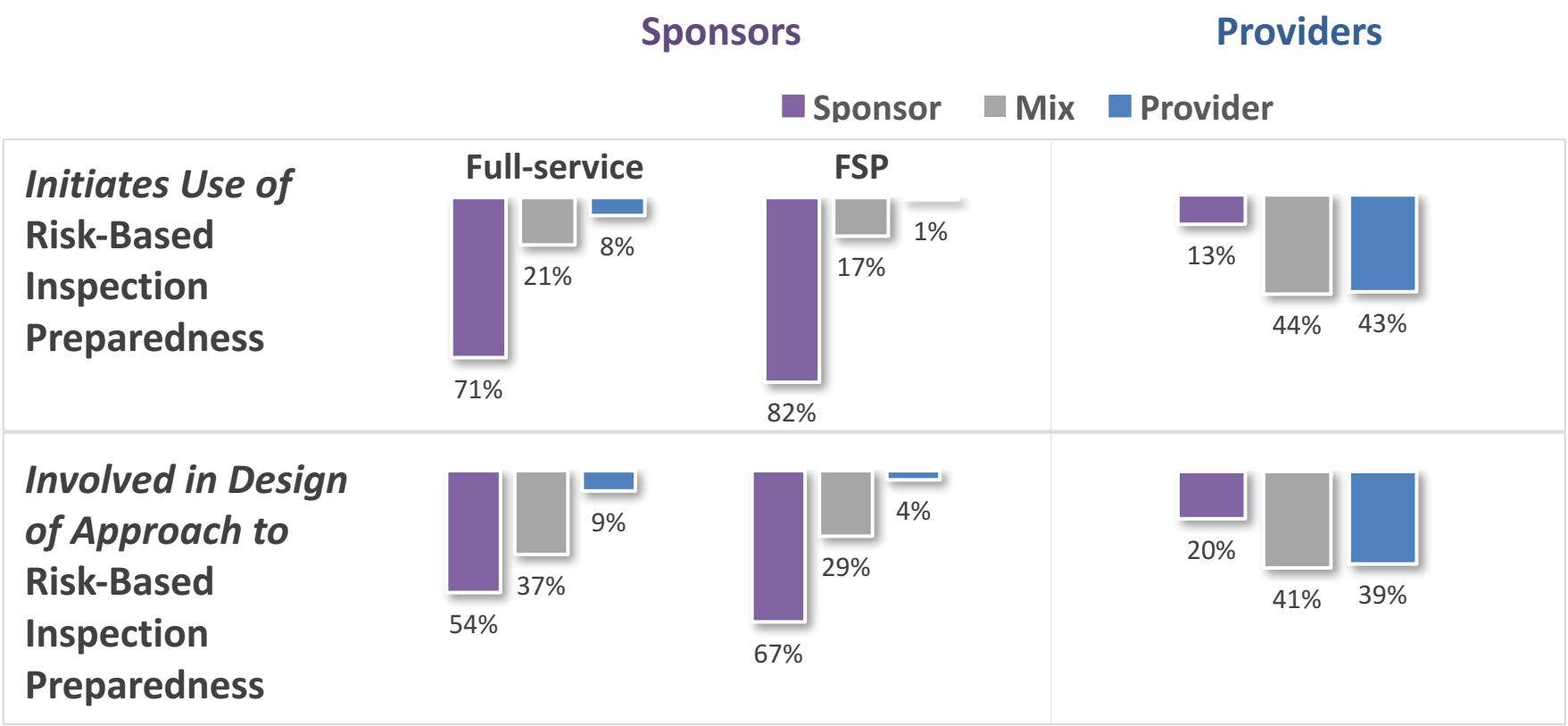
Inspection Preparedness

From the Sponsor perspective, they report primarily driving the use and design of risk-based approaches to inspection preparedness; Providers see this as more of a joint effort.



