# The 2018 Avoca Industry Report:

Perspectives on Clinical Innovation & Technology

**May 2019**

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# 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 think about and utilize technology in clinical trials. This topic is a continuation of research first conducted in 2015.

This report summarizes the key findings from our 2018 research.

# Usage Guidelines





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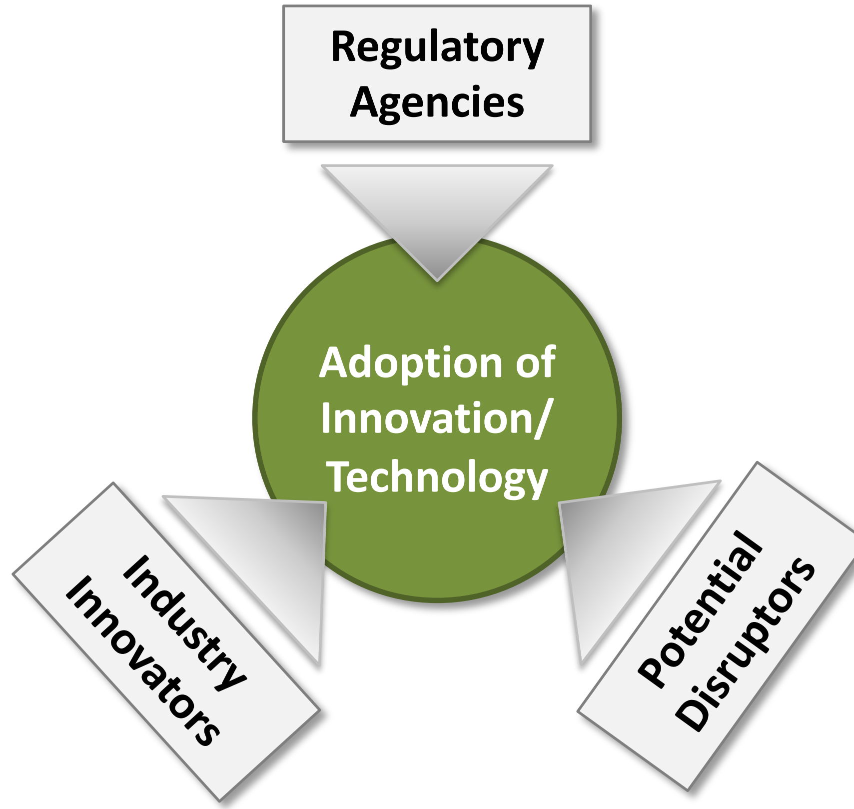
# Methodology

- All fieldwork was conducted between September and December of 2018.
- A total of 128 completed surveys were received from respondents representing 89 individual Sponsor organizations.
- A total of 159 completed surveys were collected from respondents representing 128 individual Provider organizations.
- Classification information about respondents and companies they represent can be found in the appendix of this report.

# Perspectives on Innovation

# Perspectives on Innovation

- There are many influencers in terms of how technology and innovation come into practice in clinical trials.
- In this report, we'll start by exploring who respondents perceive as key players today.
- We'll then take a closer look at technology adoption, impact, and challenges that end-users face.



# Perspectives on Innovation

## Google, Amazon, and Apple were top mentions for companies *outside* the pharmaceutical industry that could cause disruption. Their history of innovation and familiarity with and access to big data were key reasons.

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### Companies OUTSIDE of Industry with Disruptive Potential

*Size of name represents frequency of mentions*

**Among Sponsors**


**Among Providers**


*"**Google** - innovative and outside of the box thinking, big data science."*

*"**Amazon** - For being very innovative and adaptable to the requirements of the market."*

*"**Microsoft** - They have the footprint and presence to make change at a scale not possible by the pharma and/or CRO industry."*

*"**Apple** - A recent pilot trial using the iWatch to recruit patients with cardiac irregularities met its enrollment targets in 2 hours!"*

*Q. If you had to pick one company from outside the pharmaceutical industry that would be most likely to disrupt the clinical research enterprise, which company would you pick and why? OPEN END*

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# Perspectives on Innovation

Among both Sponsors and Providers, Providers are mentioned more often as bringing positive innovation to the industry. IQVIA had the highest number of mentions overall, followed by PAREXEL and Veeva.

