Navigating the Complexities of
CRO Selection

About Industry Standard Research (ISR)

The pharmaceutical industry needs higher-quality market research. We fill that need.

ISR's industry reports utilize primary research methodology, which enables us to offer novel insights into the drug development space. We leverage years of industry experience and a global proprietary Health Panel of over 3,000 healthcare and pharmaceutical professionals to provide our customers with endless innovative possibilities.

This market research is available off-the-shelf in the form of our syndicated reports, but we also frequently take on custom research projects to help drug developers and service providers make data-driven decisions with their B2B partnerships, identify new market opportunities, and stay ahead of the competition.

We host several free resources on our website as well, covering topics such as CDMO and CRO selection, clinical development, drug manufacturing, eClinical technology, decentralized trials, the cell & gene market, and more.

What makes ISR different?

We understand that you're looking for confidence in your market research. With ISR, you'll consistently receive:

Focused Domain Expertise — We've operated in pharmaceuticals for over 15 years and because it's our sole focus, our domain expertise brings value to the work that "generalist" researchers can't deliver.

Genuine Research Expertise — Our market research experience has developed over 20 years in many dynamic industries. We capture appropriate sample sizes, given the research objectives, and we use appropriately sophisticated statistics to uncover everything that's real to give you confidence in your decisions.

Transparency — If you're like many, you've been disappointed more than once by research providers who fail to live up to their promises, providing you with their "professional judgment" in place of sound data and suspect contacts instead of real decision makers. We deliver the opinions, attitudes, and recommendations of industry experts — and we'll prove it by sharing detailed demographics in our reports.

**For additional questions about any of our reports or custom research services,
please contact us at info@ISRreports.com.**

Smarter questions ∴ Smarter answers

Clinical Outsourcing
and CRO Selection Insights

JOCELYN REYNOLDS Director of Market Research, (ISR)

@ISRreports

As the biopharmaceutical industry continues to surge forward with remarkable advancements, the role of clinical research has never been more pivotal. We at Industry Standard Research have been conducting market research on the clinical services space for the last fifteen years, and although the goals of our research remain the same, the clinical services ecosystem evolves with each passing year. It can be daunting to evaluate service providers and build relationships when you find that old partners have merged with new ones, traditional processes are changing, or your favorite project team has dissolved. Industry Standard Research provides a reliable resource to turn down the noise of the industry news and tune in to the steady beat of the outsourcing community.

The articles in this ebook are based on recent data from the following reports:

- Phase II/III CRO Benchmarking (15th edition)
- Phase II/III Market Outlook (2022-2026)
- Clinical Development Outsourcing Models (5th edition)
- Phase I CRO Benchmarking (15th edition)

One of the main goals of our research in the clinical space is to help biopharmaceutical sponsor organizations make more informed CRO selection decisions. At a high level, we look at the steps to CRO selection, which starts with the process of assessing trial objectives and establishing a group of decision makers. We take a deep dive into the nuances of choosing the right outsourcing strategy to help sponsors balance the benefits of access to industry exper-

tise and more resources with the drawbacks of higher costs and more complex processes. We look closely at trends in spending in the clinical outsourcing community, identifying the motivations of sponsors and CROs of different sizes.

We also review the role of market research in helping to identify critical CRO selection metrics. With so many service providers vying for clinical work, it can be challenging to find the right fit for a specific trial. And without prior experience with a CRO, it is difficult to judge how the CRO will perform. Market research can fill the role of a trusted peer recommendation, as industry outsourcers share the criteria that are most important to them when selecting service providers and make predictions on new trends.

Our other primary goal is to help CROs optimize operational and marketing strategies. For CROs, understanding the decision-making process within sponsor organizations is indispensable. Our research is positioned to help CROs understand the drivers behind their customers' outsourcing decisions so that they may align their services accordingly. In learning more about the selection metrics that are critical to sponsors, CROs can focus on improving their performance in those key areas. CROs will also get a pulse on trends that are at the forefront of sponsors' minds, including remote monitoring, patient diversity, decentralized trials, use of sensors/wearables and more.

For sponsors and CROs alike, the path to success is illuminated by the beacon of market research. Welcome to *Navigating the Complexities of CRO Selection*, your guide into the dynamic landscape of outsourced clinical development. ISR

JOCELYN REYNOLDS
Director of Market Research, Industry Standard Research

Jocelyn joined ISR in May of 2021 and has been conducting quantitative and qualitative research since 2016. She focuses primarily on market research in the clinical development and clinical technology service provider market. At the start of her career, Jocelyn managed several large-scale government research projects at a boutique research firm for two years, where she was honored to receive the Burns "Bud" Roper award from the American Association of Public Opinion Research in 2017. More recently, Jocelyn led numerous customer survey projects across a variety of industries at a primary research firm.

BRANDON ALLISON
Director, Syndicated Sales & Marketing, Industry Standard Research

Brandon manages relationships with ISR's library subscribers and syndicated report clients. With a decade of experience in sales and customer service, he brings a unique perspective to his role in content writing and marketing strategy. Brandon contributes to ISR's marketing through content creation and distribution, helping to connect drug innovators and service providers to the information they need to make the best decisions possible for their business. He holds an undergraduate degree from Appalachian State University and has been with ISR since 2021.

JENN HOLLOWAY
Director of Market Research, Industry Standard Research

Jenn brings over a decade of experience in quantitative and qualitative methods to her role as Director of Market Research at ISR. She has successfully designed and executed a variety of research strategies, from multi-year longitudinal studies for federal agencies to custom quick-turn efforts for private equity clients and global consultancies. In addition to studying Biomedical Engineering as an undergraduate at the University of Virginia, Jenn completed a graduate-level Survey Design and Data Analysis program at George Washington University. Her work at ISR focuses on the drug development and manufacturing service provider market.

REBECCA MCAVOY
Chief Research Officer, Industry Standard Research

Rebecca has been with ISR since 2013 and has been conducting both qualitative and quantitative market research in the pharmaceutical industry since 2006. She currently leads the clinical development market research division at ISR, overseeing syndicated reports and custom studies. Much of her research has focused on brand perceptions, outsourcing behaviors, and customer needs. Prior to ISR, Rebecca spent six years at ZS Associates, conducting market research with physicians and patients.