N: SPONSOR Full Service=76-77; SPONSOR FSP=101-106; PROVIDER=75-79

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…?

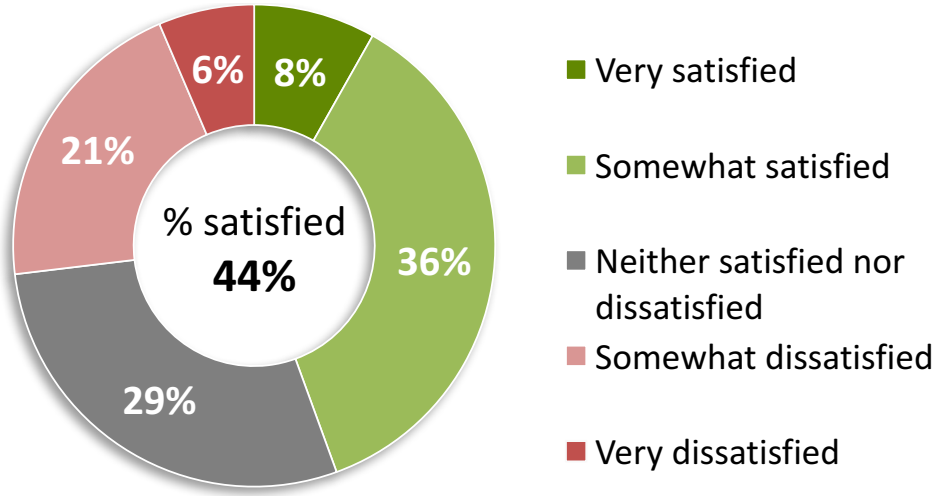
Inspection Preparedness

Sponsors express moderate satisfaction with their Providers' ability to support them in the use of risk-based approaches to inspection preparedness; Providers express more favorable self-assessments.

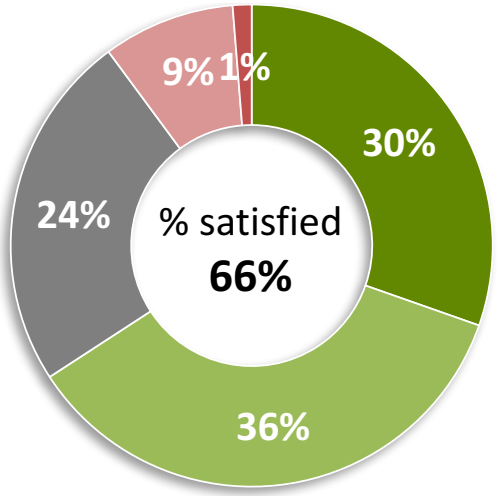
Satisfaction with Risk-Based Approach to Inspection Preparedness