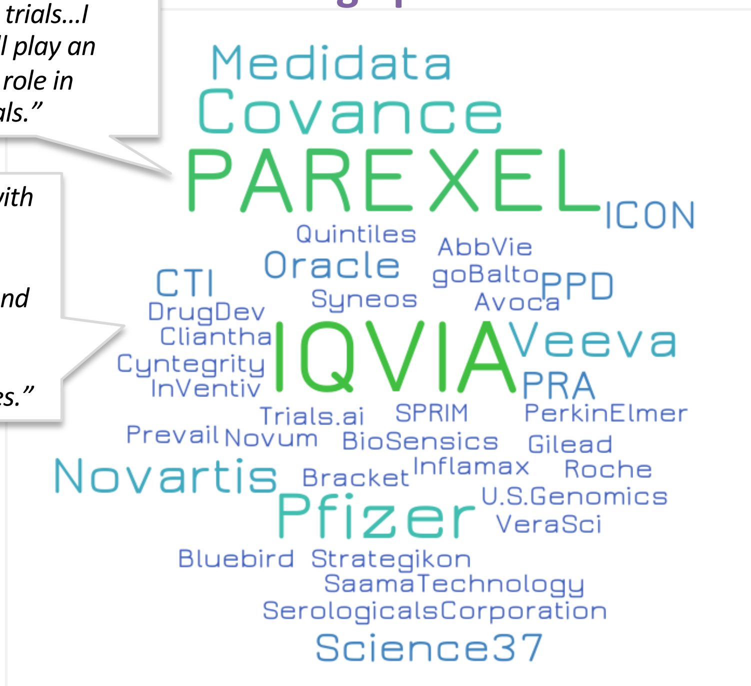
## Industry Companies Using New Technologies

*Size of name represents frequency of mentions*

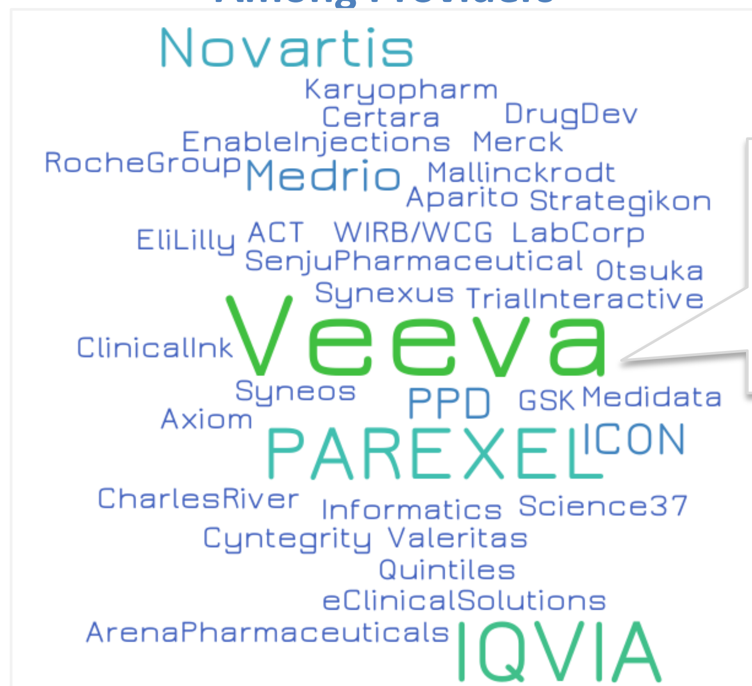
*"**PAREXEL** announces mobile technology and new wearable device for clinical trials…I think it will play an important role in clinical trials."*

*"**IQVIA** with their targeted patient and disease specific databases."*

### Among Sponsors




### Among Providers




*"**Veeva** Vault for eTMF solutions that are comprehensive and efficient."*

*Q. Which company in the clinical trials industry is using new or novel data sources and technologies most effectively to positively influence clinical development, and why? OPEN END*

