

**2011 Avoca Clinical Outsourcing
and Relationship Management Survey:
Sponsor Needs and Challenges in Clinical
Development Outsourcing**

Executive Summary

April 2011

Introduction

- ▶ Each year, The Avoca Group surveys industry executives and managers to understand trends in the outsourcing of clinical research by pharmaceutical companies and other sponsors.
- ▶ In 2011, The Avoca Group was particularly interested in performing a detailed analysis of how outsourcing strategies, practices, challenges, and outcomes differed by size of sponsor and size of provider.
- ▶ This executive summary is presented to the participants, who graciously gave their time to provide their insights and input into these data. The executive summary contains highlights of some of the data collected.

Introduction

- ▶ In particular, the survey explored the views and experiences of sponsors and providers of a wide range of sizes, regarding:
 - ◆ Provider selection
 - ◆ Provider performance (overall and by task) by both size of provider and size of sponsor
 - ◆ Sponsor strengths and weaknesses in provider engagement and management, by size of sponsor
 - ◆ Current and future (planned) approaches to the outsourcing of clinical studies
 - ◆ Cost-effectiveness of different outsourcing models
 - ◆ Costs and quality of outsourced trials vs. those performed in-house
 - ◆ Specific CROs that perform particularly well for sponsors of different sizes
 - ◆ Strategies for marketing to sponsors of different sizes
- ▶ This summary presents selected highlights of the results for a subset of these topics.

Methods

- ▶ Invitations to participate were emailed to executives and managers of sponsor and service provider companies, and were also available via selected industry websites.
- ▶ Links directed respondents to the appropriate web-based survey instruments:
 - ◆ Sponsor perspective
 - ◆ Provider perspective
- ▶ Respondents who completed the survey were offered a summary of the survey results.

Respondents

▶ 193 surveys

◆ 109 Sponsor Respondents

- 36% Large pharmaceutical companies (>1.5 Bill)
- 33% Mid/Small Pharma (<100 Mill-1.5 Bill)
- 13% Small Revenue-Generating
- 18% Pre-revenue
- 24% Executives, 55% Middle Management, 18% Project Management

◆ 84 Provider Respondents

- 34% “Top 20”
- 23% Smaller, Full Service
- 30% Niche Providers
- 51% Executives, 34% Middle Management, 12% Project Management

Sponsors - List of Companies

Actavis	Chroma	Human Genome Sciences	Otsuka
Aeterna Zentaris	Cordis	Incyte	Pfizer
AFFiRiS	Crucell	Innate	Pharmasset
Allon Therapeutics	Cubist	Ipsen	PregLem
Amgen	Daiichi Sankyo	IQ	Prosidion
ANTEIS	Digna Biotech	Ironwood	Pulmatrix
Astellia	Eagle	Jennerex	Purdue
AstraZeneca	Edimer	Johnson & Johnson	Reckitt Benckiser
Bach Pharma	Eisai	Kuros	Sandoz
Bayer HealthCare	Eli Lilly	Kyowa	Sanofi-Aventis
Bial	Endo	LEO	Satori
Biogen Idec	FBT	Lilly	Servier
BioLineRx	Ferrer	Lundbeck	Shire
Biotest	Ferring	Lupin	Sigma-Tau
BMS	Fournier	MannKind	Spmsd
Boehringer Ingelheim	Galderma	Maxx Orthopedics	Supernus
Cadence	Genzyme	Medtronic	Teva
Calistoga	Glenmark	Merck	UCB
Cardiokine	Grünenthal	Millennium	Woundsolutions
Cardiome	GSK	Mundipharma	Xention
Celator	GTC	Nycomed	ZARS
Celtic	HAL Allergy	Omjsa	
Cephalon	Hoffmann-La Roche	Orion Pharma	

Clinical Service Providers - List of Companies

ABX	Criterion	IMPACT Core	ProTrials Research
Accovion	CRO	INC Research	Quest Diagnostics
Accutest	Cyncron	Indiana University	Quintiles
Acurian	Datatrial	Kendle	Recipharm
Air Products	DDN Medical Affairs	Laureate Biopharma	REGISTRAT-MAPI
Allphase Clinical Research	DOKUMEDS	MAC Center for Pain Management and Research	Research Consultants
Arianne	DSG	Medicon	RH Bouchard & Associates
Averion	ERT	MedTrials	Rivergate Dermatology
Beardsworth	Eurofins	NCRA	RPS
Billings Clinical Research Center	Eurotrias	NEA Baptist Clinic	San Francisco Clinical Research Center
Blue Sky Broadcast	ExecuPharm	Newbould Consulting	SAS Institute
Cambridge Biomedical	eXI	NHS	SDS Clinical Trials
Chiltern	Fisher Clinical Services	NOCCR/VRG	Sentrx
Clinical Resource Network	Formatech	North Star Medical Research	Sticares Interact
Clininvent	Frontage	Omnicare Clinical Research	Symfo
Clinlogix	Fulcrum	PAREXEL	TGA Sciences
Clinquest	GFA	Penn Pharmaceutical Services	The Copernicus Group
COMSYS	Hadasit	PharmaNet	Tigermed Consulting Co.
CoreLab	Harrison Clinical Research	Pharm-Olam International	TWG
CoreRx	Higginbotham Group	PHT Corporation	United BioSource Corporation
Covance	i3	Poudre Valley Health System	Veeda Clinical Research
CRC	ICON	PPD	Veristat
CRF Health	Imaging Endpoints	PRA	Worldwide Clinical Trials

Results

The following questions will be addressed in this Summary:

1. Is there a pattern whereby sponsor companies of different sizes (small, medium large) choose to work with providers of different sizes or types?
2. Is this association rational? Do sponsors in fact select the types of providers that will provide them the best service?
3. What does the association mean for providers?
 - 3a Are providers also more satisfied when working with sponsors of corresponding size?
 - 3b Which sponsor company types are the best clients to work with? Which are best at provider selection and engagement? Which are easiest for providers to manage, and which are best at managing providers?
4. Is outsourcing equally beneficial for all sizes of sponsor companies? Does one size fit all in terms of the benefits/costs of different outsourcing models?

