

The 2017 Avoca Industry Report

Using Technology in a Risk-Based
Environment



November 2017



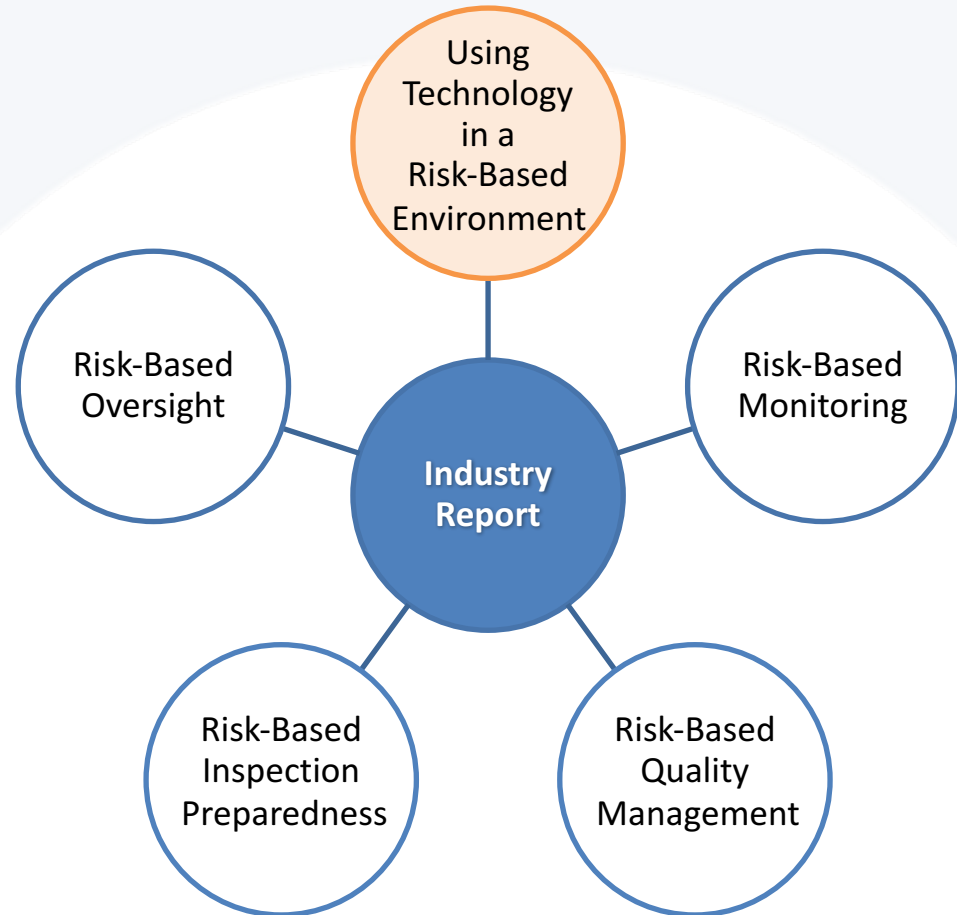
2017 Avoca Industry Report Series



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 third 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