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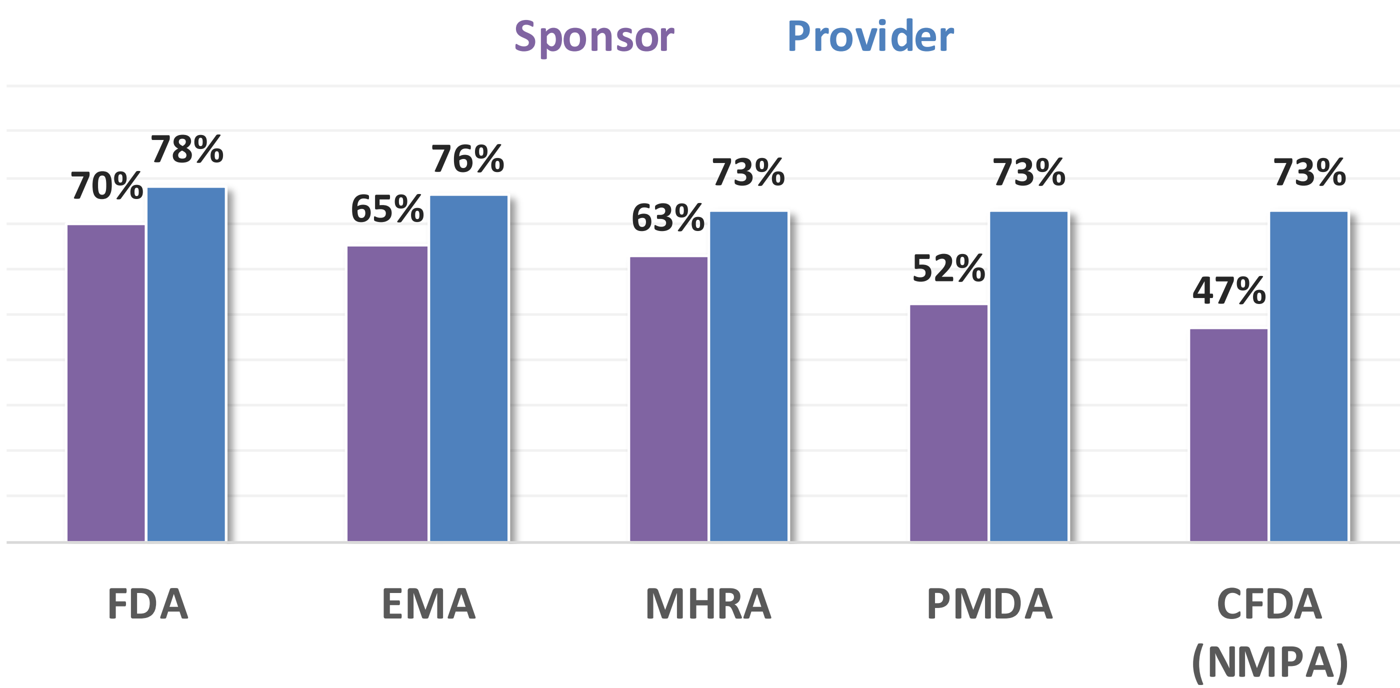
# Perspectives on Innovation

Regulatory agencies are mostly seen as encouraging innovation through the use of new data sources and technology. As was observed in Avoca's 2015 Industry Survey, the FDA and EMA are seen most favorably.

**Perceptions of Influence of Regulatory Agencies**

*% who say agency encourages innovation*




N: Sponsor=83-111, Provider=122-146

*Q. Now, for each of the regulatory agencies listed below, please select the statement that best describes your opinion regarding their level of influence over the use of new data sources and technology in clinical research. With respect to the use of new data sources and technology within the pharmaceutical industry, this agency…(1="Greatly stifles"; 5="Strongly encourages")*

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# Perspectives on Innovation

Providers express stronger agreement with statements on the adoption of innovation than do Sponsors. For both audiences, a marked increase has been observed with respect to perceptions of risk tolerance and investment in innovation since this question was asked by Avoca in 2015.

## My company…

*% of respondents that agree with statement (ratings of 4 or 5)*

| Sponsor 2015 | Sponsor 2018 | Sponsor / Provider | Provider 2018 | Provider 2015 |
|---|---|---|---|---|
| 72% | 66% | **Recognizes and adopts innovative approaches** to clinical development that are shown to be successful | 94% | 92% |
| 52% | 64% | Is **willing to try and fail in the pursuit of innovative approaches** to clinical development | 90% | 64% |
| 41% | 61% | **Invests an appropriate amount of money** and resources into innovative approaches to clinical development | 91% | 72% |

N: 2015 Sponsor=107, Provider=64; 2018 Sponsor=128, Provider=158-159

*Q: To what extent do you view your organization as innovative with respect to clinical development? Please indicate the extent to which you agree or disagree with each of the following statements using a scale of 1 to 5, with 1 being 'Strongly Disagree' and 5 being 'Strongly Agree'*

# Perspectives on Innovation

## Usage and familiarity is strongest for risk-based oversight tools. Smaller Sponsor organizations show less usage of these tools relative to larger Sponsor organizations, especially as it relates to use of RBM.