% selecting response

Sponsor Assessment of CROs/FSPs



Provider Self-Assessment



N: SPONSOR=171; PROVIDER=79

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

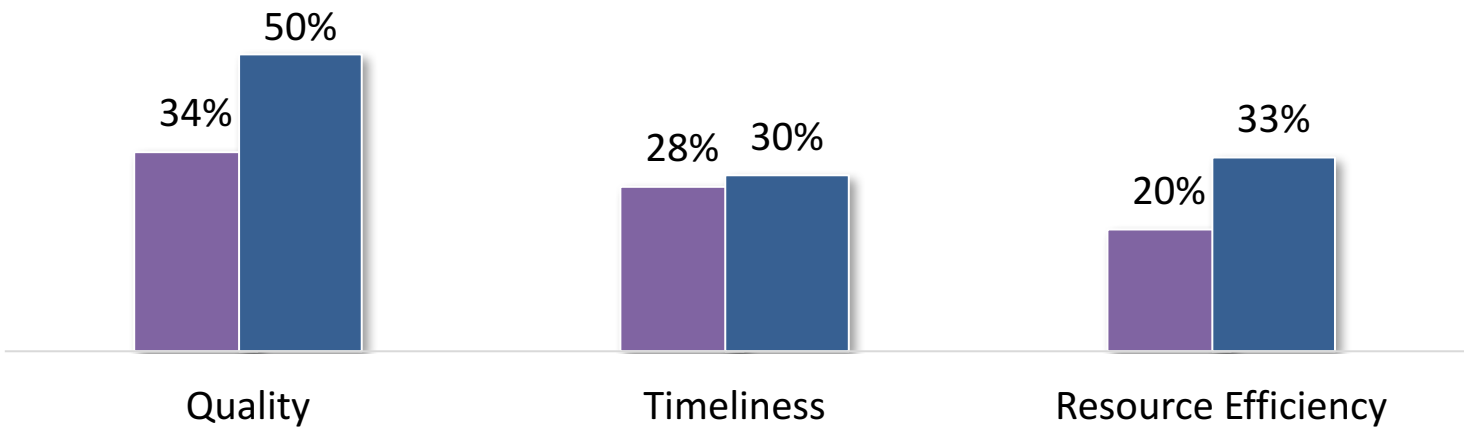
PROVIDER Q: Overall, how satisfied have you been with your company in terms of the…?

Inspection Preparedness

Risk-based inspection preparedness is seen as most impactful on quality; however, impact appears to be weak overall – generally only about one-third or less of respondents indicate this approach is having a 'significant' impact. Sponsors in full-service relationships are seeing a greater impact.

Impact of Risk-Based Approach to Inspection Preparedness on Increasing…

% "extremely" or "very impactful"



Sponsors using:	Quality	Timeliness	Resource Efficiency
Full-service	40%	34%	23%
FSP	28%	22%	18%

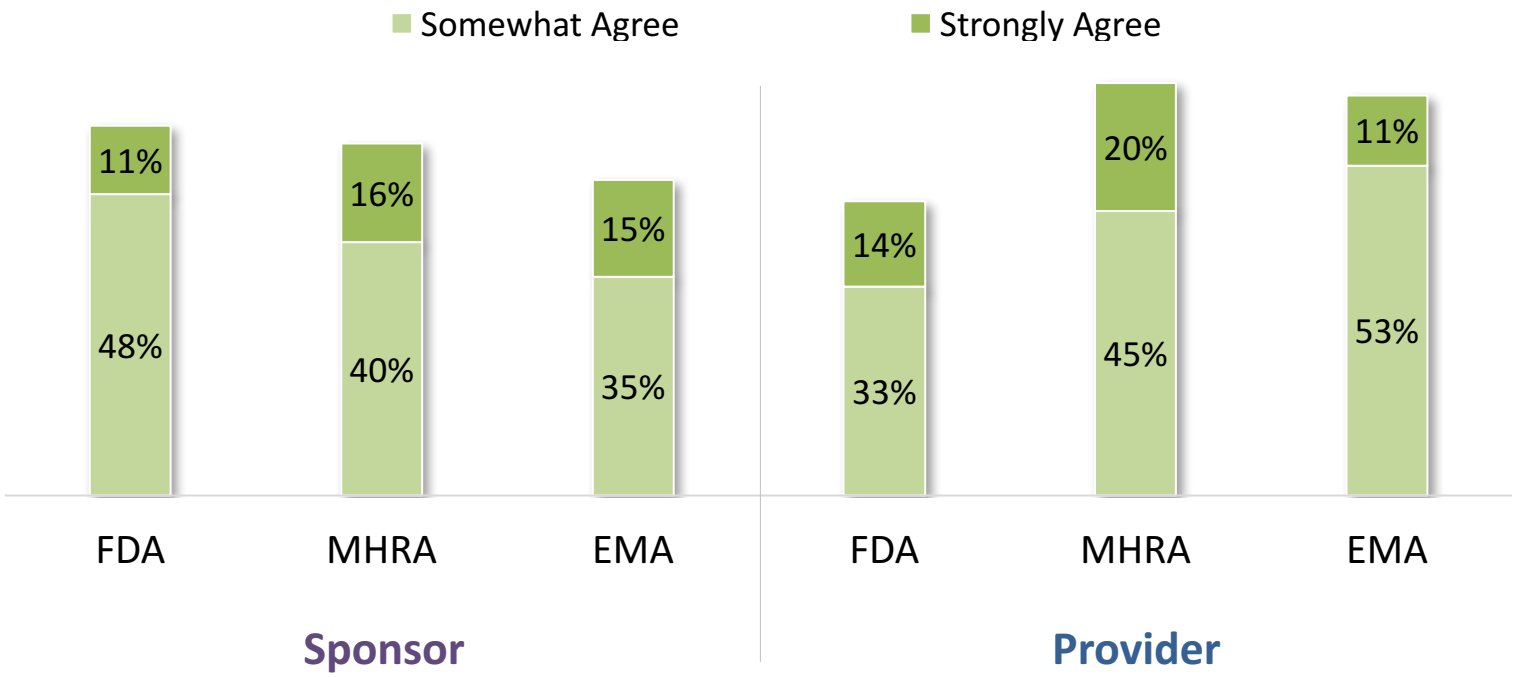
N: SPONSOR: Total=125-127, Full-service=56-57, FSP=67-71; PROVIDER=93-94

