Becoming a Sponsor or CRO of Choice

The Site Perspective

Site Perspectives on Sponsor and CRO Attributes Supporting Quality in Design and Execution of Clinical Trials

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Executive Summary

The Avoca Group and the Association of Clinical Research Professionals (ACRP) collaborated on web-based survey research early in 2018 to evaluate the key attributes that drive quality in clinical trials from the site perspective.

Nearly 300 site staff responded to the survey, providing perspectives on Sponsors and CROs in near equal proportion. Respondents evaluated up to three companies they had worked with in the past year and shared perspectives on what actions Sponsors and CROs can take to improve quality in working with investigative sites.

In aggregate, Sponsors received more favorable ratings from sites, though the most appealing qualities sites look for when working with a clinical trial partner remained the same for both Sponsors and CROs: effective communication, thoughtful protocol design, and a sense of partnership. These sentiments were reinforced by quantitative data where communication style, communication during the study, and protocol ease of execution held the strongest correlations to likelihood to recommend a Sponsor or CRO.

A clear call to action arose from the research for Sponsors and CROs to focus on protocol quality and site feasibility, ensure staff are trained and knowledgeable regarding the protocol, provide clear and timely communication, and support sites throughout the lifecycle of the study – including during inspection preparation.

As a result of the survey, ACRP and The Avoca Group issued the following awards during the ACRP 2018 annual conference:

ACRP-Avoca CRO Quality Award	ACRP-Avoca Sponsor Quality Award
First Place: Medpace	**First Place:** Abbott Laboratories
Second Place: PAREXEL	**Second Place (Tie):** Eli Lilly and Sanofi
Third Place: Chiltern, A Covance company	**Third Place:** Merck & Co

Background & Methodology

The Avoca Group and ACRP collaborated on site-focused research evaluating attributes that drive quality in clinical trials.

An online survey was conducted between January and March 2018 among clinical research site staff, representing a range of site roles

A total of **151** respondents evaluated Sponsor organizations and **130** respondents evaluated Providers

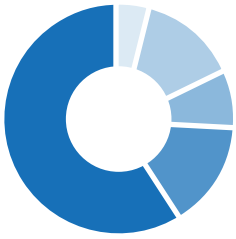
Respondents were able to evaluate up to three companies with whom they have participated in a clinical trial over the past twelve-month period*

*Where appropriate to do so, ratings of companies have been aggregated across respondents to get to a "total" level view of performance for the purposes of comparison

Characteristics of Respondents

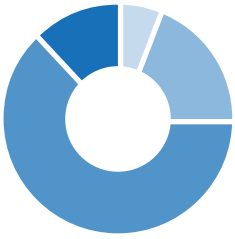
Sponsors

Number of Trials in Past 12 Months



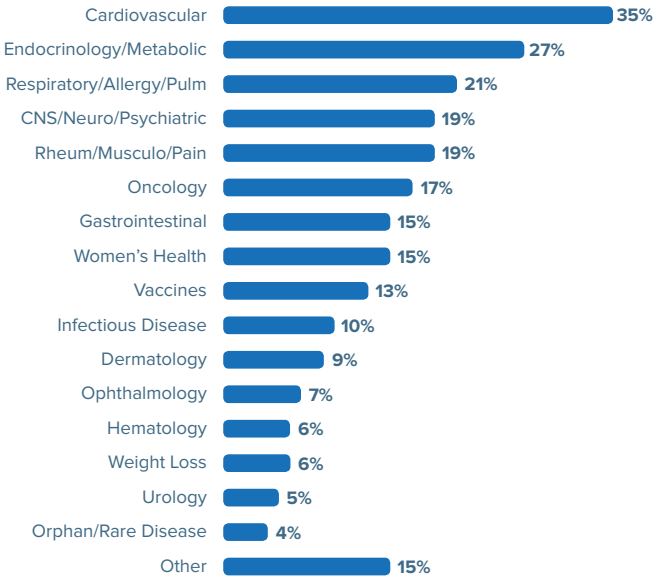
- 2 to 3: **4%**
- 8 to 9: **15%**
- 4 to 5: **14%**
- 10 or more: **59%**
- 6 to 7: **8%**

Role



- PI/Sub PI: **6%**
- Site Director or Administrator: **19%**
- Clinical Research Coordinator: **63%**
- Other: **12%**