Welcome to
Industry Standard Research

NAVIGATING THE COMPLEXITIES OF CRO SELECTION

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Five Steps
to CRO Selection

BRANDON ALLISON Director, Syndicated Sales & Marketing, ISR   🐦 @ISRreports

Sponsors can facilitate successful CRO partnerships by clearly defining the goals of the clinical trial, choosing an outsourcing model that considers project needs and internal capabilities/resources appropriately, communicating consistently and effectively during the decision-making process, and informing provider selection with trustworthy market research. With these steps in mind, drug developers can foster fruitful outsourcing relationships with clinical trial providers that will best support their business goals.

1. ASSESS THE GOALS AND NUANCES OF THE CLINICAL TRIAL

Clearly describing a clinical trial's intricacies and potential challenges will allow sponsor companies to proceed with a more informed approach to CRO selection. This helps ensure that sponsors are well-equipped to communicate their trial's nuances to potential CROs and evaluate a provider's ability to effectively meet their needs.

- **Define Trial Objectives:** Determine the specific goals, endpoints, and expected outcomes of the clinical trial. What does a successful trial look like for your project?

- **Assess Trial Complexity:** Evaluate the trial's complexity in terms of patient population, therapeutic area, trial phase, geography, and regulatory requirements.

- **Identify Key Challenges:** Explore potential challenges such as patient recruitment difficulties, data management needs, regulatory hurdles, and any unique aspects of the trial.

- **Develop a Request for Proposal (RFP):** Draft a project overview that clearly communicates your expectations to CROs, outlining the trial's objectives and scope of work. Make sure to include the nuances of patient recruitment, regulatory requirements, data management, budget, and timelines.

2. CHOOSE THE RIGHT OUTSOURCING MODEL FOR THE PROJECT

Top level drivers like internal resource levels, patient recruitment strategy, and therapeutic expertise can direct a drug developer towards the outsourcing model best suited for a specific trial. Outsourcing strategies in the biopharmaceutical sphere include:
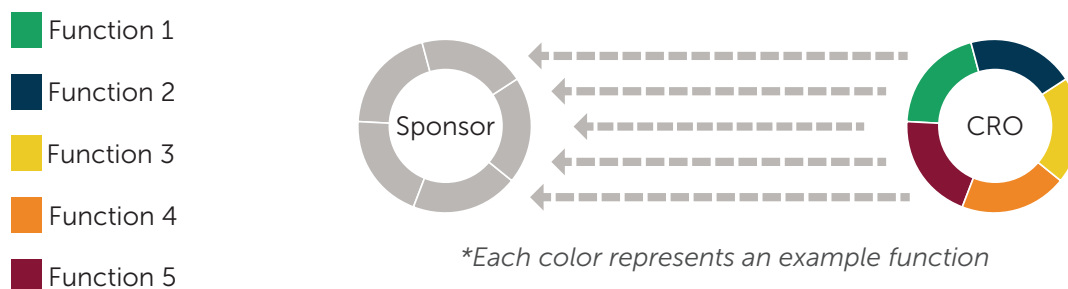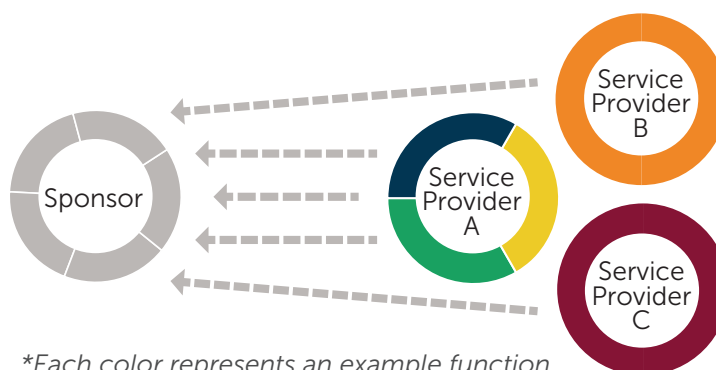

- Function 1
- Function 2
- Function 3
- Function 4
- Function 5

Each color represents an example function

Fig. 1 – Fully Outsourced to One Provider

Legend (Fig. 2):
- Function 1
- Function 2
- Function 3
- Function 4
- Function 5

Sponsor

Service Provider A

Service Provider B

Service Provider C

Each color represents an example function

Fig. 2 – Fully Outsourced to Multiple Providers

Legend (Fig. 3):
- Function 1
- Function 2
- Function 3
- Function 4
- Function 5

Sponsor

Service Provider A

Service Provider B
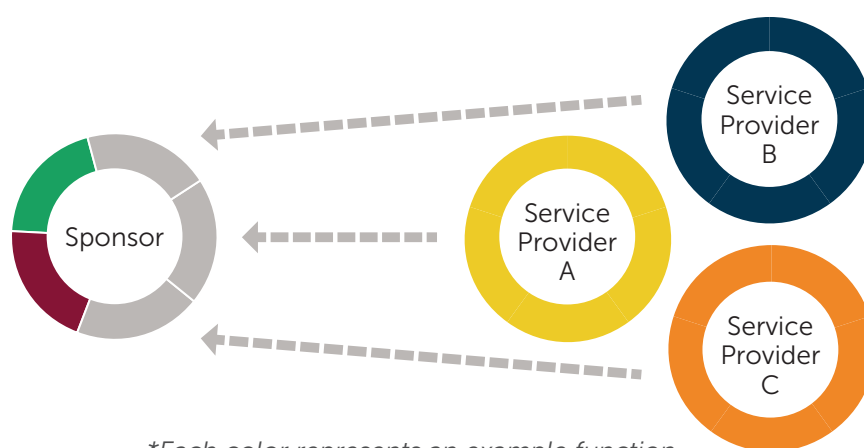
Service Provider C

Each color represents an example function

Fig. 3 – Internal + Functional Service Provider (FSP)

3. COMMUNICATE THROUGHOUT THE DECISION-MAKING PROCESS

Bring all players to the table to discuss selection criteria, project goals and timelines, available resources, and input from key decision-makers. Here are some of the key roles and responsibilities involved in trial design and execution:

DECISION-MAKING ROLES	RESPONSIBILITIES DURING DESIGNAND EXECUTION
• Clinical Operations (including clinical monitoring, clinical project management, etc.) • Data Management • Executive Management • Functional Leads (e.g., biostatistics, technology, safety, regulatory) • Medical Director • Outsourcing/Procurement Representative • Research & Development • Therapeutic Area Head	• Allocating budget • Choosing CROs to invite to bid • Deciding to outsource • Directly managing CROs • Evaluating and selecting CROs • Managing clinical operations • Setting study objectives (designing trial protocol, etc.)