Q: How impactful have the following risk-based approaches been in terms of increasing …?

Inspection Preparedness

Approximately half to two-thirds of respondents express agreement with the idea that regulatory agencies approach inspections in a way that is aligned to regulatory guidelines on risk-based approaches.

Agreement that Inspections are Conducted to Align to Risk-Based Approaches Indicated by Regulatory Guidance



N: SPONSOR=121-137, PROVIDER=36-51

Q: Thinking about your experience with regulatory inspections over the past 12 months, 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".

Key Take-Aways for Risk-Based Inspection Preparedness

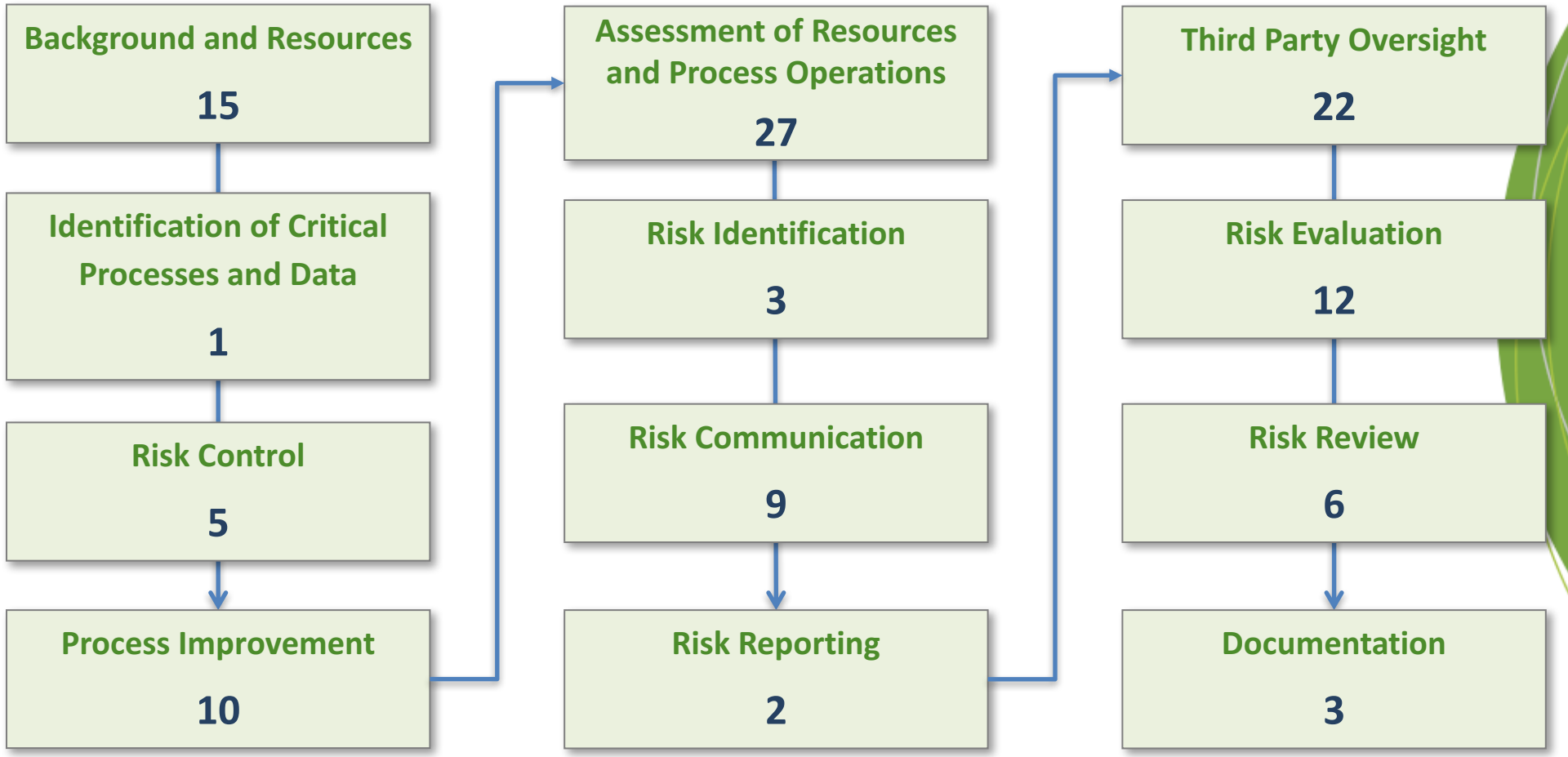
- Overall, Sponsors and Providers report a fairly good understanding of best practices in risk-based inspection preparedness today; however, **knowledge is not translating from experts in the Quality Function to their colleagues in Clinical Operations**.