Therapeutic Area

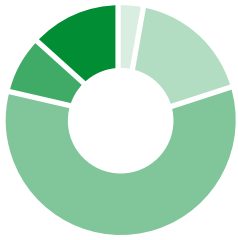


CROs

Number of Trials in Past 12 Months

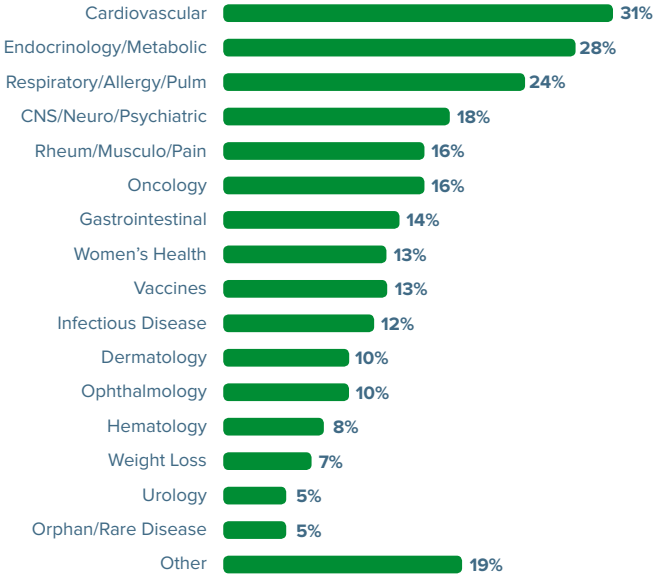
- 2 to 3: **7%**
- 8 to 9: **7%**
- 4 to 5: **11%**
- 10 or more: **61%**
- 6 to 7: **15%**

Role



- PI/Sub PI: **3%**
- Site Director or Administrator: **17%**
- Clinical Research Coordinator: **58%**
- Regulatory Coordinator: **8%**
- Other: **13%**

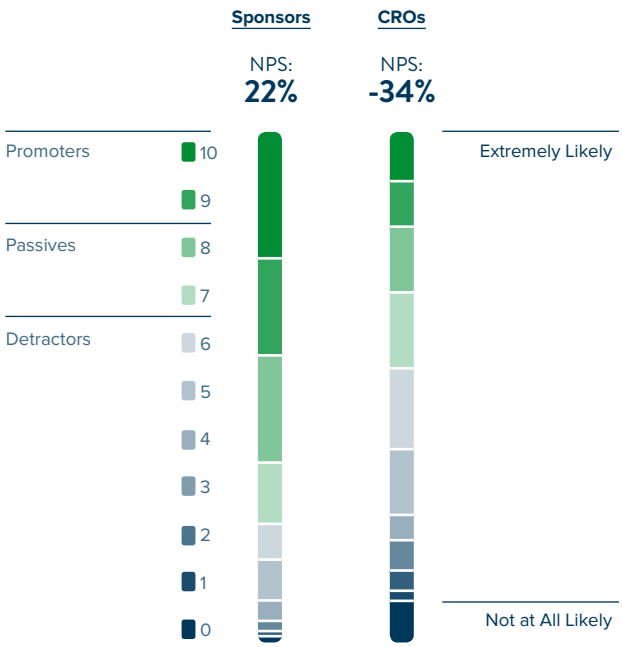
Therapeutic Area



Key Findings

Site personnel rated Sponsors more favorably than CROs overall; in aggregate, providing a higher Net Promoter Score for Sponsors.

Likelihood to Recommend/NPS



Sites expressed satisfaction across all attributes of study design assessed; on a relative basis, consideration of the patient perspective and ease of execution of the trial ranked lowest.

Satisfaction with Study/Protocol Design

Mean Rating: 1=Very Dissatisfied and 5=Very Satisfied

Ratings of Sponsors

Medical and scientific merit of the protocol design	4.4
Clarity of eligibility criteria	4.3
Clarity of direction/schedule of events of study visits and procedures to be performed	4.2
Consideration of the patient perspective	4.1
Overall ease of execution of the trial	4.1

Notably, ease of execution showed the strongest correlation to NPS despite relatively weaker satisfaction expressed by site staff.