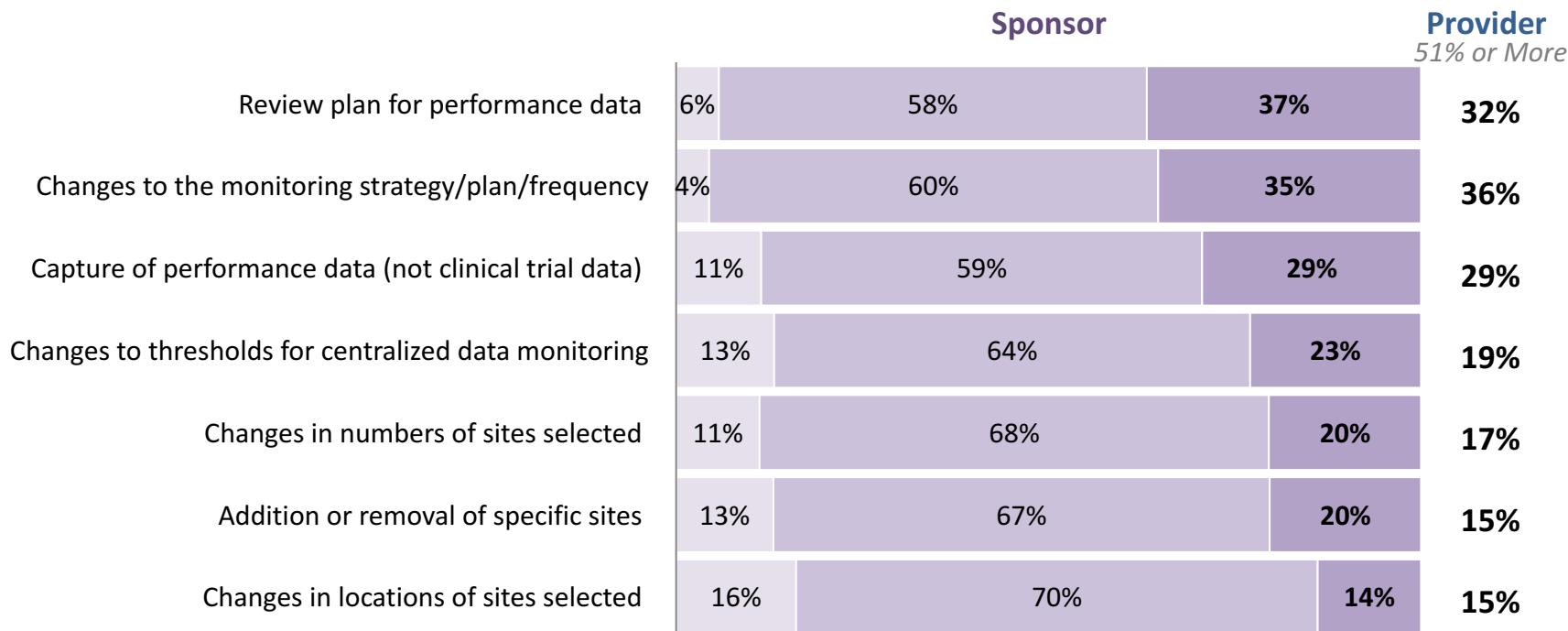
*Utilization and Impact
of Risk Assessment &
Risk-Based Approaches*

Risk Assessment & Management

Refinements to the review plan for performance data and changes to monitoring strategy are the most prevalent actions taken in response to risk assessments; changes to trial operations, including those impacting decisions around site and metric thresholds, are less common.

Types of Refinements Made Based on Risk Assessment

% of trials: ■ Never ■ Between 1% and 50% ■ 51% or More



N: SPONSOR=174-204; PROVIDER=63-74

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?