4. IDENTIFY YOUR CRO SELECTION CRITERIA

Understanding and discussing the needs of the company, the project, and strengths of the CRO can foster a successful and efficient drug development process. Acknowledgement of resources internally and of the CRO enables contract researchers to build complimentary teams with the ability to meet requirements. Here are a few of the most important CRO selection attributes according to ISR's respondents from sponsor organizations:

- Expectations for data quality
- Experience with similar study types
- Global footprint
- Low cost
- Metrics for meeting overall project timelines
- Offers innovative solutions
- Operational excellence
- Patient recruitment strategy
- Prior positive experience with service provider
- Therapeutic expertise

5. UTILIZE MARKET RESEARCH, EXPERIENTIAL DATA, AND PEERS' RATINGS TO FIND THE BEST CRO FOR YOUR PROJECT

The CRO landscape is not small and selecting the best CRO for your project is no easy task. Utilizing performance benchmarking studies, drawing upon the experience of your peers, and hearing verbatim reasons for why recent users of CROs rated their satisfaction with a CRO as they did, will lead you to more informed decisions. With Industry Standard Research studies, uncover and learn:

- Satisfaction and performance ratings for more than 30 CROs for Phase I and Phase II/III studies
- Familiarity, reported usage rates, and perceptions of leadership for multiple CROs
- Your peers' preference of CRO if the choice were entirely up to them

By strategically managing outsourcing relationships with service providers, drug sponsors can encourage the success of their clinical trials and potentially form lasting partnerships. Explore the reports below to learn more about the importance of developing an outsourcing plan, anticipated future trends in outsourced clinical development, and benchmarking CRO performance to be as informed as possible when selecting a service provider:

Benefits and Drawbacks of Clinical Development Outsourcing Strategies

Perspectives on Clinical Development Outsourcing

JENN HOLLOWAY Director of Market Research, ISR   @ISRreports

Outsourcing plays a vital role in the clinical development programs of biopharmaceutical companies, offering increased flexibility; access to external expertise and technological advancements; and improved efficiency. Our research on clinical development outsourcing models provides valuable insight into the outsourcing strategies employed in the clinical trial space. Respondents at midsize ($100M to $999M annual R&D) and large ($1B+ annual R&D) sponsor organizations shared their perspectives on the benefits and drawbacks they experience when using the following approaches to outsourcing clinical development activities:

Internal + Functional Service Provider (FSP)
A sponsor executes some clinical development activities for a study internally but outsources all or most of one or multiple functions (e.g., data management, biostatistics, pharmacovigilance, etc.).

Fully Outsourced to One Provider
A sponsor outsources all services for a study to a single CRO. The CRO may or may not subcontract to other providers.

**Fully Outsourced to
Multiple Providers (best-of-breed/FSP)**
A sponsor fully outsources the execution of a study but contracts directly with various "best-of-breed" providers to mix and match services for a custom approach to completing a clinical development project.

In-sourcing
A sponsor brings in contractors/personnel from a staffing agency or other service provider to augment internal staff. These resources are managed by the sponsor.

BENEFITS OF CLINICAL DEVELOPMENT OUTSOURCING STRATEGIES

The most commonly cited benefits across outsourcing strategies, on average, are *Increased resource flexibility, Access to specific skills/expertise not present within the organization*, and *More efficient clinical development activities*. A directionally larger proportion of users cited *Increased resource flexibility* as a benefit of the "Internal + FSP" model, suggesting that leveraging internal resources with supplemental support from functional service providers (FSPs) offers the most bespoke approach to managing clinical development activities.

The "Fully Outsourced to Multiple Providers" model is perceived to enable *Access to specific skills/expertise not present within the organization* by over three-quarters of survey participants who use the strategy. Furthermore, this strategy was praised for providing *Access to technology* not available within the organization.