  - *How can we create a cross-functional culture of quality?*

- **Sponsors report primarily initiating and designing these approaches and are only moderately satisfied with Providers' performance in this area,** while Providers see this as a joint effort and assess their own performance more favorably.
  - *What role can standards of practice play in bringing Sponsors and Providers into alignment?*

- These approaches are seen as having the greatest impact on quality; however, **risk-based approaches impact on quality is weak overall.**
  - *What can you do today to positively influence future outcomes?*

12 Steps to ICH E6 (R2) Compliance

AQC Process Map and Number of Tools



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Thank you

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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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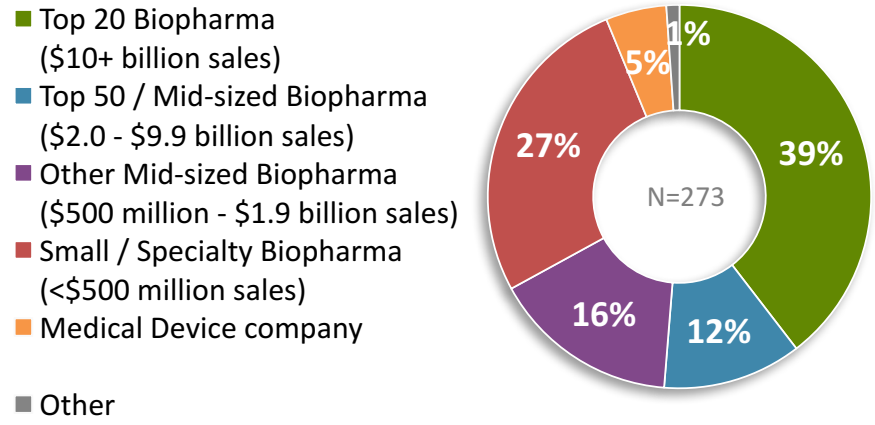
Appendix