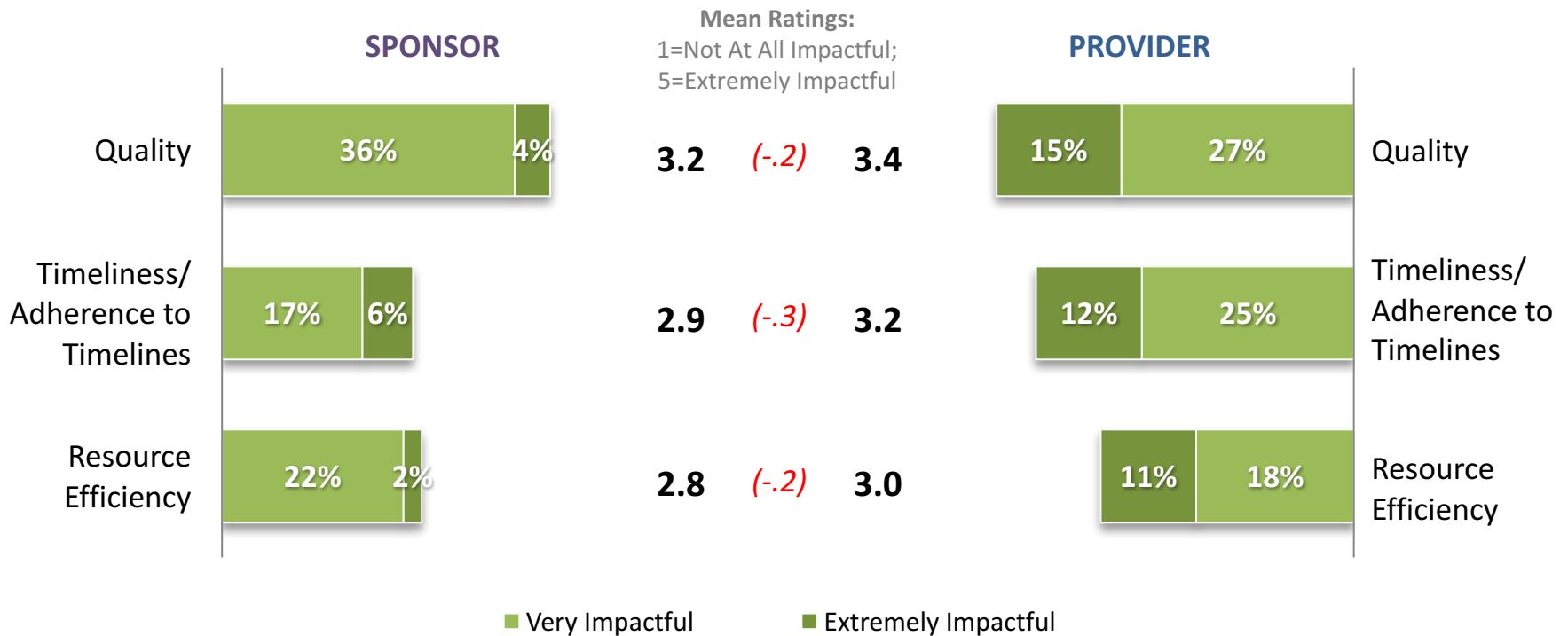


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Risk Assessment & Management

Risk assessment and management approaches are thought to have only a moderate impact on increasing quality and efficiency; this may be attributable to low overall prevalence of meaningful changes to clinical trial operations as a result of risk assessments.

Impact of Risk Assessment on Increasing...



Risk Assessment & Management

Further, there is a disconnect between Sponsors' and Providers' perceptions of performance on risk identification and management activities. This disconnect may also contribute to neutral sentiment regarding the impact risk assessment has had on quality and efficiency.

Satisfaction with Risk Activities

% very or somewhat satisfied

	SPONSOR <i>Assessment of CROs</i>	PROVIDER <i>Self-Assessment</i>
Proactive identification of potential risks	46%	73%
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%

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?



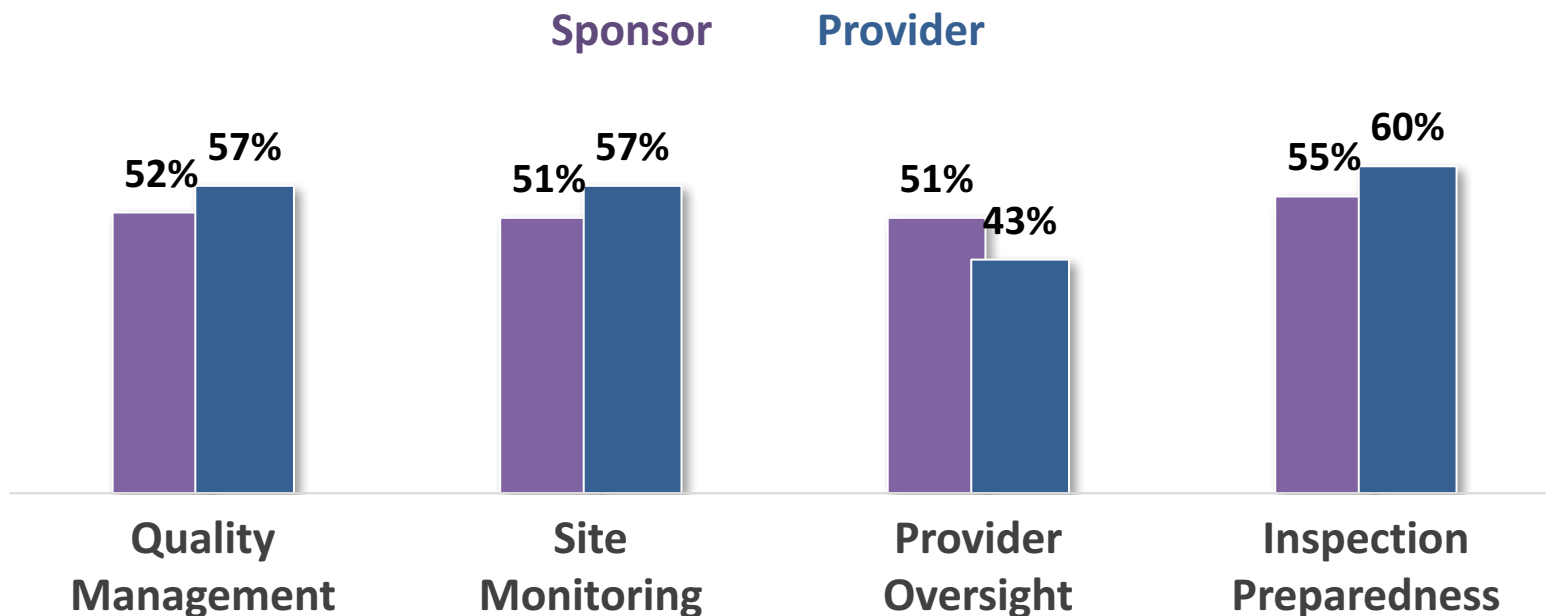
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Risk-Based Approaches

Relative to risk assessment, a larger proportion of Sponsors and Providers – between 50% and 60% of respondents – report risk-based approaches are being used in more than half of their trials today to manage quality, monitor sites, oversee providers and prepare for inspections.