The "Fully Outsourced to One Provider" model stood out for its positive impact on *Service provider relationships/deeper partnerships* and *Vendor consolidation*. More than half of users also acknowledged the "In-sourcing" approach for enabling *Faster decision-making*. In addition to the benefits highlighted here, our research includes data on the outsourcing strategies that respondents think offer *Lower costs* and boast *Lower employee turnover*.
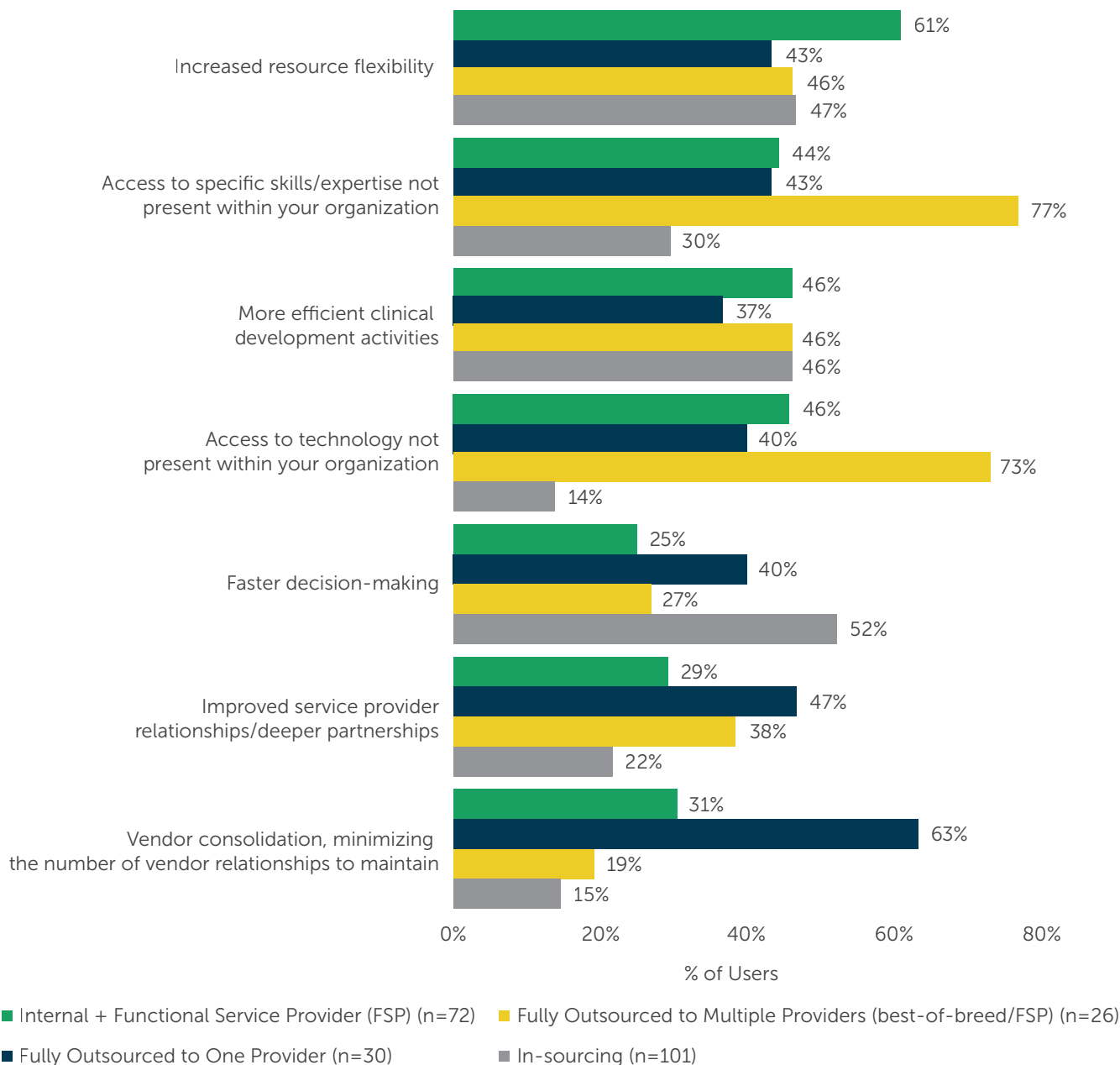
Fig. 1 – *Top Benefits of Clinical Development Outsourcing Strategies*

DRAWBACKS OF CLINICAL DEVELOPMENT OUTSOURCING STRATEGIES

The data highlight several trends in the perceived drawbacks of different outsourcing models for clinical development. *High costs, High training/onboarding requirements*, and *Lack of integration* were most frequently mentioned as key challenges across the examined strategies, on average.

Over half of users faced a *Lack of ultimate control* and *High costs* when employing the "Fully Outsourced to One Provider" model. Users of the "Fully Outsourced to Multiple Providers" approach were more likely to face challenges with *High training/onboarding time* and *Lack of integration with other employees*, suggesting that managing multiple providers in this model can necessitate increased oversight from sponsors to ensure synergy across teams.
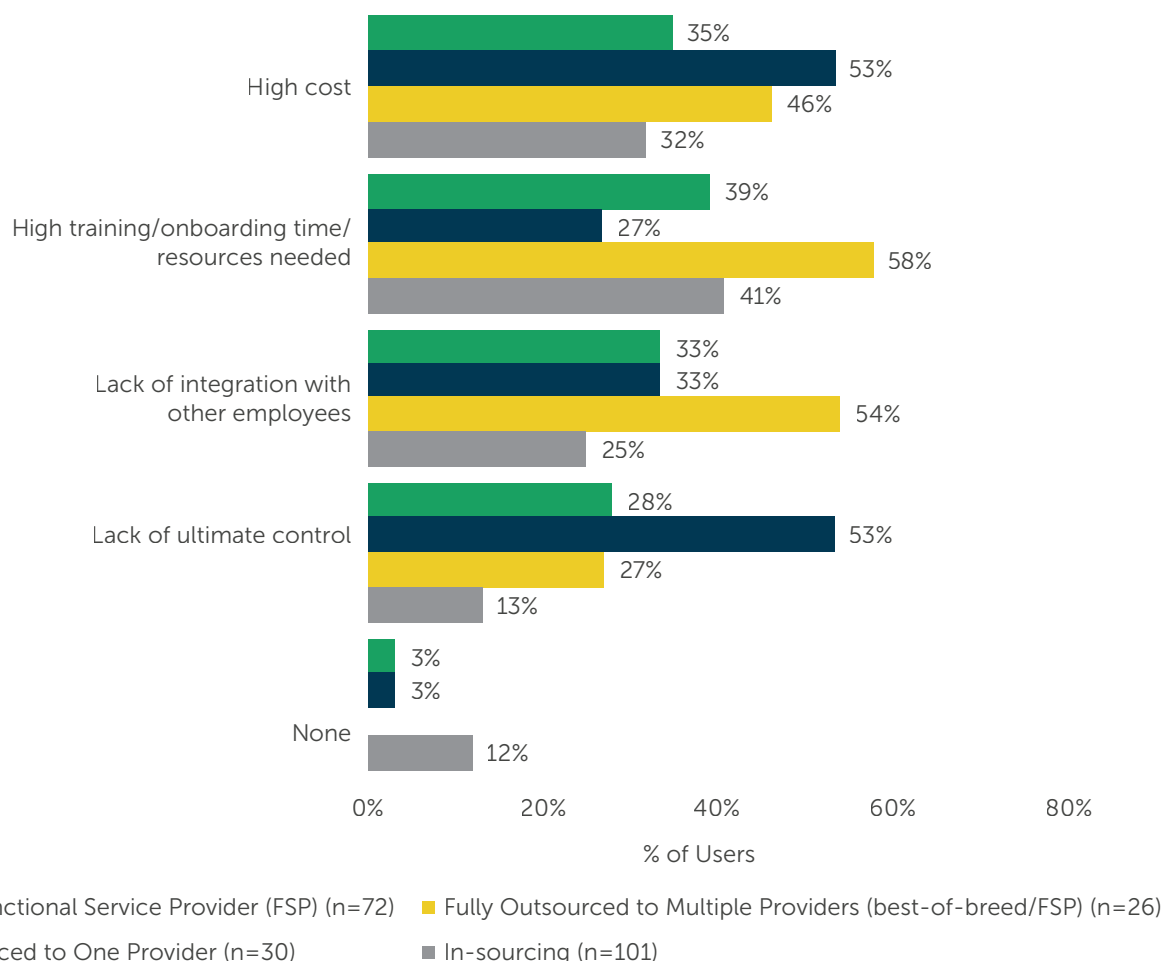
Fig. 2 – Top Drawbacks of Clinical Development Outsourcing Strategies