Correlation Between Study/ Protocol Design Attributes and NPS

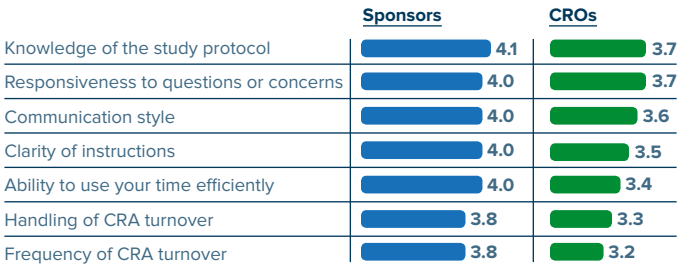
Correlation Coefficient*

Sponsor Correlations	
Overall ease of execution of the trial	0.69
Clarity of direction with respect to the schedule of events of study visits and procedures to be performed	0.65
Consideration of the patient perspective	0.62
Clarity of eligibility criteria	0.61
Medical and scientific merit of the protocol design	0.51

Site perceptions of satisfaction with attributes of the study personnel they interact with were aligned across Sponsors and CROs, though with CROs receiving somewhat lower ratings.

Satisfaction with Study Personnel

Mean Rating: 1=Very Dissatisfied and 5=Very Satisfied



Aspects of how Sponsors and CROs communicate with site staff showed the strongest correlations to NPS.

Correlation Between Study Personnel Attributes and NPS

Correlation Coefficient*

	Sponsor	CRO
Communication style	0.72	0.79
Ability to use your time efficiently	0.72	0.81
Clarity of instructions	0.72	0.77
Responsiveness to questions or concerns	0.70	0.78
Knowledge of the study protocol	0.68	0.74
Handling of CRA turnover	0.67	0.72
Frequency of CRA turnover	0.60	0.68

Correlation coefficients can range between -1 and 1; the closer the number is to 1, the stronger the relationship between variables.

Sites expressed satisfaction across all study execution attributes with Sponsors; slightly less so with CROs.

Satisfaction with Study Execution

Mean Rating: 1=Very Dissatisfied and 5=Very Satisfied

	Sponsors	CROs
Reliability of drug/other clinical supplies	4.4	4.0
Study close-out activities	4.2	3.7
Site initiation/training	4.1	3.7
Support for patient recruitment & retention	4.1	3.6
Inspection preparation support	4.1	3.5
Setting of realistic patient recruitment goals	4.1	3.5
Start-up processes	4.1	3.5
Ease of use of EDC system	4.1	3.7
Design of CRF	4.1	3.7
Communication during the study	4.1	3.6
Timeliness/clarity of queries	4.0	3.4

Study close-out, inspection preparation support, and communication showed strong correlations with NPS.

Correlation Between Study Execution Attributes and NPS

Correlation Coefficient*

	Sponsor	CRO
Study close-out activities	0.76	0.73
Communication during the study	0.75	0.83
Inspection preparation support	0.75	0.74
Start-up processes	0.72	0.68
Timeliness/clarity of queries	0.68	0.71
Site initiation/training	0.67	0.57
Setting of realistic patient recruitment goals	0.64	0.61
Reliability of drug and/or other clinical supplies	0.64	0.53
Design of CRF	0.61	0.60
Support for patient recruitment and retention	0.60	0.62
Ease of use of Electronic data capture (EDC) system	0.55	0.56

Trial volume did not appear to have impact on the perceptions of satisfaction from site staff.

Attribute Ratings by Number of Trials

Mean Rating: 1=Very Dissatisfied and 5=Very Satisfied

	Sponsor		CRO	
	>10	<10	>10	<10
Study/Protocol Design Attributes	4.3	4.2	n/a	n/a
Study Personnel Attributes	4.1	3.9	3.6	3.4
Study Execution Attributes	4.3	4.0	3.6	3.6

Correlation coefficients can range between -1 and 1; the closer the number is to 1, the stronger the relationship between variables.

Sites are looking for the same things in the Sponsors and CROs that they interact with – effective communication, sound and thoughtful protocol design, and quality partners.

Prompt communication, knowledge of protocol and being organized/prepared are the key qualities that sites desire. At the center of this is having a CRA who has the know-how and soft skills to deliver on these needs.

Appealing Qualities of Clinical Trial Partners

Communication

"The biggest quality, other than compensation, is organization. **If the sponsor is organized in their levels of command, communication, partners, and study materials/design, everything is fixable and workable** even if not perfect."

"Availability for questions, guidance from someone who knows the protocol and the Sponsor's nuances, their ability to help with the everyday patient challenges we see at the site level."

"CRAs who understand the protocol and are able to respond to queries quickly and with clear instructions."