### Risk-Based Oversight Tools & Technologies

*% familiar and no plan to use/% familiar and plan to use/% familiar & have used/total % familiar*

| | Sponsors | | | | Providers | | | |
|---|---|---|---|---|---|---|---|---|
| Risk-based monitoring tools | 6% | 30% | 62% | 98% | 6% | 26% | 68% | 100% |
| Electronic investigator site files | 12% | 27% | 54% | 94% | 10% | 33% | 56% | 99% |

| | Smaller Sponsors *(<$2 Billion in Sales)* | | | | Larger Sponsors *(>$2 Billion in Sales)* | | | |
|---|---|---|---|---|---|---|---|---|
| Risk-based monitoring tools | 8% | 33% | 55% | 96% | 2% | 28% | 70% | 100% |
| Electronic investigator site files | 18% | 27% | 49% | 94% | 7% | 29% | 58% | 93% |

N: Sponsor=124-125, Provider=157-158; Smaller Sponsor=51, Larger Sponsor=59-60

*Q: Now thinking specifically about your current company, please rate your familiarity with the following data-focused clinical trial tools and services.*

# Perspectives on Innovation

## Save for RIM, usage of decision support tools is relatively low today; however, there is strong potential for implementation. By Sponsor size, larger Sponsors show greater usage of predictive modeling; use of other decision support tools is similar between the two Sponsor groups.

### Decision Support Tools & Technologies

*% familiar and no plan to use/% familiar and plan to use/% familiar & have used/total % familiar*

| | Sponsors | | | | Providers | | | |
|---|---|---|---|---|---|---|---|---|
| Regulatory information/intelligence | 14% | 28% | 52% | 93% | 5% | 34% | 59% | 97% |
| Predictive modeling of trial operational performance | 21% | 40% | 32% | 93% | 6% | 62% | 26% | 95% |
| Clinical supply forecasting tools | 15% | 34% | 42% | 91% | 7% | 47% | 40% | 94% |
| Protocol feasibility modeling and simulation | 17% | 40% | 31% | 88% | 12% | 60% | 24% | 95% |

| | Smaller Sponsors (<$2 Billion in Sales) | | | | Larger Sponsors (>$2 Billion in Sales) | | | |
|---|---|---|---|---|---|---|---|---|
| Regulatory information/intelligence | 18% | 22% | 51% | 90% | 7% | 36% | 54% | 96% |
| Predictive modeling of trial operational performance | 32% | 34% | 26% | 92% | 13% | 43% | 40% | 97% |
| Clinical supply forecasting tools | 18% | 29% | 43% | 90% | 11% | 36% | 45% | 91% |
| Protocol feasibility modeling and simulation | 22% | 33% | 27% | 82% | 13% | 45% | 36% | 95% |

N: Sponsor=118-124, Provider=154-156; Smaller Sponsor=49-51, Larger Sponsor=55-60

*Q: Now thinking specifically about your current company, please rate your familiarity with the following data-focused clinical trial tools and services.*

# Perspectives on Innovation

Today, utilization of wearables and virtual trials is low, but show strong intent to use among Providers, who may be anticipating industry trends. Larger Sponsors appear to have greater utilization potential for virtual trials than do smaller.

## Wearables and Virtual Trials

*% familiar and no plan to use/% familiar and plan to use/% familiar & have used/total % familiar*

| | Sponsors | | | | Providers | | | |
|---|---|---|---|---|---|---|---|---|
| Wearables/sensor data collection | 28% | 36% | 31% | 94% | 9% | 65% | 24% | 99% |
| Virtual/site-less trials/telehealth | 30% | 29% | 25% | 83% | 10% | 71% | 14% | 95% |

| | Smaller Sponsors (<$2 Billion in Sales) | | | | Larger Sponsors (>$2 Billion in Sales) | | | |
|---|---|---|---|---|---|---|---|---|
| Wearables/sensor data collection | 30% | 34% | 30% | 94% | 25% | 36% | 34% | 95% |
| Virtual/site-less trials/telehealth | 37% | 21% | 19% | 77% | 26% | 39% | 26% | 91% |

N: Sponsor=115-121, Provider=155-156; Smaller Sponsor=43-47, Larger Sponsor=57-59

*Q: Now thinking specifically about your current company, please rate your familiarity with the following data-focused clinical trial tools and services.*

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# Perspectives on Innovation

## All enrollment and engagement tools showed far greater usage by Providers. Larger Sponsors generally use these technologies more, especially online patient communities and POC integration.