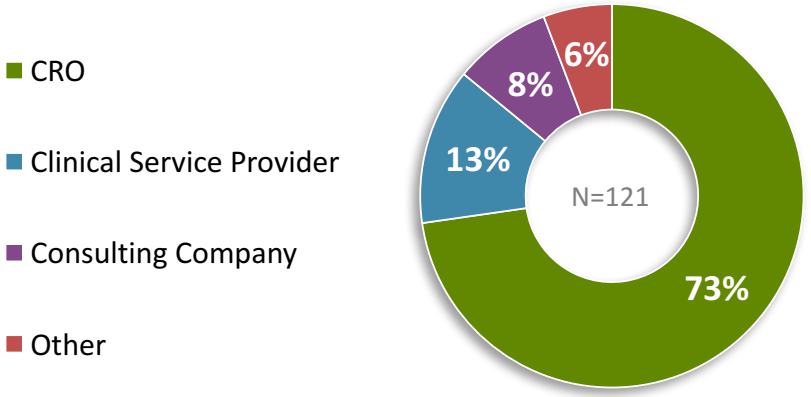
Demographics

Company Characteristics

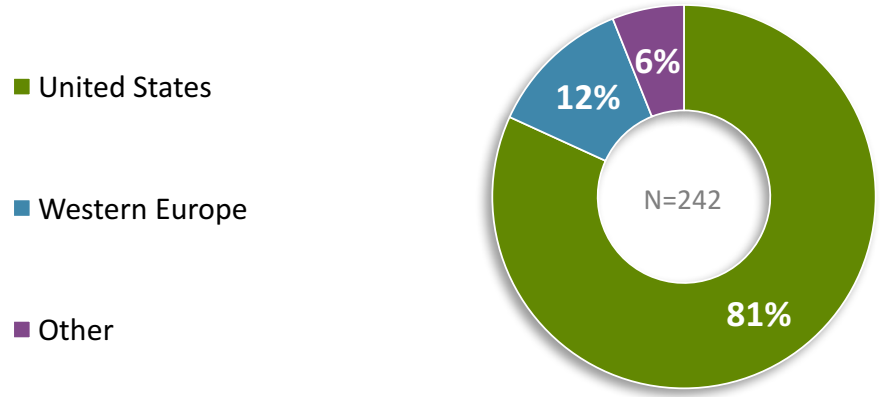
SPONSOR: Company Size



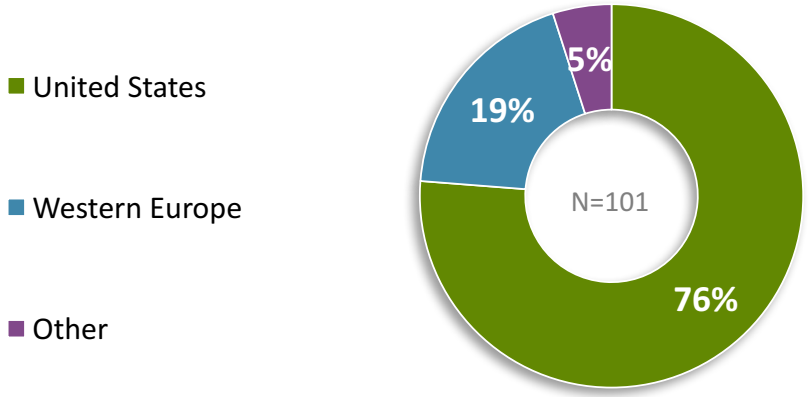
PROVIDER: Company Type



SPONSOR: Company Headquarters



PROVIDER: Company Headquarters



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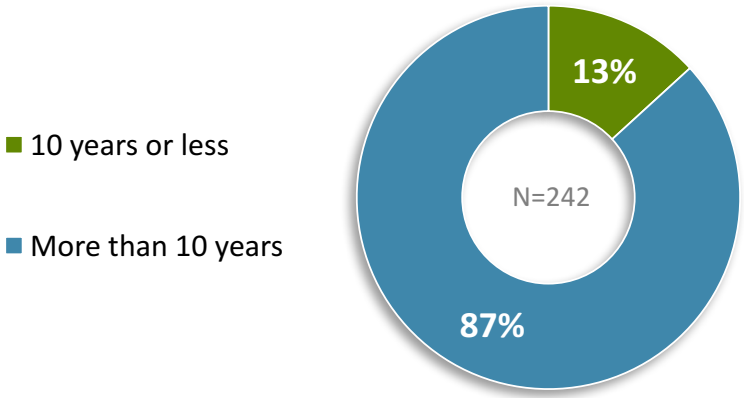