Roughly one-in-ten respondents reported no drawbacks to the "In-sourcing" strategy of leveraging contractors/personnel from a staffing agency or other service provider. Additional information about which models respondents think lead to *Poor work quality* are available in our full *Clinical Development Outsourcing Models* report.

BENCHMARK YOUR OWN OUTSOURCING PRACTICES

Our *Clinical Development Outsourcing Models* report offers novel insight into some of the outsourcing models commonly employed in the clinical trial space. Each model presents a unique approach to outsourcing, allowing sponsors to tailor their clinical development projects according to specific needs. By exploring respondents' perspectives, the report provides a nuanced understanding of how outsourcing models are perceived within the industry. This information can aid sponsors in identi-

fying potential gaps or areas for improvement when adopting different outsourcing strategies. Sponsors can benchmark their own outsourcing practices against industry peers, explore the advantages and disadvantages of each model, and gain insights into respondent perceptions of the best and worst outsourcing strategies for different clinical trial scenarios. They can also understand how other outsourcers employ service providers, including the use of strategic partners and preferred providers.

Additionally, service providers can gain valuable insight into sponsors' outsourcing decisions, understand sponsor satisfaction with different outsourcing models, identify the top drivers for changing outsourcing strategies, and align their services with predicted trends in the clinical outsourcing space. This information can help service providers better understand the needs and preferences of sponsors and tailor their offerings to meet those needs effectively. **I S R**

2023 CRO
BENCHMARKING DATA

Legend:
- STRONGLY AGREE
- MODERATELY AGREE
- SLIGHTLY AGREE
- SLIGHTLY DISAGREE
- MODERATELY DISAGREE
- STRONGLY DISAGREE

(2023) Rare disease / orphan drugs will comprise much more of my company's development activities over the next two years (n=299)

| Strongly Agree	Moderately Agree	Slightly Agree	Slightly Disagree	Moderately Disagree	Strongly Disagree
20%	19%	24%	16%	9%	11%
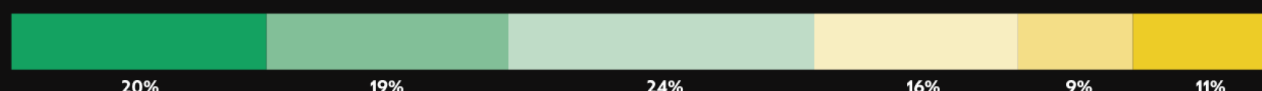
(2022) Rare disease / orphan drugs will comprise much more of my company's development activities over the next two years (n=260)

21%	20%	22%	14%	12%	12%

(2021) Rare disease / orphan drugs will comprise much more of my company's development activities over the next two years (n=272)

17%	20%	26%	15%	11%	11%
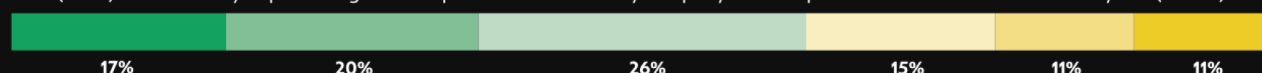
(2020) Rare disease / orphan drugs will comprise much more of my company's development activities over the next two years (n=329)
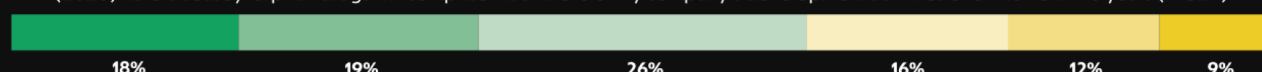
18%	19%	26%	16%	12%	9%

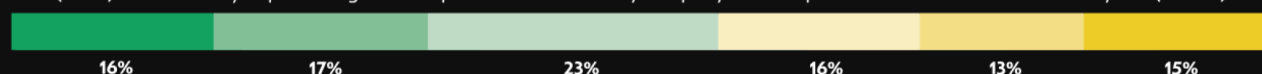**(2019) Rare disease / orphan drugs will comprise much more of my company's development activities over the next two years (n=508)**

16%	17%	23%	16%	13%	15%

(2023) Management of CROs and other service providers is taking up too much of my time (n=299)

15%	26%	31%	17%	8%	3%

(2022) Management of CROs and other service providers is taking up too much of my time (n=260)

15%	22%	33%	22%	6%	3%

STRONGLY AGREE **MODERATELY AGREE** **SLIGHTLY AGREE**

SLIGHTLY DISAGREE **MODERATELY DISAGREE** **STRONGLY DISAGREE**

(2023) My organization will increase the use of specialized site identification companies over the next two years (n=299)

| 10% | 17% | 42% | 15% | 9% | 7% |

(2022) My organization will increase the use of specialized site identification companies over the next two years (n=260)

| 8% | 20% | 38% | 22% | 8% | 3% |

(2021) My organization will increase the use of specialized site identification companies over the next two years (n=272)