### Enrollment and Engagement Tools & Technologies

*% familiar and no plan to use/% familiar and plan to use/% familiar & have used/total % familiar*

| | Sponsors | Providers |
|---|---|---|
| Online patient communities | 22% / 39% / 33% / 94% | 7% / 28% / 60% / 95% |
| EHR data-mining | 22% / 34% / 31% / 87% | 9% / 14% / 69% / 92% |
| Patient location/segmentation tools | 22% / 32% / 31% / 85% | 11% / 18% / 66% / 95% |
| POC integration of clinical research as a care option | 26% / 29% / 30% / 84% | 7% / 22% / 62% / 91% |
| Patient data-sharing tools | 18% / 33% / 31% / 83% | 12% / 15% / 66% / 93% |

| | Smaller Sponsors (<$2 Billion in Sales) | Larger Sponsors (>$2 Billion in Sales) |
|---|---|---|
| Online patient communities | 27% / 42% / 25% / 94% | 19% / 35% / 40% / 95% |
| EHR data-mining | 29% / 27% / 24% / 80% | 16% / 40% / 37% / 93% |
| Patient location/segmentation tools | 26% / 30% / 28% / 83% | 18% / 31% / 36% / 85% |
| POC integration of clinical research as a care option | 33% / 27% / 16% / 76% | 23% / 30% / 36% / 89% |
| Patient data-sharing tools | 15% / 30% / 33% / 78% | 18% / 35% / 31% / 84% |

N: Sponsor=,115-119 Provider=152-153; Smaller Sponsor45-48, Larger Sponsor=55-57

*Q: Now thinking specifically about your current company, please rate your familiarity with the following data-focused clinical trial tools and services.*

# Perspectives on Innovation

On an *unaided* basis, Sponsors and Providers shared similar feelings regarding obstacles to technology adoption, namely, cost considerations, managing internal shift in mind-set/cultural change, integration/implementation issues, and lack of familiarity.

## Primary Challenges to Utilizing New Technologies

### Cost

- "The cost of bringing those technologies in-house including validation, training, etc." [Provider]
- "Cost and integration with the systems of a small company." [Sponsor]

### Acceptance/Cultural Change

- "Overcoming resistance to change, convincing colleagues to take the time to learn/understand new technologies." [Provider]
- "Sponsor resistance to change and the risks involved in changing process." [Provider]

### Integration/Implementation

- "Harmonization of processes & data tools across multiple players in clinical research." [Sponsor]
- "Integration and interpretation of multiple data/information streams. Regulatory hurdles, i.e., EU challenges to e-consent." [Provider]

### Lack of Familiarity/Risk Perception

- "Familiarity, early adoption (open mindedness), credibility, courage to change." [Provider]
- "Lack of overall knowledge and experience by decision makers." [Sponsor]

*Q. Still thinking about your current company, what would you say is the primary challenge to using novel data sources and technologies more effectively in clinical trials? OPEN END*



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# Perspectives on Innovation

When asked directly to rate challenges, similar ideas rose to the top as being 'most challenging.'

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## Top 4 Challenges to Using Novel Data Sources/Technology

*Based on % top 3 box on 10-pt. scale*

*"Company uses a different system while CRO uses another. It is always a challenge to integrate."*

| | Sponsors | Providers |
|---|---|---|
| 1 | System Integration | System Integration |
| 2 | Legal/Compliance (including Privacy) | Legal/Compliance (including Privacy) |
| 3 | Regulatory | Cultural Challenges with Sponsor Company |
| 4 | Cultural | Regulatory |

*"Sponsor often wants to use their system, regardless of lack of sophistication."*

N: Sponsor=121-125, Provider=150-159

*Q: Still thinking about challenges to using novel data sources and technologies to improve the execution of and/or outcomes from clinical trials, please rate the following challenge areas on a scale of 1-10, with 1 being 'Not at all challenging' and 10 being 'Extremely challenging'.*

# Perspectives on Innovation

In order to help overcome these challenges, Sponsors are looking to Providers for validation and evidence that supports the use of new technology, evidence-based results, assistance with integration, and a promise of data security.