Is there an association between sponsor size and provider size?

1.

Is there a pattern whereby sponsor companies of different sizes (small, medium, large) choose to work with providers of different sizes or types?

Is there an association between sponsor size and provider size?

Yes, there is an association between sponsor size and provider size.

For example...

▶ Sponsor data:

- ◆ For 67% of the “big pharma” companies surveyed, most of their outsourcing spend goes to “Top 5” CROs.
- ◆ Only 10% of the small (revenue-generating) sponsor companies surveyed spend the majority of their outsourcing budget with Top 5 CROs. 70% of small companies dedicate <10% of their outsourcing spend to Top 5 CROs.

▶ Provider data:

- ◆ For most of the “Top 5” CROs, the majority of revenue comes from big pharma. Less than 25% derives from small sponsor companies.
- ◆ For most of the small, full-service CROs surveyed, the reverse is true: less than 25% of revenue derives from big pharma, and most derives from small biotechnology and pharma companies.

2.

Is this association rational?

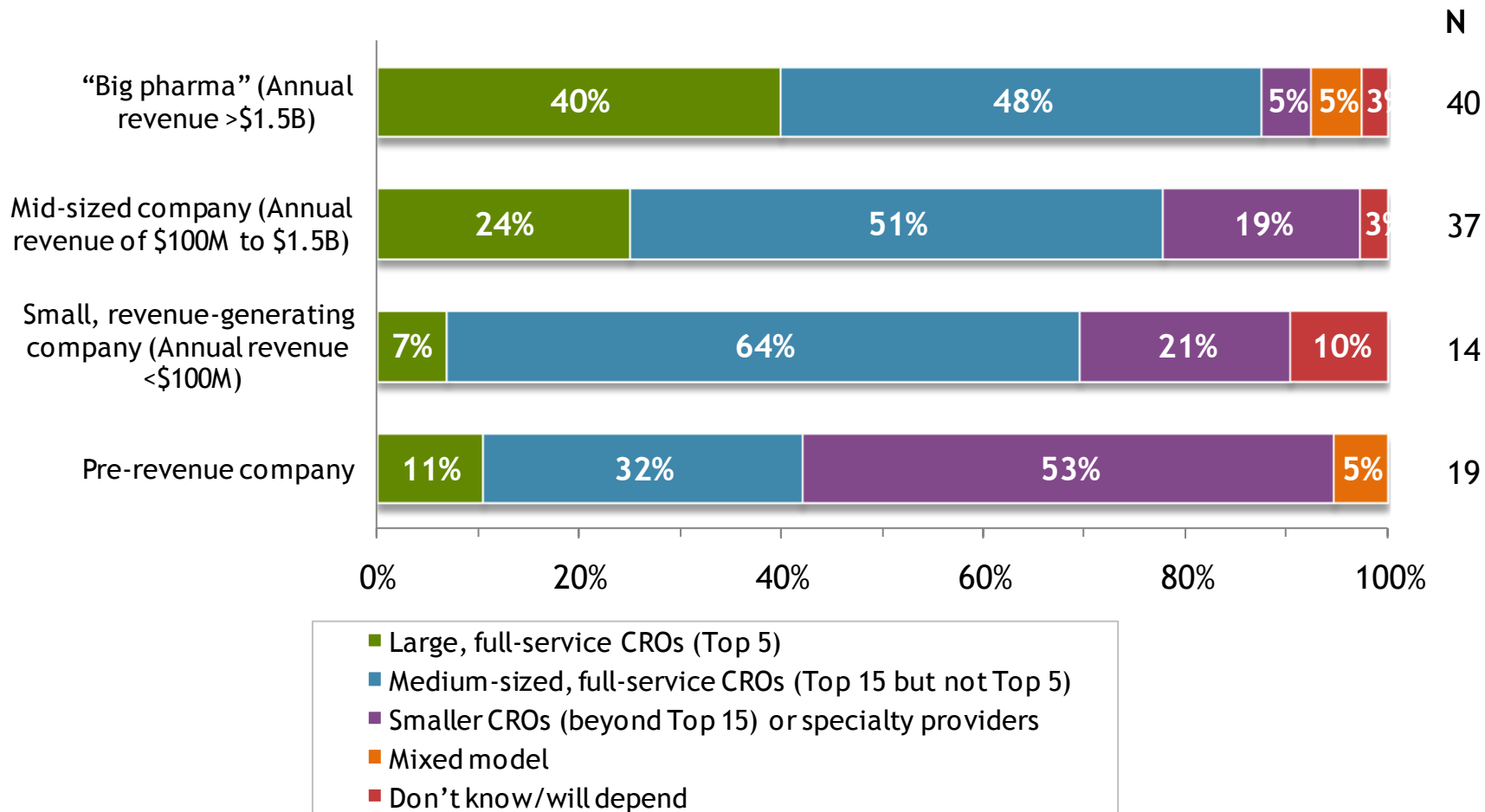
Do sponsors in fact associate with the types of providers that will provide them the best service?

