

Research Overview & Respondent Characteristics

Each year, The Avoca Group surveys industry executives and managers to understand trends in clinical development, with a focus on working relationships between research Sponsors and Providers. In this year’s survey, the goal was to understand trends towards utilizing innovative approaches to clinical development to enhance R&D efficiency and effectiveness.

Respondents to the 2015 survey are characterized below.

Sponsors

- 156 respondents from 86 companies
- Half from Top 20/50 organizations
- Half from Clinical Operations; the other half mixed from Quality Assurance, Procurement, Executive Management, and other functions
- Majority have 10+ years of experience in the industry

Providers

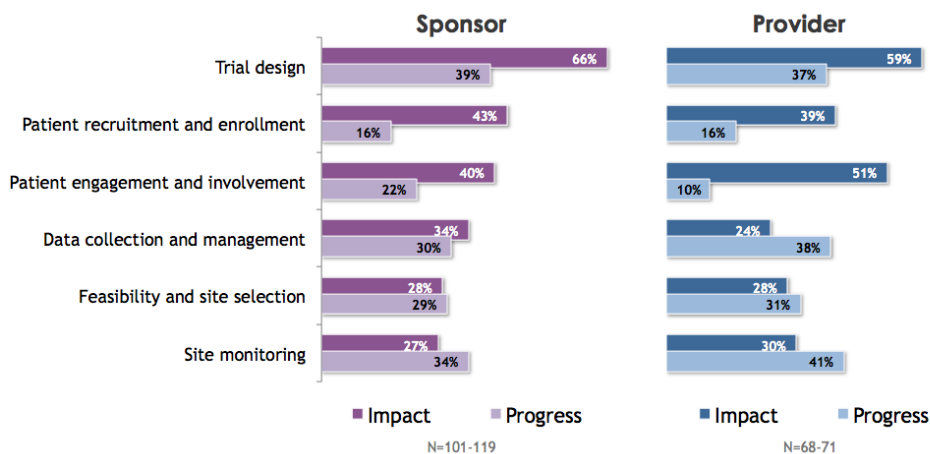
- 90 respondents from 61 companies
- Two-thirds from CROs
- 40% from Clinical Operations; one-quarter from Executive Management
- Nearly all have 10+ years of experience in the industry

Key Findings

Company Behavior/Strategy Related to Innovation

Among both Sponsors and Providers, a primary goal of innovation is to reduce development timelines, followed by improving success rates, getting more value from clinical data, and reducing cost. To this end, trial design, patient recruitment/enrollment, and patient engagement/involvement are the top three areas where it is believed innovation can have the greatest impact. These same three areas are also the ones that show the largest deficit in terms of progress in utilizing innovation (see graph below).

Top Activities Where Innovation Can Have An Impact and Where Progress Has Been Made



Key Findings

Overall, Sponsors appear to be lagging behind Providers on the innovation adoption curve, as evidenced by various findings:

- Sponsors use innovative approaches in approximately one-third of their trials (vs. 42% among Providers), and just over 40% view their organizations as above average in innovation (vs. 75% of Providers surveyed).
- Sponsors show weaker agreement than Providers with statements about adopting innovation (e.g., willingness to try and fail in pursuit of innovation, company investment in innovation).
- Sponsors show a greater deficit than Providers on ratings of success in achieving innovation goals.
- Very few Sponsors (15%) indicate that their organizations have measures in place to assess the ROI of innovative approaches, compared to nearly half of Providers.

Both audiences cited risk aversion, cost, and timelines as key internal barriers to utilizing innovative approaches. Providers say that risk aversion is a challenge internally (getting stakeholders aligned) and externally (aligning with Sponsors).

“Decision makers would rather stick to conservative measures than to take the risk to spend money on new innovative approaches; often decision making takes too long to allow selected measures to show an effect.”

Innovation and Provider Relationships

When asked who primarily drives the use of innovation in outsourced clinical trials, both Sponsors and Providers favored their own organizations. Data suggest that there are variables that influence the use of innovation in outsourced trials, including:

- Level of Engagement: The higher the level of engagement with a Provider, the more positive the impact on innovation. Partnerships and preferred providers skewed positive in their impact, while transactional relationships were generally considered to have little impact on innovation.

“In our long-term relationships with Providers we have KPIs around expected innovation and improvement. Projects must be jointly resourced and valuable to each party.”

- Company Size: There is an inverse relationship between size and perceived innovativeness – Small/Specialty Sponsors and CROs are seen as most innovative.

Sponsors and Providers are well aligned in their thinking about innovation investment, with many indicating that Providers should be making investments on their own (in addition to using awarded funds). They are also in agreement about the key challenges to the adoption of innovation – namely alignment on responsibilities and goals, risk aversion, and cost.

Future Outlook on Innovation

Both Sponsors and Providers see Biopharma companies as being best positioned to drive adoption of innovation; large and small/specialty CROs were also frequently selected. When asked to look ahead, three-quarters of respondents from each group agreed that innovation will significantly improve clinical development in the next five years.

About The Avoca Group

The Avoca Group is a consulting and research firm based in Princeton, NJ specializing in clinical outsourcing. In 2011, Avoca launched the Avoca Quality Consortium, an industry-wide collaborative that brings together pharmaceutical and biotech companies, CROs and specialty providers. Through the development and implementation of leading practices and standards, The Quality Consortium is helping its Members to optimize proactive approaches to managing quality and risk in outsourced trials. Avoca is committed to fostering productive relationships between sponsors and their service providers, improving quality in clinical trials and increasing efficiency in the pharmaceutical industry.

For more information on The Avoca Group, Danya.Burakoff@TheAvocaGroup.com www.TheAvocaGroup.com (609) 759-2856