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

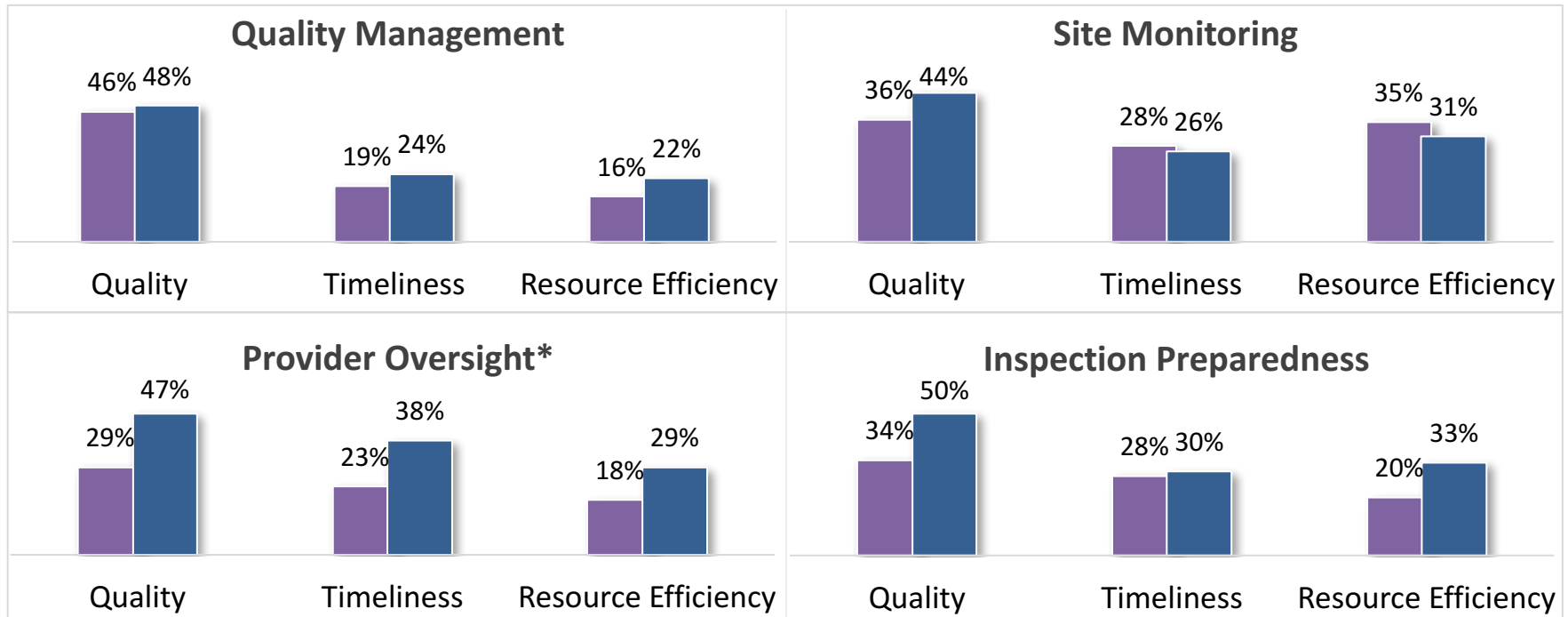
As observed with risk assessment, risk-based approaches are having only a weak to moderate impact on quality, time and resource management.