Is the size association rational?

- ▶ The data in **Slide 14** illustrate that respondents from big pharma, medium-sized pharma, and small, revenue-generating pharma were all most likely to feel best served by mid-sized CROs as opposed to Top 5 CROs or smaller providers.
 - ◆ 40% of big pharma respondents felt best served by Top 5 CROs, compared to 24% of those from medium-sized pharma and 7% of those from small, revenue-generating pharma.
 - ◆ Reciprocally, 53% of pre-revenue sponsor companies felt best-served by smaller providers, compared to only 5% of those from big pharma.
- ▶ The data in **Slide 15** illustrate that most provider respondents feel that large pharmaceutical companies are best served by Top 5 CROs. Only 15% of provider respondents feel that small to mid-sized sponsor companies are best served by Top 5 CROs.
 - ◆ 41% of providers feel that small and mid-sized pharma companies are best served by mid-sized CROs, and 35% feel that this segment is best-served by small CROs.

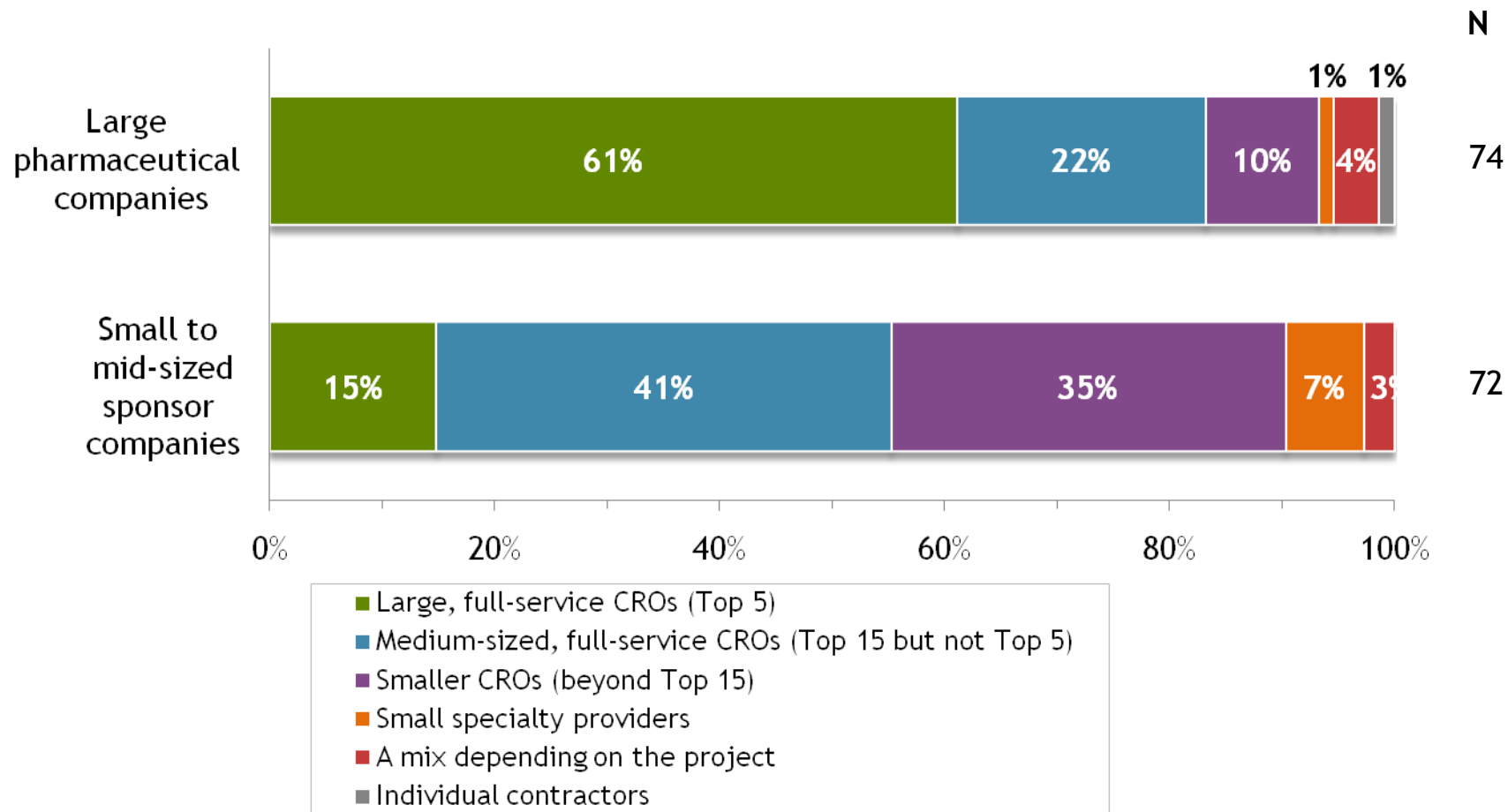
Is the association rational?

Sponsors: What size of clinical service provider do you feel provides the best service, overall, to companies with a level of outsourcing experience similar to that of your company?



Is the association rational?

Providers: What size of clinical service provider do you feel provides the best service, overall, to sponsor companies?