"Having supportive CRAs that come to the site to work with you and not against you and the trial. Their helpfulness makes site want to recruit more for their trial because they support you and answer all your questions. CRAs can make the trial for the Sponsor as well as the site with total cooperation."

"Clear, concise, courteous responses to questions."

"A good monitor or contact person with the Sponsor that is **knowledgeable of the therapeutic area involved and the study protocol."**

Protocol design was another key mention and includes setting realistic guidelines and expectations, and keeping the patient and site perspective in mind.

Protocol Design

"Executable protocols with reasonable inclusion/exclusion criteria."

"A group that has the Subject/Patient and Research Staff in mind. The CRO representative should know the protocol, advocate for the Clinical Site, and intervene with the Sponsor as needed."

"Realistic goals, and knowing the medical field, not just rules and regulations. We're doing research for our patients, not to meet their deadlines for metrics."

"Many sponsors begin aggressive study start-up tactics with sites before the protocol/study design has been adequately vetted; this behavior of "putting the cart before the horse" usually results in a multitude of amendments and is an unnecessary waste of time. **Appealing Sponsors are adequately prepared before they start recruiting sites, with great consideration for the realistic operational feasibility of the protocol** (i.e., what looks good on paper may not be feasible in real-life scenarios)."

"CROs that are there when you need them and out of your hair when you don't. Some of them set unrealistic goals on patient recruitment and will bug you weekly about it."

"Sponsors should know their protocols and run mock patients prior to opening any site. Sponsors should have an outside set of eyes review the amendments prior to IRB approval to cut down on multiple amendments."

Of note, those evaluating Sponsor companies also made mention of the quality of Providers selected by Sponsors; some said they prefer to work with Sponsors directly.

Quality Partners

"We have found, almost universally, that **Sponsors who employ their own research personnel instead of utilizing a CRO are much easier to work with.** Not only do all of the staff have better working knowledge, but they are also in much closer contact with the people who designed the studies. Additionally, CRAs from Sponsors who employ their own research staff seem to have much lower turnover rate, are more available, and overall seem much happier."

"Choosing a good CRO or no CRO at all."

"Having a monitor that works for the Sponsor rather than for a CRO has been immensely helpful in my experience, although that rarely (if ever) happens anymore."

"They hire a CRO that is organized, efficient, communicates well, and has the ability to make basic decisions."

"I prefer to work with a Sponsor that does not use a CRO. I find that Sponsors who are in charge of their own monitoring activities and do not contract out many of their services, tend to have a better handle on the studies. Responses to questions come quicker, less turnover in staff, and better trust in the system for the sites. Also, finding a sponsor that shares in the same mission as your site, makes partnerships easier."

Conclusions

To become a Sponsor or CRO of choice among sites:

1. Focus on protocol quality and design studies with site feasibility in mind; specifically focusing on entry criteria and schedule of visits and procedures

2. Ensure that staff are adequately trained and knowledgeable regarding the protocol and indication under study

3. Commit to provide sites with clear, concise, and timely communication and be available and responsive to questions and/or concerns

4. Support the site throughout the lifecycle of the study, including study close-out and inspection preparation

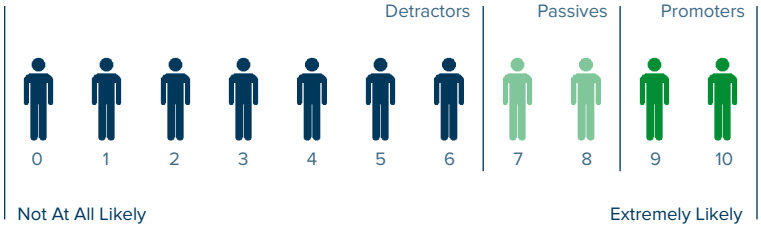
Appendix

Net Promoter Score Background

- The Net Promoter Score was introduced in 2004 in a Harvard Business Review article by Fred Reichheld
- Reichheld and team tested a number of different measures to determine which would be most predictive of business growth
- Likelihood to recommend a brand/company/product/service was found to be the measure that was most highly correlated to in-market behavior
    - *"High scores on this question correlated strongly with repurchases, referrals, and other actions that contribute to a company's growth. In 11 of the 14 industry case studies that the team compiled, no other question was as powerful in predicting behavior."*

Net Promoter Score Measurement & Calculation

Test Question Based on your experience working with the following organizations, how likely is it that you would recommend each to a clinical research colleague?



Net Promoter Score = **% Promoters** - **% Detractors**