| 6% | 21% | 36% | 18% | 13% | 7% |

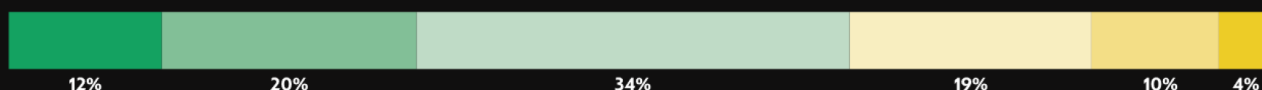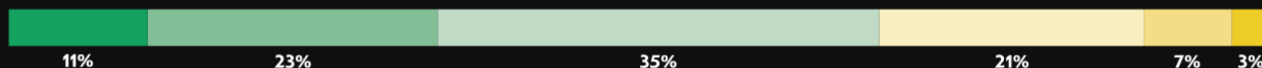### (2020) My organization will increase the use of specialized site identification companies over the next two years (n=329)

| 10% | 23% | 35% | 22% | 7% | 3% |

(2023) My organization will spread its outsourced work over more CROs over the next two years (n=299)

| 12% | 20% | 34% | 19% | 10% | 4% |

(2022) My organization will spread its outsourced work over more CROs over the next two years (n=260)

| 11% | 23% | 35% | 21% | 7% | 3% |

(2021) My organization will spread its outsourced work over more CROs over the next two years (n=272)

| 11% | 19% | 35% | 21% | 10% | 3% |

(2020) My organization will spread its outsourced work over more CROs over the next two years (n=329)

| 9% | 23% | 36% | 21% | 7% | 3% |

(2019) My organization will spread its outsourced work over more CROs over the next two years (n=508)

| 4% | 17% | 35% | 25% | 12% | 6% |

STRONGLY AGREE | **MODERATELY AGREE** | **SLIGHTLY AGREE**
SLIGHTLY DISAGREE | **MODERATELY DISAGREE** | **STRONGLY DISAGREE**

(2023) My organization will run a clinical trial within the next two years where the majority of activities occur in the participant's home (n=299)

| 8% | 12% | 31% | 18% | 17% | 14% |

(2022) My organization will run a clinical trial within the next two years where the majority of activities occur in the participant's home (n=260)

| 10% | 11% | 29% | 18% | 18% | 13% |

(2021) My organization will run a clinical trial within the next two years where the majority of activities occur in the participant's home (n=272)

| 9% | 13% | 26% | 23% | 16% | 14% |

(2020) My organization will run a clinical trial within the next two years where the majority of activities occur in the participant's home (n=329)
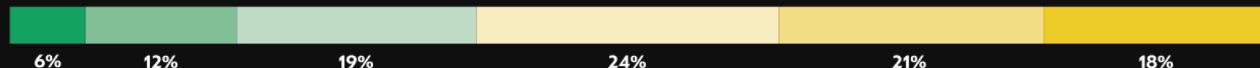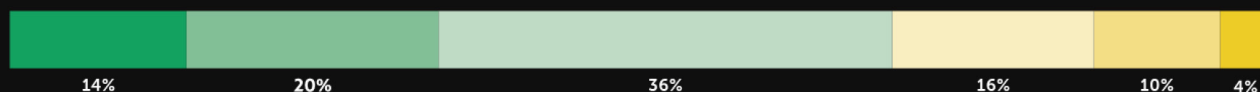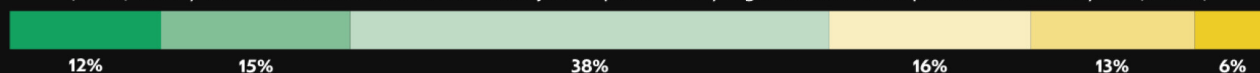
| 6% | 12% | 19% | 24% | 21% | 18% |

(2023) Decentralized clinical trials will be a major component of my organization's clinical portfolio within two years (n=299)

| 14% | 20% | 36% | 16% | 10% | 4% |

(2022) Virtual/ decentralized clinical trials will be a major component of my organization's clinical portfolio within two years (n=260)

| 12% | 15% | 38% | 16% | 13% | 6% |

(2021) Virtual/ decentralized clinical trials will be a major component of my organization's clinical portfolio within two years (n=272)

| 7% | 18% | 33% | 19% | 14% | 8% |

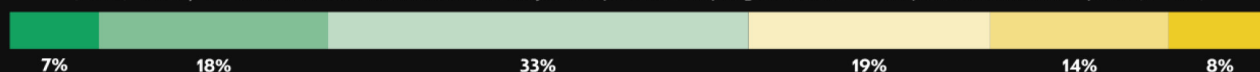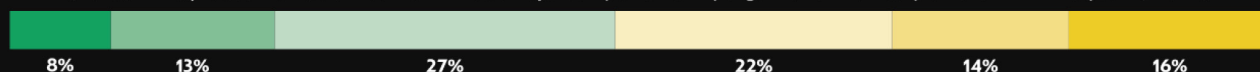(2020) Virtual/ decentralized clinical trials will be a major component of my organization's clinical portfolio within two years (n=329)

| 8% | 13% | 27% | 22% | 14% | 16% |

STRONGLY AGREE

MODERATELY AGREE

SLIGHTLY AGREE

SLIGHTLY DISAGREE

MODERATELY DISAGREE

STRONGLY DISAGREE

(2023) Clinical trial designs at my company are focusing on enrolling a demographically diverse population (n=299)

| 25% | 25% | 32% | 9% | 6% | 2% |

(2022) Clinical trial designs at my company are focusing on enrolling a demographically diverse population (n=260)

| 27% | 24% | 30% | 12% | 5% | 2% |

(2021) Clinical trial designs at my company are focusing on enrolling a demographically diverse population (n=272)

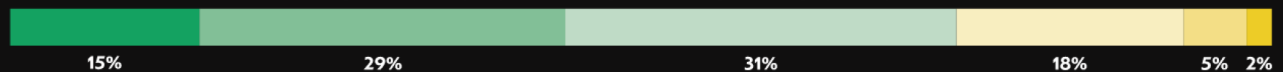| 15% | 29% | 31% | 18% | 5% | 2% |

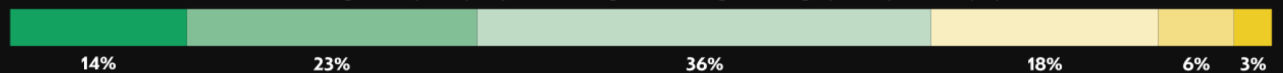(2020) Clinical trial designs at my company are focusing on enrolling a demographically diverse population (n=329)

| 14% | 23% | 36% | 18% | 6% | 3% |

Navigating The Complexities
Of CRO Selection

REBECCA MCAVOY Chief Research Officer, ISR   @ISRreports

The world of clinical trials continues to grow ever more complex. Across many recent ISR studies, data point to an increasing number of moving parts to manage in a clinical trial. Naming just a few of the trends we've noticed in recent years — increased focus on diversity, greater use of decentralized trials, increased use of specialized providers, growing interest in rare disease trials — provides a peek behind the curtain at the evolving nature of clinical trials.