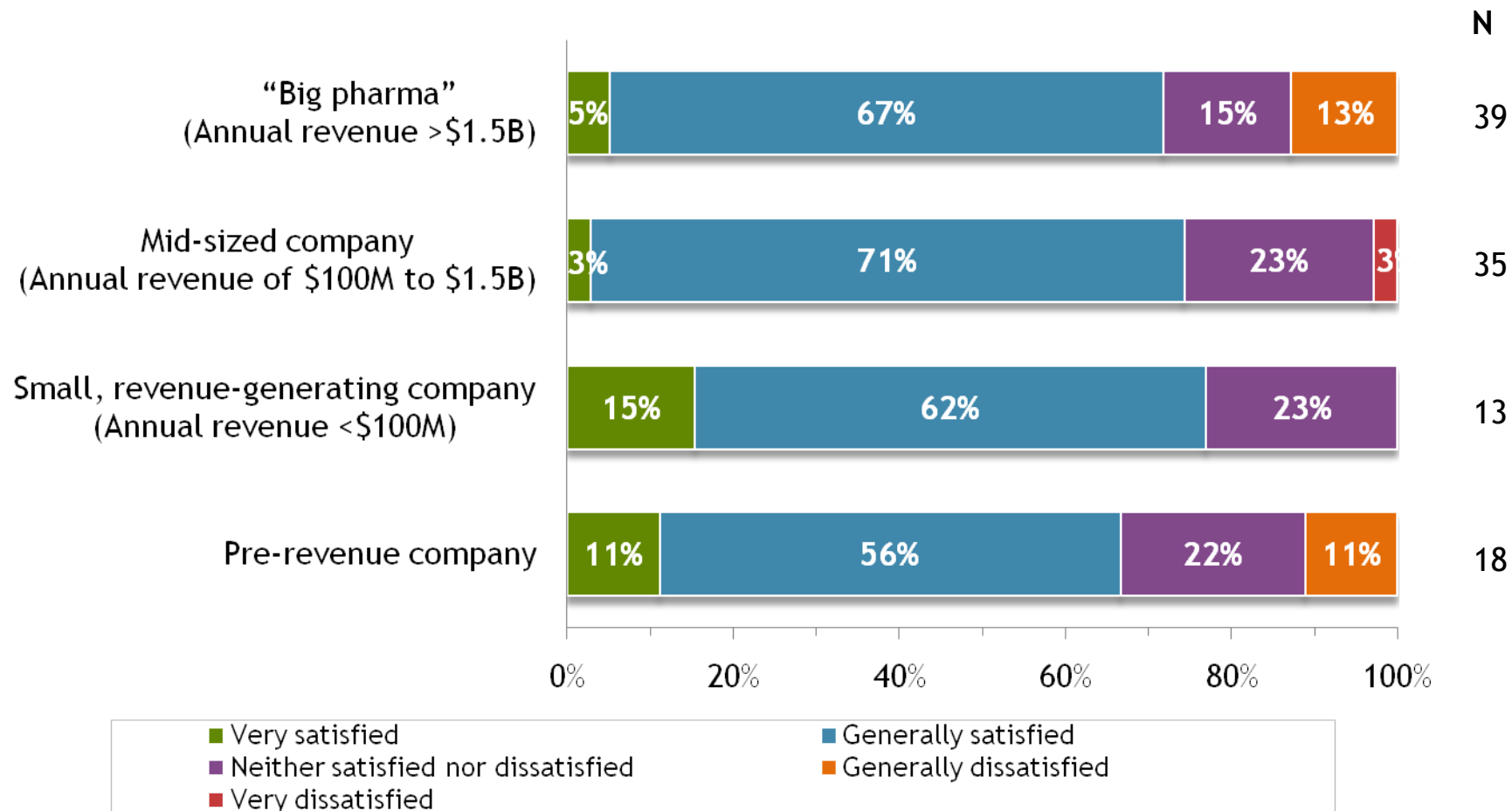


Is the size association rational?

- ▶ The data in **Slides 17 and 18** show that despite the fact that sponsors of different sizes generally select different sets of providers, their satisfaction rates are remarkably similar.
 - ◆ Smaller company respondents are more likely than big company respondents to be satisfied with the attention they receive from senior staff, and are less likely to be satisfied with providers' adherence to budgets. Other than these, clear differences in satisfaction by size of client company were not apparent.
- ▶ The data in **Slides 19, 20, and 21** show that small and mid-sized sponsors who use Top 5 CROs to meet $\leq 25\%$ of their outsourcing needs are generally more satisfied than are small and mid-sized sponsors who use Top 5 CROs more liberally.
 - ◆ In contrast, large sponsors who use Top 5 CROs to meet at least 50% of their outsourcing needs are generally more satisfied than are large sponsors who use Top 5 CROs less.
- ▶ Thus it does appear that the observed association is rational.

Is the association rational?

Sponsors: Overall, how satisfied are you with the work that has been done for you by Clinical Service Providers?



Is the association rational?

On average, how satisfied are you with your CROs in each of the following areas?