## What can Providers do to overcome challenges?

*From Sponsor Perspective*

**Validate Data Quality/Integrity**

"**Provide better real-life success stories or strategies** which have the potential for successful review by health authorities."

**Prove Results/ROI**

"**Reflect the value of innovative approaches more concretely**. Put skin in the game for outcomes of these alongside better research into the value proposition."

**Assist with Integration/Implementation**

"**Make the data set interoperable** (using CDISC standards) and **easy integration with leading EDC systems**."

**Ensure Data Privacy & Security**

"**Strong security protocols**."

*Q. If you could suggest one way for your Providers to help overcome this challenge, what would it be? OPEN END*

# Perspectives on Innovation

Providers look to Sponsors to get engaged with smarter/more advanced data collection tools, a greater level of collaboration, and openness to risk/change.

## What can Sponsors do to overcome challenges?

*From Provider Perspective*

"**Adopting the most advanced data acquisition technology and equipment**."

**Smart Data Collection**

"**Collaboration and communication with regulators and other industry personnel** to determine how to utilize the technologies and understanding what expectations are from regulatory agencies."

**Be More Collaborative**

"**Be supportive of innovation and willing to invest up front** for future savings in time or money."

**Be Open to *Some* Risk/Change**

"Industry-wide skilling up effort for staff in many disciplines."

**Cross-disciplinary Staff Development**

*Q. If you could suggest one way for your Sponsors to help overcome this challenge, what would it be? OPEN END*

# Perspectives on Innovation

Providers, who generally report greater utilization of innovation, are also more likely to indicate that innovation has had an impact on performance/outcomes. The weakest impact is on cost, which was reported to be one of the key challenges of technological implementation.

## Impact of New Technologies on…

% Rating 1 to 5 (Lower Impact) | % Rating 6 to 10 (Higher Impact)

| | Sponsors | | Providers | |
|---|---|---|---|---|
| | % Rating 1 to 5 (Lower Impact) | % Rating 6 to 10 (Higher Impact) | % Rating 1 to 5 (Lower Impact) | % Rating 6 to 10 (Higher Impact) |
| Deriving more value from clinical data collected | 29% | 71% | 20% | 80% |
| Being proactive around quality and compliance | 30% | 70% | 19% | 81% |
| Improving how I work with Providers/Sponsors | 34% | 66% | 21% | 79% |
| Enhancing focus on patients | 37% | 63% | 23% | 77% |
| Reducing timelines | 37% | 63% | 20% | 80% |
| Improving how I work with sites | 38% | 63% | 21% | 79% |
| Mitigating risk | 39% | 61% | 18% | 82% |
| Reducing cost | 42% | 58% | 23% | 77% |

N: Sponsor=112-115, Provider=148-152

*Q: Thinking about the use of new data sources and technologies at your company, how impactful, if at all, have these been on achieving the following goals? Please use a 1-10 scale with 1 being "Not at All Impactful" and 10 being "Extremely Impactful."*

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# Perspectives on Innovation

A common theme in closing comments was that of taking the lead on change, being a proactive force towards progress rather than following the crowd.

## What would you like to see your company do?

*Select Quotes*

### Sponsor Comments

"**Serve as change agent** and invest to validate."

"**Take a leading approach by going to regulatory bodies with new data sources** versus waiting for the guidance from the regulatory bodies."

"**Keep an eye out on the new technological advances and implement promising technologies** to improve research and compliance."

"**Be change leaders** in implementing new data sources and technologies."

"I would like the company to **be more supportive of their [data sources & technologies] uses and move towards using them**."

"**Earlier adoption to be leader**."

"**Be more of a front runner rather than an adaptor**."

### Provider Comments

"**Convince others to also adopt** so industry can move forward collectively."

"I would like us to **continue to adopt proven new technologies as they arise**. We want to keep up with industry standards."

"**Make aggressive push to revamp product architecture** with an emphasis on visualizations and reporting, API development, and data integration for RBM."

"**Remain open minded. Accept given levels of risk**. Both statements speak to the baseline requirements of trying new data/tech."