Figure 1 illustrates some of these trends. We surveyed 299 outsourcers of Phase I and/or Phase II/III clinical development activities in Q4 of 2022. More than 80% of respondents in these studies believe their organization's use of remote monitoring will increase in the next two years and believe their company is focusing on designing demographically diverse trials. Almost two-thirds of respondents or more agree that decentralized trials will be a major component of their clini-

cal portfolio, that rare disease/orphan drugs will comprise more of their company's development activity, and that use of wearable sensors/ connected health devices will increase.

These trial practices will hopefully lead to more efficient trials, increased ability to reach patients, improved trial experiences, and the production of therapies for patients with few treatment options. However, incorporating these practices comes with the cost of designing and managing more complicated trials. As sponsors work to evolve their trial processes, knowledgeable CRO partners with well-functioning teams will become even more valuable. Over 70% of respondents agree with the statement, "Management of CROs and other service providers is taking up too much of my time," perhaps highlighting an opportunity for CROs to find ways to reduce the vendor management burden on sponsors.
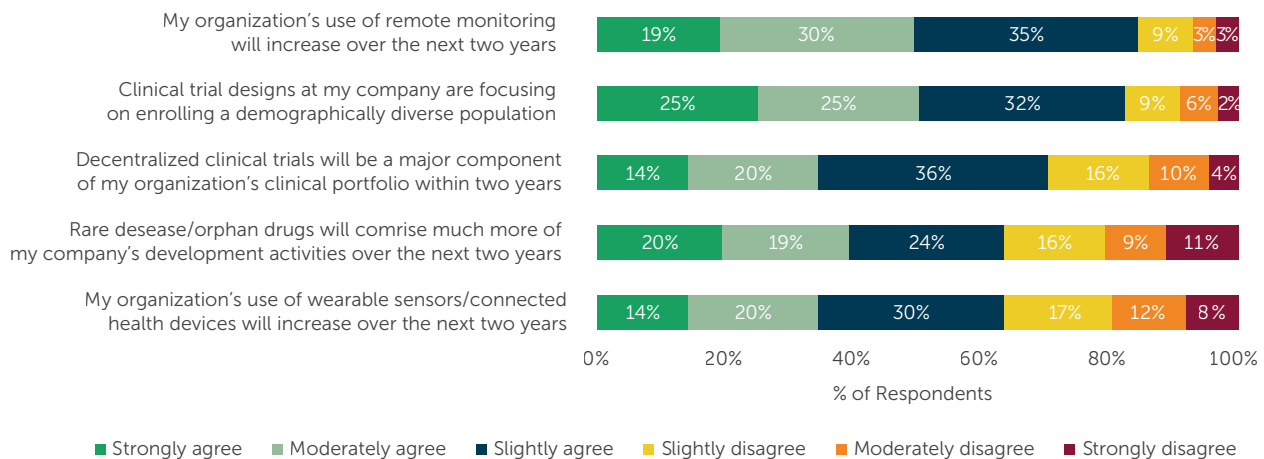

■ Strongly agree   ■ Moderately agree   ■ Slightly agree   ■ Slightly disagree   ■ Moderately disagree   ■ Strongly disagree

Fig. 1 — "Please indicate your level of agreement with each of the following statements:" (n=299)

Growing trial complexity means that selecting the right service providers takes on even greater importance. However, with a wide range of providers vying for clinical trial work, it can be challenging for a sponsor organization to find the right fit. Sometimes a provider with which a sponsor already has experience will fit the bill but, in other circumstances, previously used CROs might not have the capabilities required or perhaps didn't perform up to snuff in past engagements. It is challenging to estimate how well a new CRO will perform without prior experience working with them. As ISR's research finds time and again, peer recommendations carry significant weight when outsourcers are learning about new providers. But what is an outsourcer to do when their peer network doesn't have experience with the provider in question?

To use an example from another industry, in the world of consumer goods, online product reviews have become critical factors in product selection. The number of stars for a product on a retail website, along with positive and negative comments from past purchasers, are an easy way for potential buyers to gain insight into how satisfied others were with their purchase, what aspects they like, and what went wrong. These days, online product reviews have become so ubiquitous it's almost hard to imagine buying a product without first checking its reviews.

Similarly, customer evaluations of CRO performance can be useful in the provider selection process. ISR collects experiential data from customers about CROs they have worked with in the past 18 months. Unlike product reviews on retail websites, however, ISR carefully screens the customers providing feedback on CROs to ensure high-quality data. ISR gathers these data to gauge how providers have performed compared to customer expectations on metrics such as data quality, therapeutic expertise, and meeting overall project timelines. Sponsor customers share thoughts on their overall satisfaction, likelihood to recommend, and likelihood to use that CRO again. They also contribute open-ended explanations of their satisfaction ratings to relay pertinent details about their experiences. These data offer a view into what it might be like to work with a particular CRO.

The data ISR collects on CRO performance can be immensely helpful in evaluating potential CRO options. However, it is a lot of information to ingest. Having a framework in mind to sift through the information can be a helpful place to start. To this end, we also ask survey respondents to share their thoughts on the criteria they consider when selecting CROs. Understanding how other outsourcing decision-makers in the industry select providers can help a sponsor organization assess its process to determine if any new angles or criteria should be considered.

This year's data show that the top selection attributes for Phase II/III providers have remained fairly steady across ISR's years of performing this research. Attributes around strength of operations, prior positive experience, provider experience with similar study types, data quality expectations, and therapeutic expertise top the list. Following these are attributes related to meeting timelines, patient recruitment strategy, offering innovative solutions, and low cost.