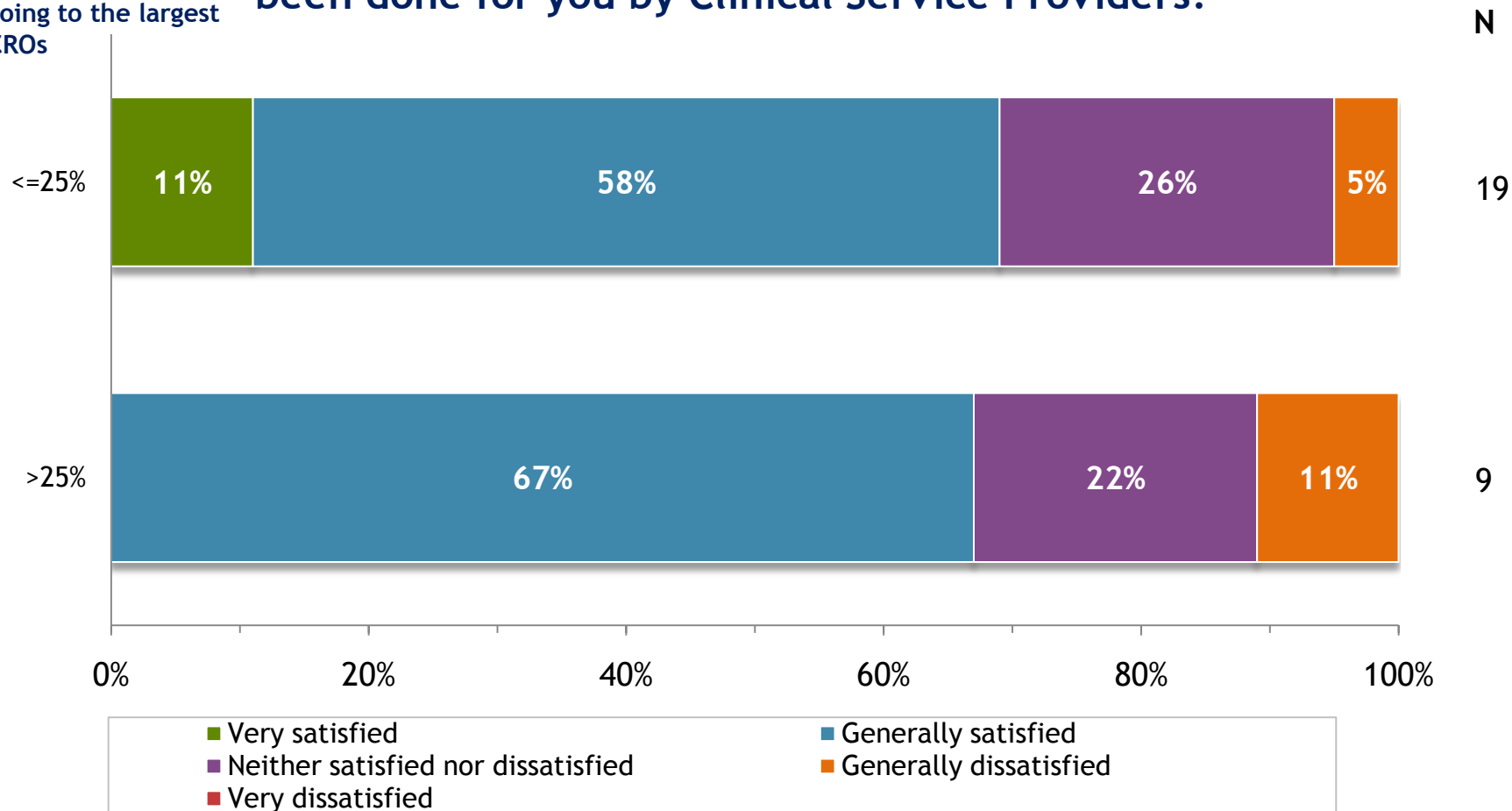
	“Big pharma” (Annual revenue >\$1.5B)	Mid-sized company (Annual revenue of \$100M to \$1.5B)	Small, revenue- generating company (Annual revenue <\$100M)	Pre-revenue company
N=	40	37	14	20
Availability of quality personnel for my projects	3.3	3.4	3.5	3.4
Staff turnover on projects	3.0	2.7	3.1	2.9
Attention from senior staff	3.6	3.5	3.9	3.8
Adherence to agreed timelines	3.4	2.9	3.2	3.3
Adherence to agreed budgets	3.0	2.7	2.5	2.7
Strategic advice	3.0	2.7	3.0	3.1
Operational advice	3.4	3.3	3.2	3.4
Governance of quality	3.3	3.1	3.1	3.4
Customer relationship management	3.7	3.5	3.6	3.4

Is the association rational?

Small Sponsors:

Overall, how satisfied are you with the work that has been done for you by Clinical Service Providers?