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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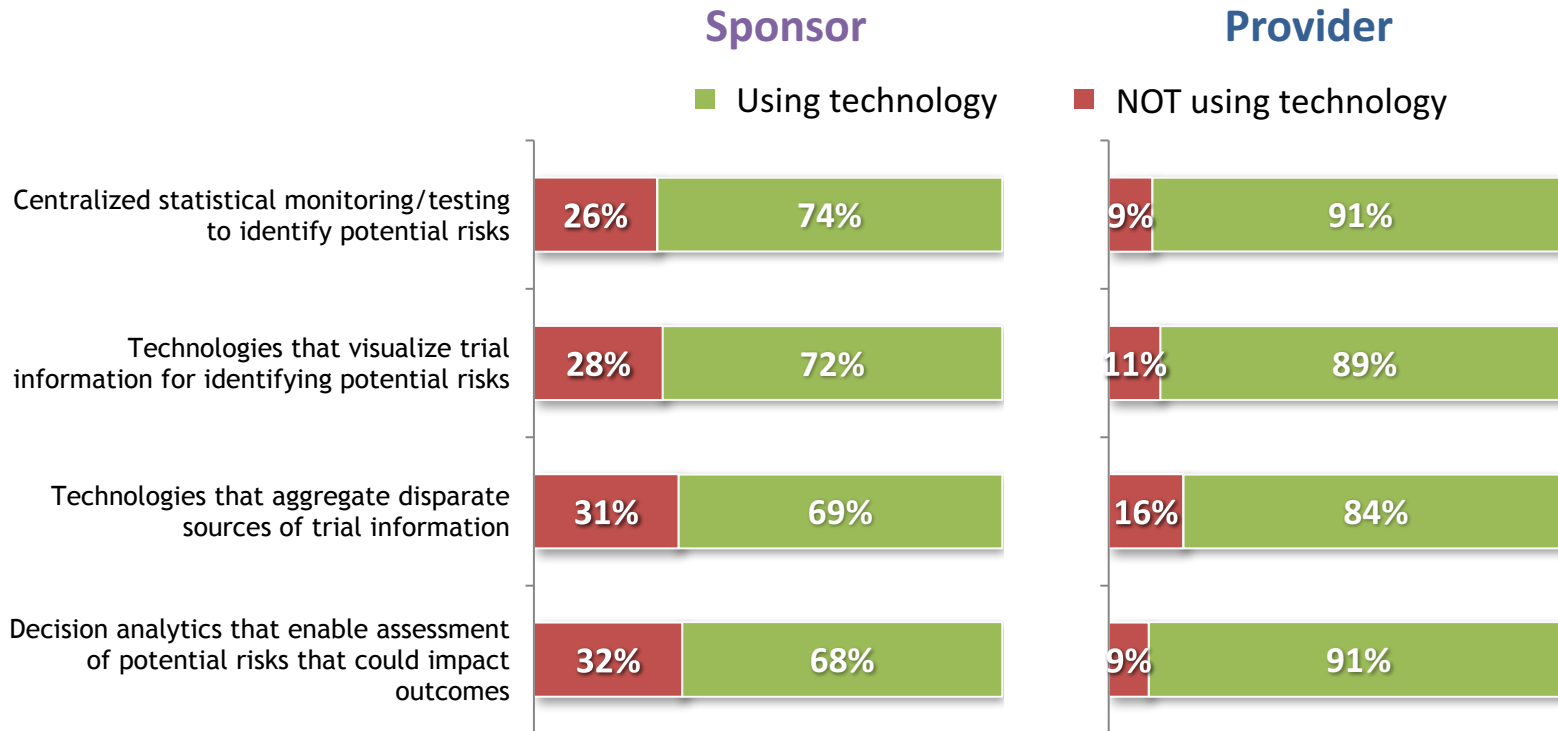
Key Findings

*Using Technology in a
Risk-Based
Environment*

Technology in a Risk-Based Environment

Though a majority of both Sponsors and Providers report using technology in risk-based approaches, Providers showed higher adoption across the range of technologies evaluated.

Use of Technology to Aid in Risk-Based Approaches



N: SPONSOR=148-167; PROVIDER=68-74

Q: Now please consider the following technologies and select those, if any, that your company uses for each risk-based approach.



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Technology in a Risk-Based Environment