*Q. What would you like to see your company do with respect to implementing new data sources and technologies for clinical research and why? OPEN END*

# Perspectives on Innovation: Key Takeaways

- Providers are seen as leading the way in terms of innovation, especially, IQVIA, PAREXEL, and Veeva.
- Google, Amazon, and Apple are thought of as potential disruptors in the pharmaceutical space.
- Generally, regulatory agencies are seen as encouraging innovation, with the FDA being rated most favorably in this respect.
- Compared to Avoca's 2015 research, both Sponsors and Providers express stronger agreement with statements about organizations' willingness to take risk and invest in innovation.
- Though specific technologies are widely known by both audiences that were surveyed, Providers show broader adoption.
- Technologies supporting oversight (e.g., RBM tools, eISF) are at the greatest stage of adoption, though still not uniformly common practice as many firms are still in planning stages.

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# Perspectives on Innovation: Key Takeaways

- Predictive modeling and decision support tools are ‘on deck’ with 80% of Sponsors and 90% of Providers having used or are planning to use these in protocol design, operations, and supplies management.
- Enrollment and engagement tools are in prevalent use among Providers and may be an opportunity for Sponsors to leverage partnering to gain access and experience to facilitate adoption.
- Wearables, sensors, and virtualized trial tools are gaining familiarity and use more rapidly among Providers as compared to Sponsors, strengthening the case for partnering to facilitate improved use and adoption.
- Integration, cost, compliance concerns, lack of familiarity, and the need for cultural change are key barriers to further adoption.
- Sponsors are looking to Providers to provide “hard evidence” that supports and validates new technology’s data quality and results/ROI. They are also looking for assistance with integration.

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# Perspectives on Innovation: Key Takeaways

- As Providers are utilizing innovation to a greater extent, it is not surprising that they are also more likely to report a positive impact on outcomes.
- Respondents are looking to their organizations to be change leaders at the forefront of technological adoption as tools and systems continue to evolve.

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# Thank You!


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# Appendix

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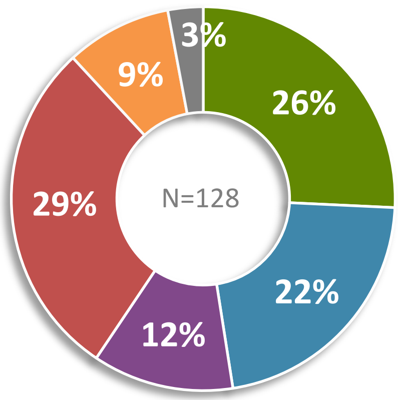
# Company Characteristics

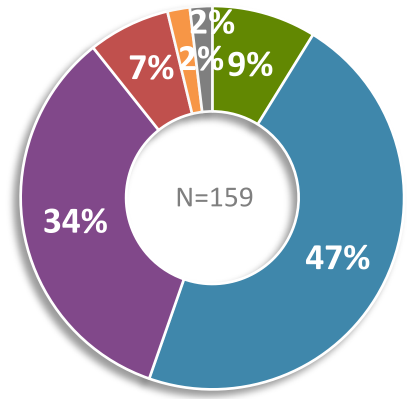
## Sponsor: Company Size

- 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



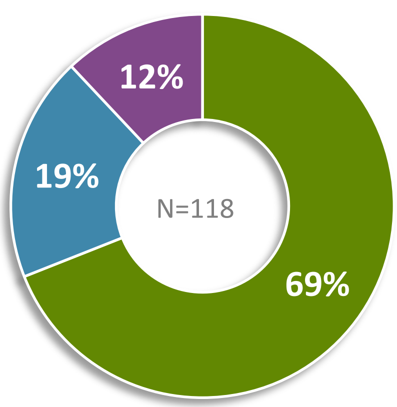

## Provider: Company Type

- Large CRO ($500+ million sales)
- Mid-size CRO ($50 - $500 million sales)
- Small/Specialty CRO (<$50 million sales)
- Non-CRO Clinical Service Provider
- Consulting Company
- Other