% of clinical outsourcing spend going to the largest global CROs

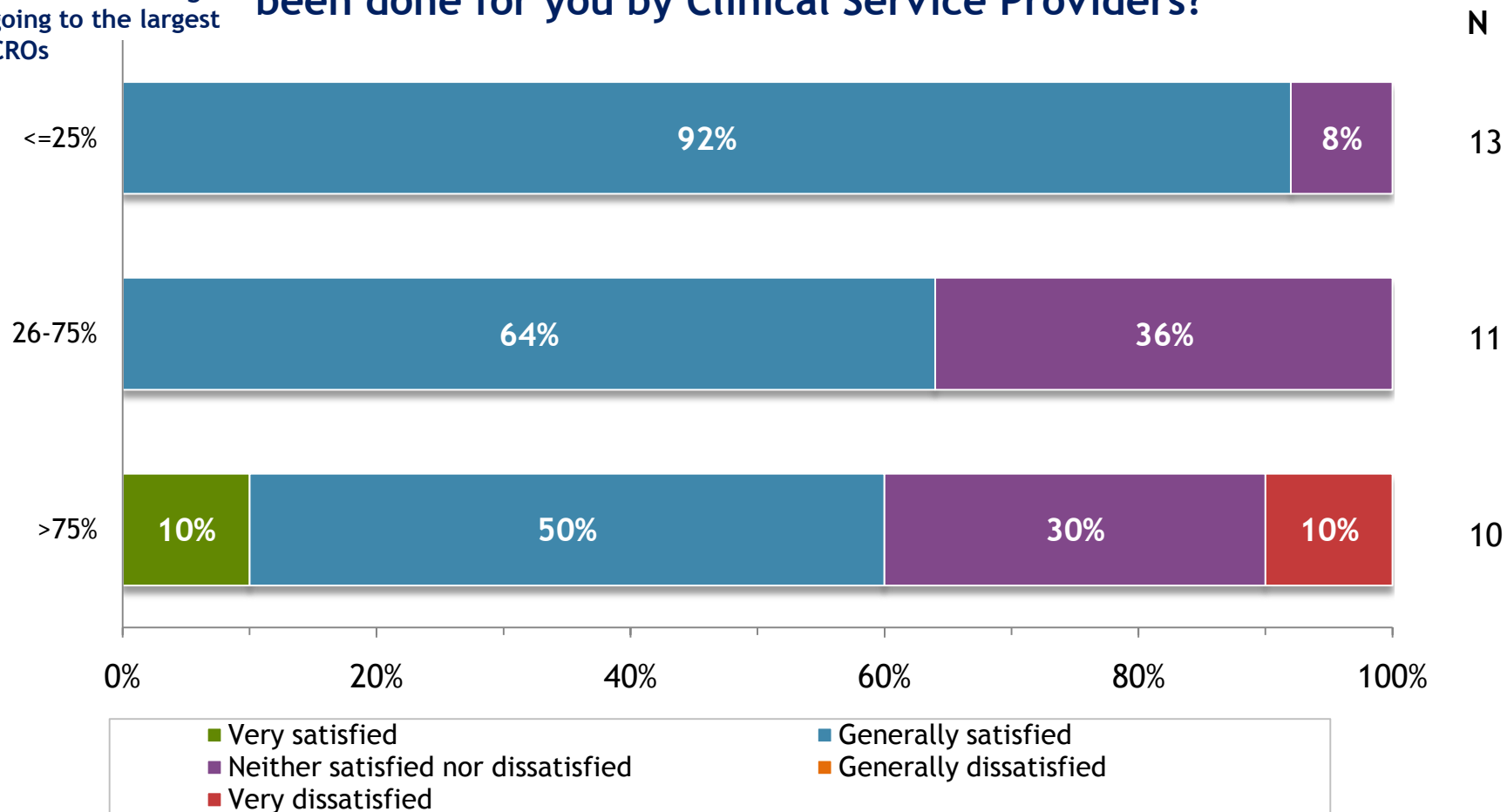


Is the association rational?

Mid-Sized Sponsors:

Overall, how satisfied are you with the work that has been done for you by Clinical Service Providers?