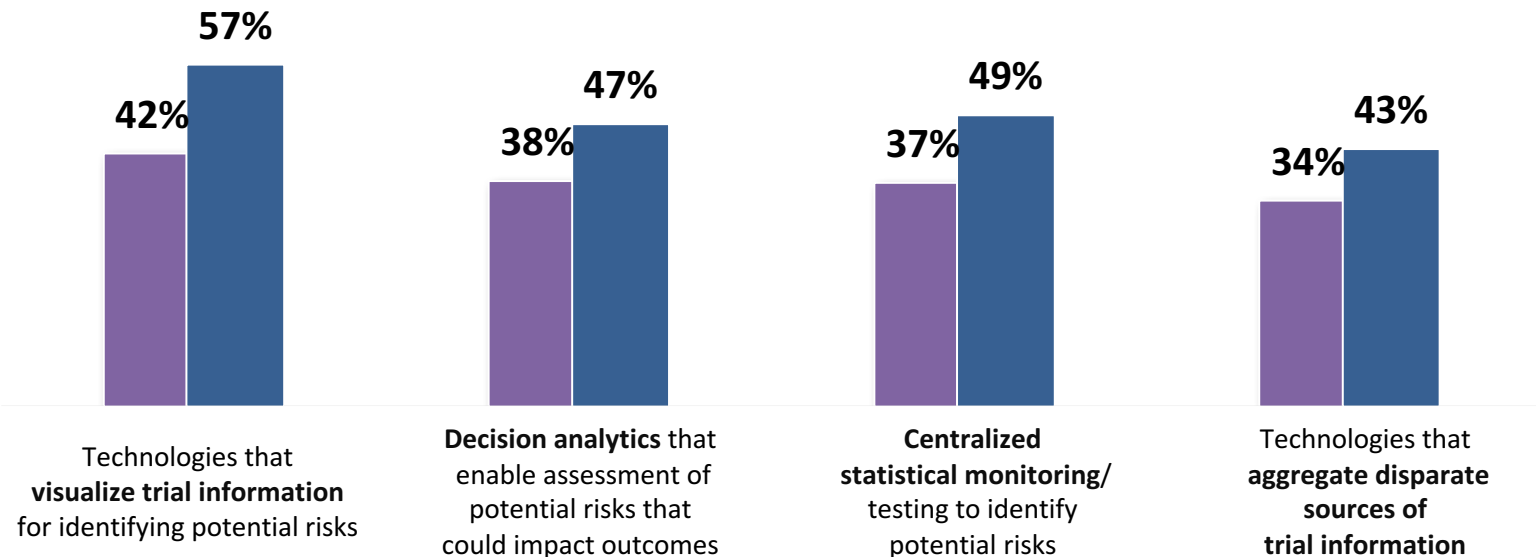
Evaluations of the impact of technological approaches shows promise – approximately half of providers say the approaches are having a “very positive” impact. Sponsors were somewhat weaker in their response, which may be due to them being in the earlier stages of adoption of these approaches.

Impact of Technological Approaches to Managing Risk in Clinical Trials

% indicating the approach has a “very positive impact”

Sponsor

Provider



N: SPONSOR=165-178; PROVIDER:=68-72

Q: Considering these same technologies, based on your knowledge and/or experience, how would you rate their impact on supporting risk-based approaches to managing quality and oversight of clinical trials?



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Technology in a Risk-Based Environment

Risk-based site monitoring is the “sweet spot” for technology use among both audiences; technology is also being used in risk-based quality management, but to a lesser extent than is observed for monitoring.

Use of Technology in Managing Risk in Clinical Trials

% indicating use of technology for risk-based approach

<i>Sponsor Provider</i>	Centralized Statistical Monitoring/Testing	Technologies that Visualize Information	Technologies that Aggregate Disparate Information	Decision Analytics
Site Monitoring	50% 77%	46% 72%	42% 69%	41% 70%
Quality Management	26% 42%	30% 56%	27% 50%	31% 55%
CRO/FSP Oversight	22% 15%	32% 25%	28% 22%	27% 23%
Inspection Preparedness	15% 9%	16% 11%	11% 16%	16% 9%
Oversight of Other Providers	12% 18%	18% 30%	18% 31%	21% 36%

N: SPONSOR=148-167; PROVIDER=68-74

Q: Now please consider the following technologies and select those, if any, that your company uses for each risk-based approach.