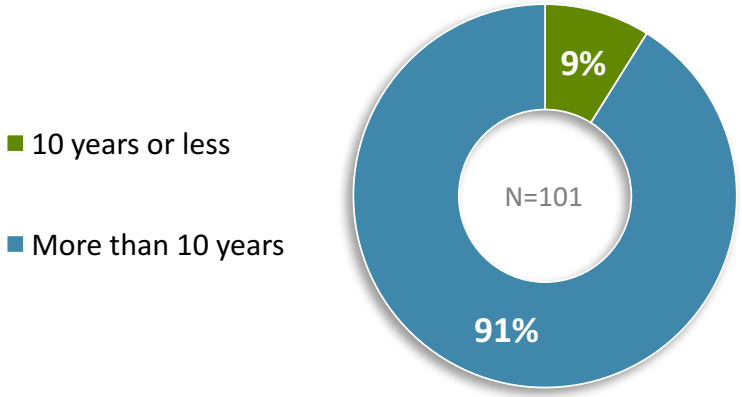
Respondent Characteristics

SPONSOR: Time in Industry

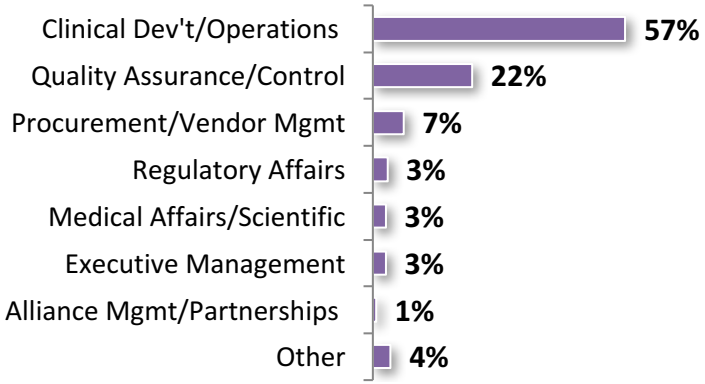


PROVIDER: Time in Industry



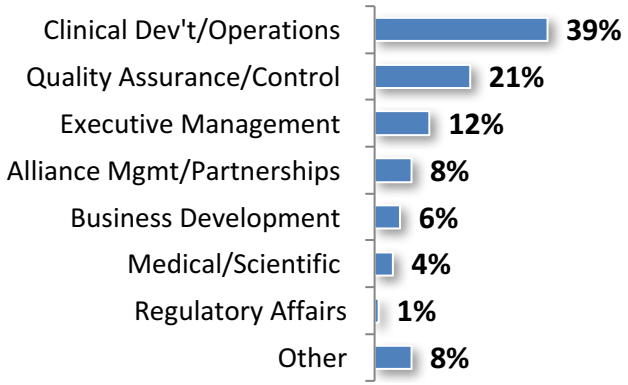
SPONSOR: Primary Functional Area

N=273



PROVIDER: Primary Functional Area

N=121



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