% of clinical outsourcing spend going to the largest global CROs

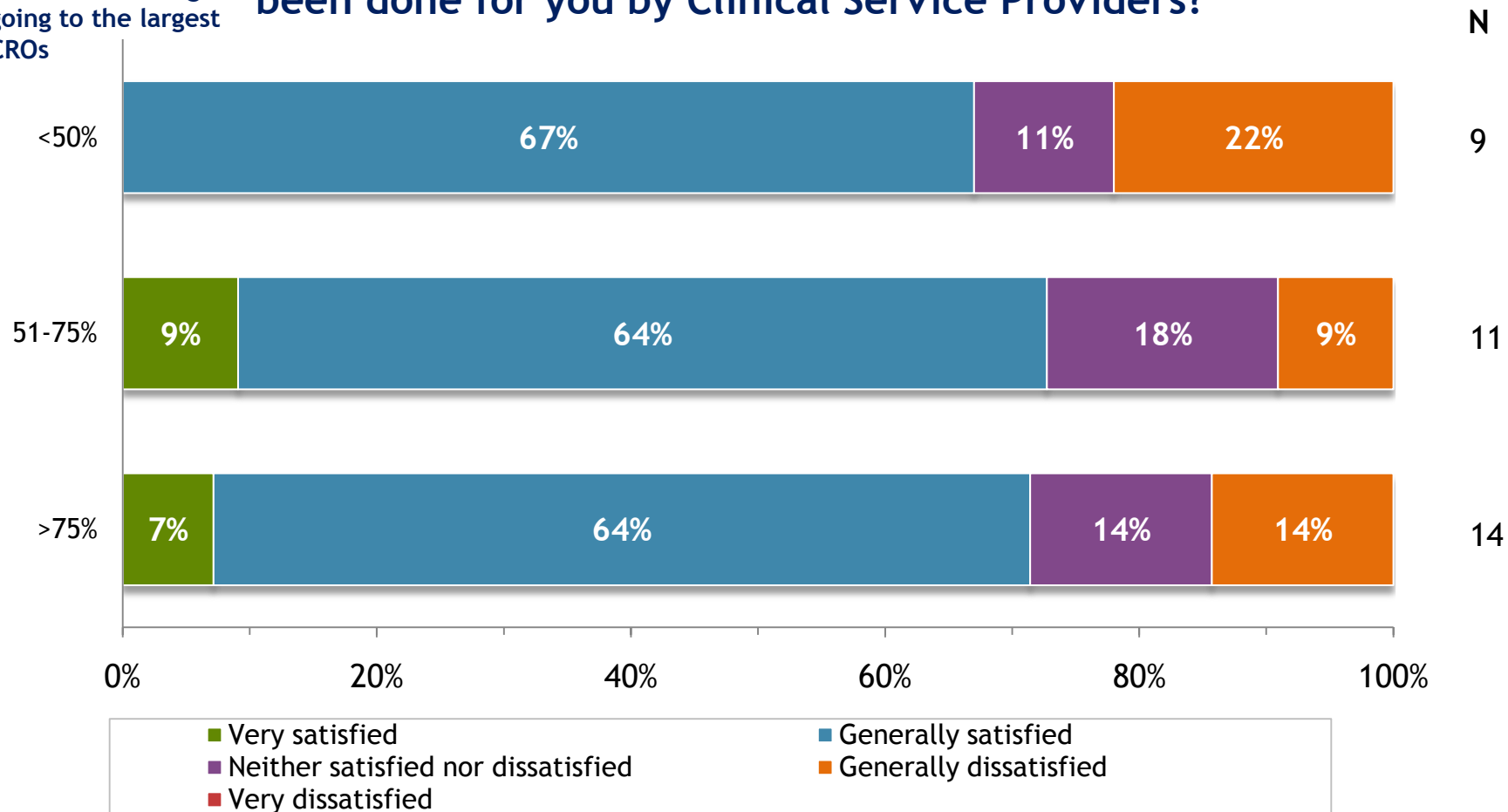


Is the association rational?

“Big pharma”:

Overall, how satisfied are you with the work that has been done for you by Clinical Service Providers?

% of clinical outsourcing spend going to the largest global CROs



Is the association rational?

When asked to explain why they felt that a particular size of clinical service provider provided the best service to companies such as their own, sponsor respondents most commonly cited the following themes:

- ▶ Large, full-service CROs (Top 5) are best when it comes to...
 - ◆ Global footprint and infrastructure; deep experience
 - ◆ Capacity; ability to risk-share
 - ◆ Well standardized procedures including training and QC activities
- ▶ Medium-sized CROs (Top 15 but not Top 5) are best when it comes to...
 - ◆ Value: good depth of experience and quality systems for lower cost
 - ◆ Less staff turnover than found with larger CROs
 - ◆ Flexibility, quality personal service and senior management involvement
 - “Top 5 CROs seem to focus on big-deals...”
- ▶ Smaller CROs (beyond Top 15) are best when it comes to...
 - ◆ Flexibility, responsiveness, attention, senior management involvement
 - ◆ Less staff turnover than found with larger CROs
 - ◆ Cost effective: not maintaining huge infrastructure that doesn't benefit small clients
 - ◆ “...better personnel assigned for small companies. Big CROs tend to treat smaller costumers worse.”

What does the association mean for providers?

3.

What does the association mean for providers?

3a

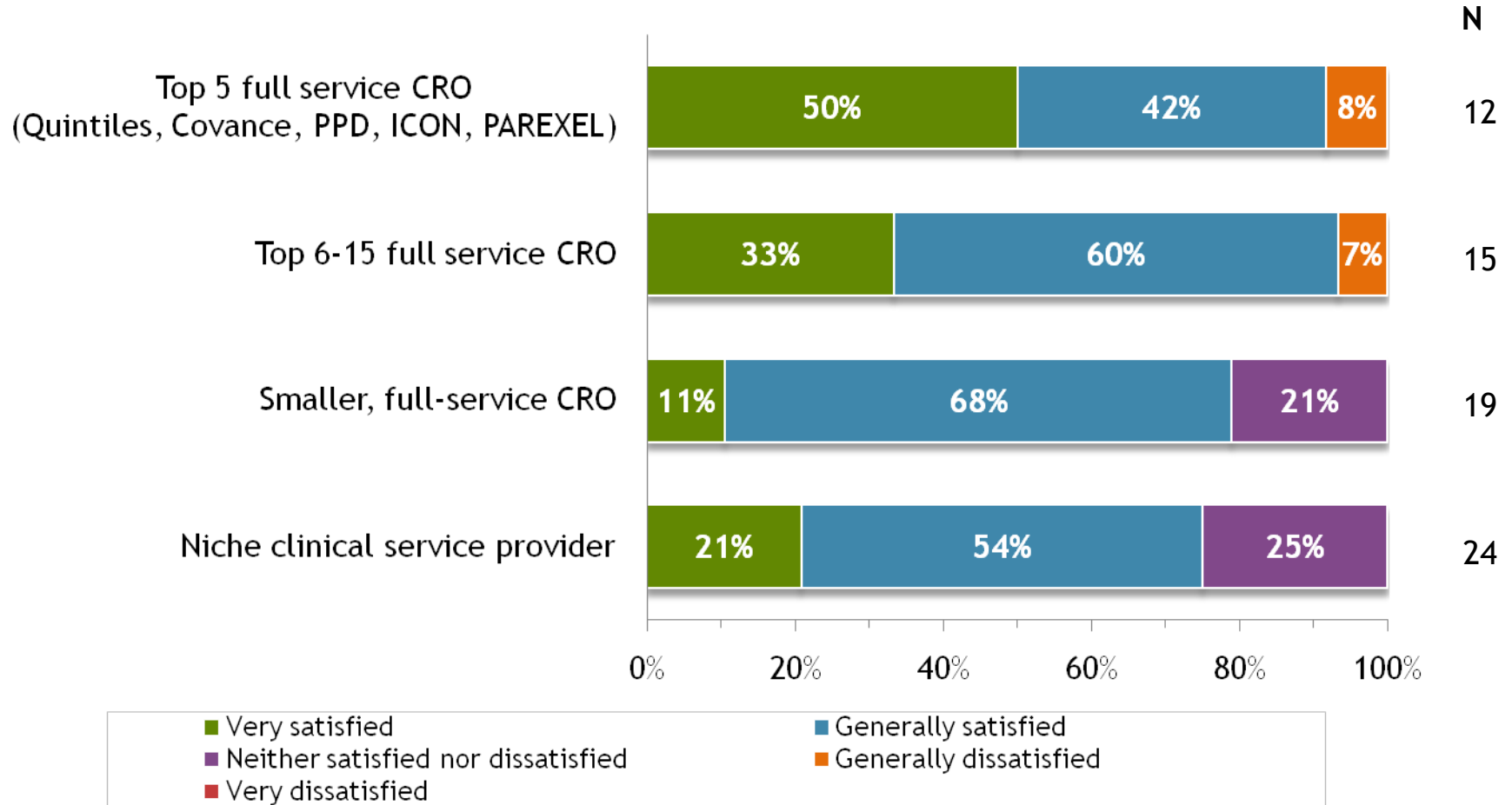
Are providers also more satisfied when working with sponsors of corresponding size?