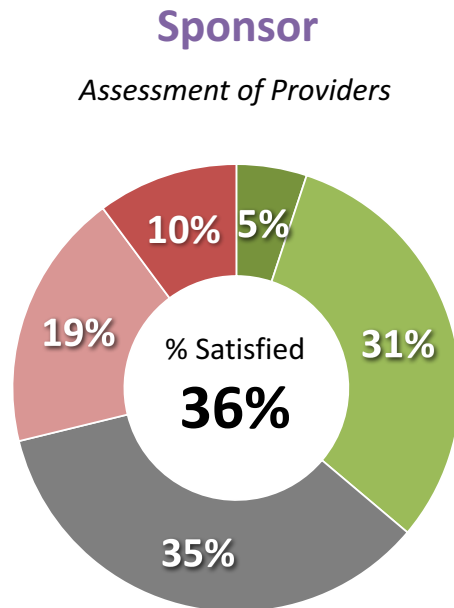


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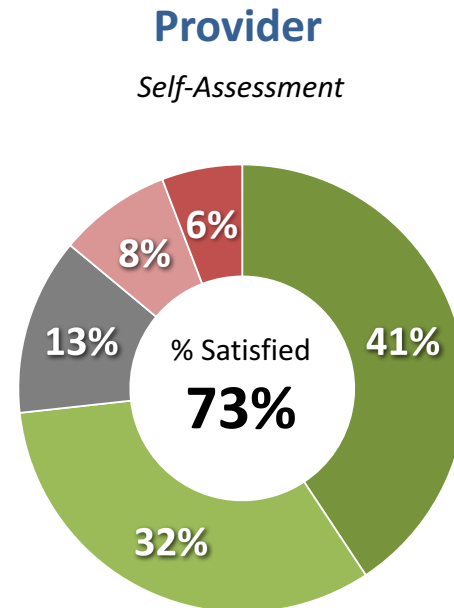
Technology in a Risk-Based Environment

Satisfaction with Providers' use of innovation and technology in risk-based monitoring and quality management was weak among Sponsors; Providers were much more favorable in their self-assessments of the same measure.

Satisfaction with Innovation and Technology in Risk-Based Approaches



1=Very Dissatisfied to 5=Very Satisfied



1=Very Dissatisfied to 5=Very Satisfied

N: SPONSOR=177; PROVIDER=86

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

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



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Technology in a Risk-Based Environment

Qualitatively, respondents volunteer that having a more comprehensive view of trial data through technology has allowed for more data-driven decision-making that is proactive versus reactive.

Positive Impacts of Risk-Based Approaches to Clinical Trial Conduct

“Ability to find risk by comparing multiple pieces of data and seeing correlations and then inverse correlations.”

“Building a risk tool to allow for proactive identification of risks.”

“Technological innovation and continued adoption of predictive analytics.”



“Adopting/implementing our own technology platforms and forcing providers to work in our systems as opposed to having data and information in a number of locations with a number of vendors. This is the first step in a strategy to facilitate more centralized analytics for early risk detection and mitigation. This will also allow us to be more vendor-agnostic and to more readily change vendors when early efforts to improve performance problems are ineffective.”

Technology in a Risk-Based Environment

Technological integration has been a key challenge in achieving this comprehensive vantage point, as have securing funding and resources and gaining internal alignment.

Challenges of Risk-Based Approaches to Clinical Trial Conduct

"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."

"IT integration across multiple CROs, EDCs, CTMS, and integration with 3rd party suppliers. Getting monitoring workforce to adapt to the change."



"Getting people to align and invest \$ in an internal system."

"We're doing things from scratch with limited personnel and tools. The systems in place do not have automation processes in place to make a risk-based approach feasible."

"Internal buy-in for resourcing the systems and staff to effectively and continuously manage risk."

Key Take-Aways for Technology in a Risk-Based Environment

- Today, risk-assessment and risk-based approaches to trial management are not being used as extensively as they could be, and also are not having a strong positive impact on increasing quality and efficiency.
- Results indicate that implementation of technology to assist in risk-based trial management could have promise, but appears to be in the earlier stages of adoption, especially in Sponsor organizations.
- While respondents see value in taking a more data-driven, comprehensive approach, gaining alignment on the use of technology to achieve this, and securing the funding and resources necessary to fuel this change are challenges.





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Thank you

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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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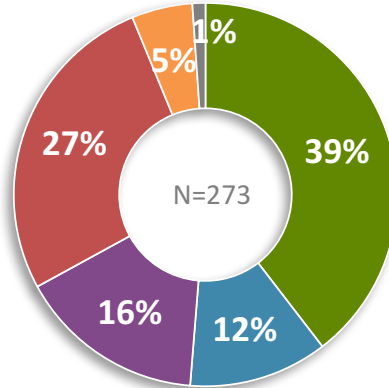
Appendix