Not every sponsor organization necessarily values provider characteristics in the same order, but learning how other companies make their decisions provides worthwhile food for thought. As the clinical trial realm continues to grow in complexity and incorporate new practices, sponsors can utilize available data to enhance their selection process to find providers that can function as strong partners. CROs can better understand the needs of their customers and how their recent performance has been viewed so they can market their capabilities accordingly and tighten up any potential areas for improvement. Ⓘ Ⓢ Ⓡ

Phase II/III Outsourced Spend
Across Provider Types

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I ndustry Standard Research conducted a 2022 survey with outsourcers of Phase II/III clinical development activities to better understand the dynamics in this space. Learning how respondents from sponsor organizations apportion their outsourced work across different provider types was of particular interest.

Overall, half of Phase II/III outsourcing spend goes to large, full-service CROs (51%) while one-quarter of spend (26%) goes to midsize, multi-service CROs. Small or niche service CROs and academic medical centers (AMCs) receive the remaining 14% and 9% of spend, respectively. Some interesting differences in outsourced Phase II/III spend emerge when the data are analyzed by size of the sponsor organization. The proportion of spend allocated to large, full-service CROs increases as sponsor size increases. Respondents from large sponsors report allocating three out of five Phase II/III outsourced dollars to big providers while those at small sponsors allocate only one-third of their outsourced spend to large CROs. Respondents indicate that use of midsize, multi-service providers is slightly higher among midsize (33%) and small sponsor organizations (32%) than it is among large sponsors (19%). Small sponsors allocate more Phase II/III spend to small CROs than midsize or large sponsors (27% vs. 10%-11%), but sponsors of all sizes equally engage AMCs for their outsourcing needs. Respondents expect the proportion of outsourcing spend allocated to each provider type to remain relatively steady over the coming years.
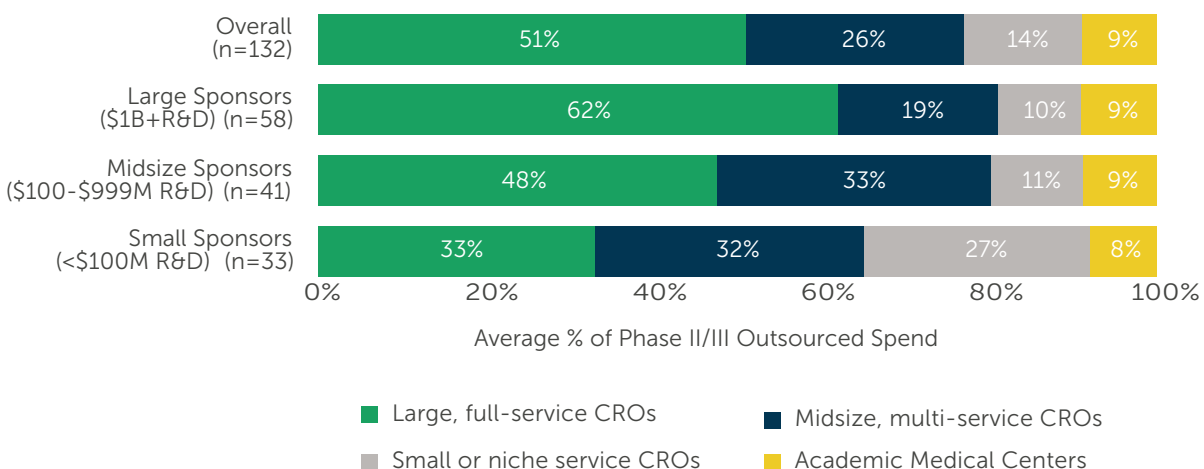

Fig. 1 – "Please estimate the percent of your company's Phase II/III outsourcing spend with each of the following types of service providers. Your best estimate is fine. Columns must total 100%."

PHASE II/III OUTSOURCED SPEND | By R. McAvoy

Prior ISR research indicates that large CROs are leveraged for their *Global footprint, Breadth of service*, and *Capacity/resource availability*. Midsize providers stand out for *Quality, Project management*, and *Flexibility*. Small or niche service CROs are considered to have the benefit of *Flexibility* as well as *Specialized focus*, *Local knowledge*, and *Low cost*. AMCs are also noted for having the benefit of a *Specialized focus* while *KOL access*, *Strong investigator relationships*, and *Specialized facilities/equipment* arise as differentiators for AMCs.

A sponsor's needs and preferences can certainly vary from trial to trial. A global CRO that can handle a full-service Phase II/III project may be perfect for one trial while a smaller, more specialized CRO might be a better choice for a different trial. Understanding the industry's perceptions of the benefits of each provider type can be useful to a sponsor team when selecting their next CRO and can be similarly helpful to CRO teams when bidding for services either within or outside of their perceived wheelhouse. **ISR**

Six Questions to Ask About Your Market Research

How do you guarantee the research you buy will give you confidence in your decisions? Here's how we ensure you're getting the value you should expect from quality market research.

How Many Participants Take the Study?

Understanding your margin of error gives you accurate expectations, making you more likely to hit your performance metrics. We provide a vast sample of participants from our proprietary Health Panel to make sure our studies reach the correct number of participants needed for accurate analysis.

Where Did the Participants Come From?

Eliminating sample bias translates into accurate competitive information and improves service quality by ensuring your decisions are the right ones. Our Health Panel provides an array of participants from all company sizes within the pharmaceutical industry.

When Were the Data Collected?

This should be the first question you receive during a presentation and saying "I don't know" doesn't sound so good. In all our research products, we collect up-to-date data relevant to the project at hand.

Who Sponsored the Research?

We're an independent, third-party data source. We provide clean, unbiased data and clean data means you can confidently stand behind your analysis and presentations.

What is the Responsibility Profile for the Participants?

Nothing stops a presentation faster than management questioning the basis of your research. Confidently project the research knowing that we pull information from key decision makers.

What is the Background of the Analyst Who Managed the Project and Reporting?

We have experienced analysts with hands-on industry knowledge. Their insights can quickly be turned into fit-for-purpose recommendations for your organization.