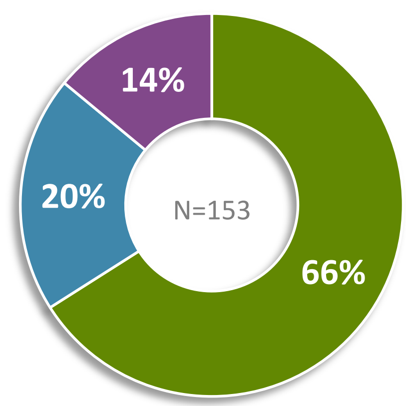

## Sponsor: Company Headquarters

- United States
- Western Europe
- Other



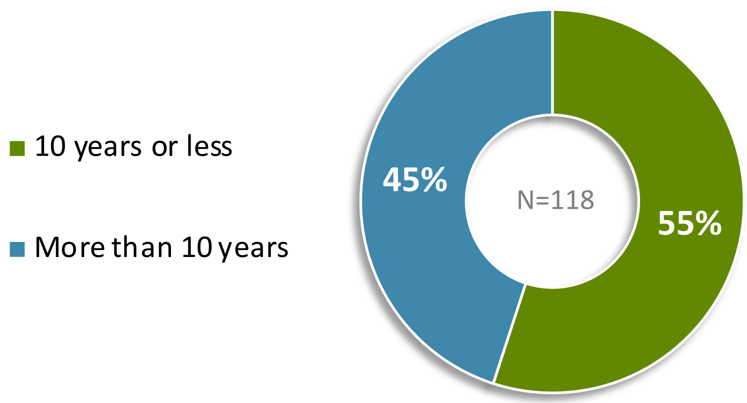

## Provider: Company Headquarters

- United States
- Western Europe
- Other

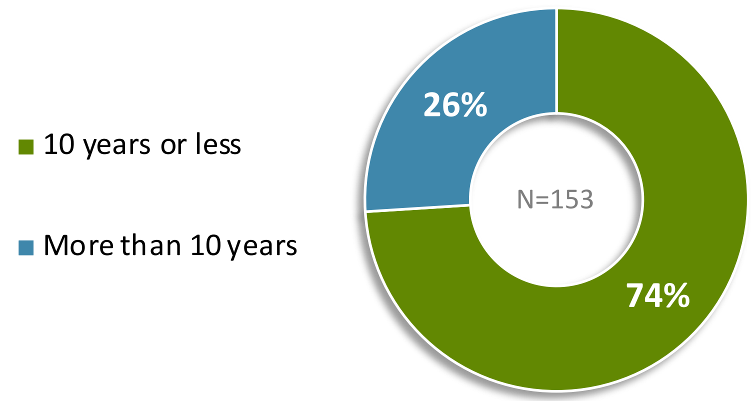


# Respondent Characteristics

## Sponsor: Time in Industry

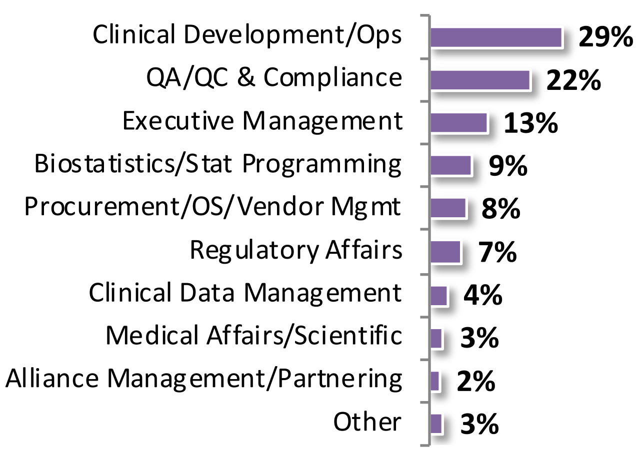



## Provider: Time in Industry



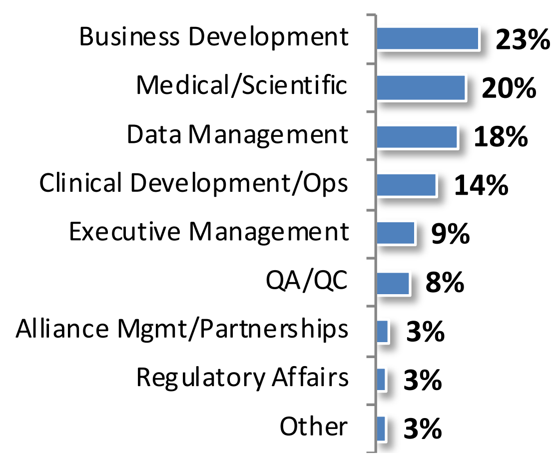

## Sponsor: Primary Functional Area

N=128




## Provider: Primary Functional Area

N=159

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