Demographics

Company Characteristics

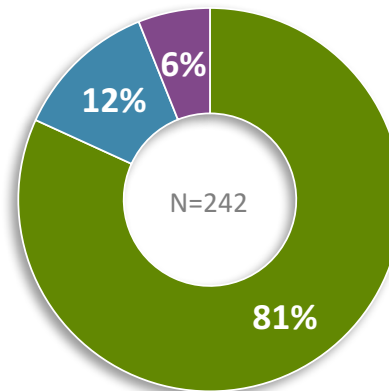
SPONSOR: Company Size

- 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



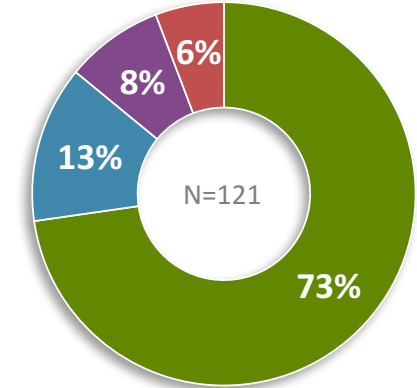
SPONSOR: Company Headquarters

- United States
- Western Europe
- Other



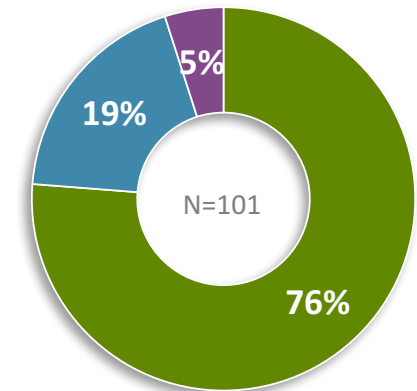
PROVIDER: Company Type

- CRO
- Clinical Service Provider
- Consulting Company
- Other



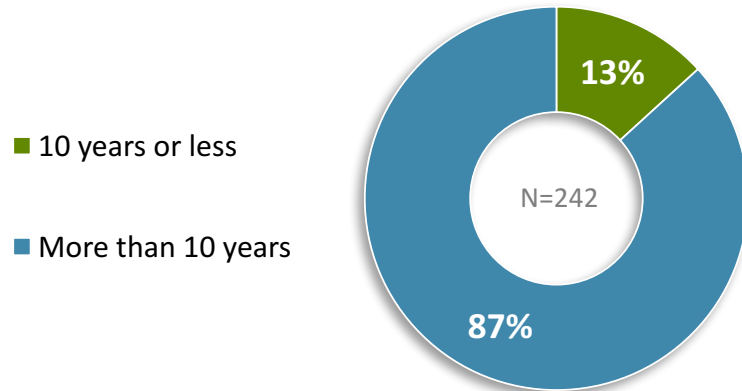
PROVIDER: Company Headquarters

- United States
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- Other

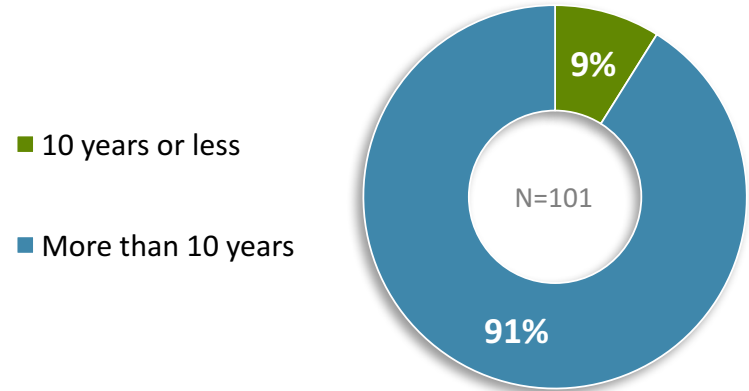


Respondent Characteristics

SPONSOR: Time in Industry

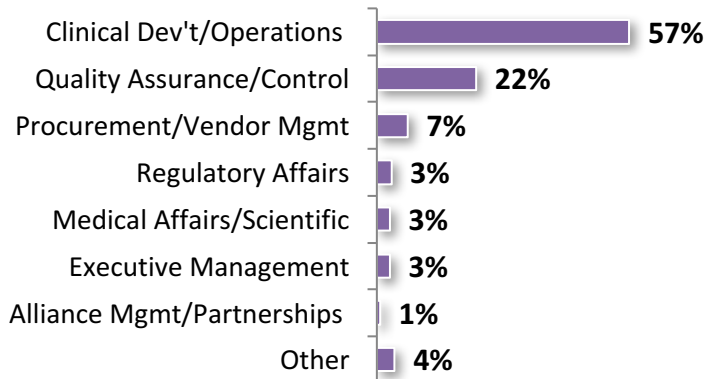


PROVIDER: Time in Industry



SPONSOR: Primary Functional Area

N=273



PROVIDER: Primary Functional Area

N=121