Are providers more satisfied when working with sponsors of corresponding size?

- ▶ The data in Slide 26 illustrate that respondents from Top 5 CROs are more likely than are respondents from other provider groups to be very satisfied with their relationships with big pharma clients.
 - ◆ Rates of satisfaction with these relationships decline as provider size declines.
- ▶ The data in Slide 27 illustrate that respondents from Top 5 CROs are less likely than are respondents from other provider groups to be very satisfied with their relationships with small to mid-sized pharma clients.
 - ◆ Rates of satisfaction with these relationships are highest among small, full-service CROs.

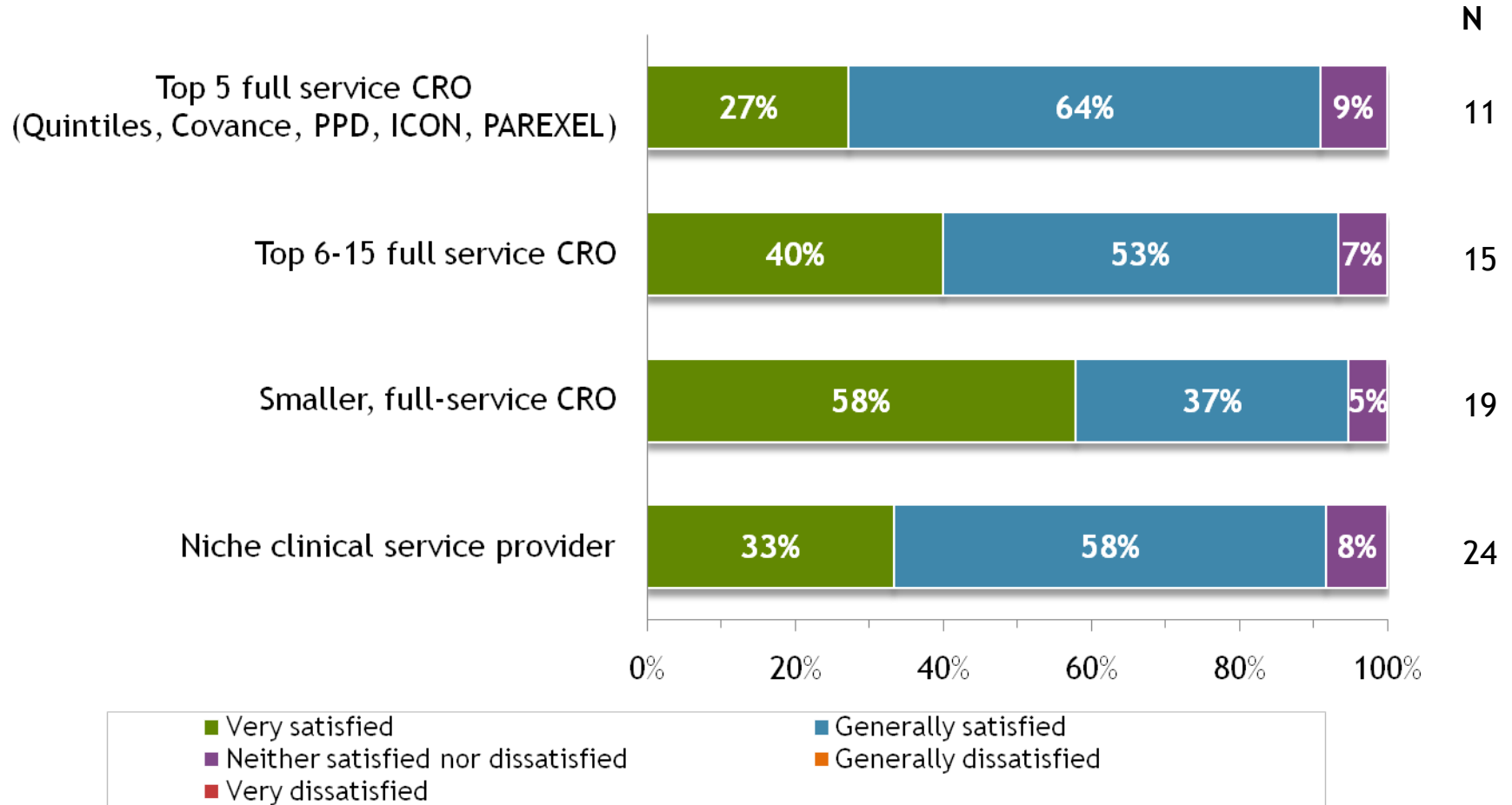
Are providers more satisfied when working with sponsors of corresponding size?

Providers: Overall, how satisfied would you say that your company is with its relationships with its “big pharma” clients?



Are providers more satisfied when working with sponsors of corresponding size?

Providers: Overall, how satisfied would you say that your company is with its relationships with its small to mid-sized client companies?



Which sponsor company types are the best clients?

3b

Which sponsor company types are the best clients?

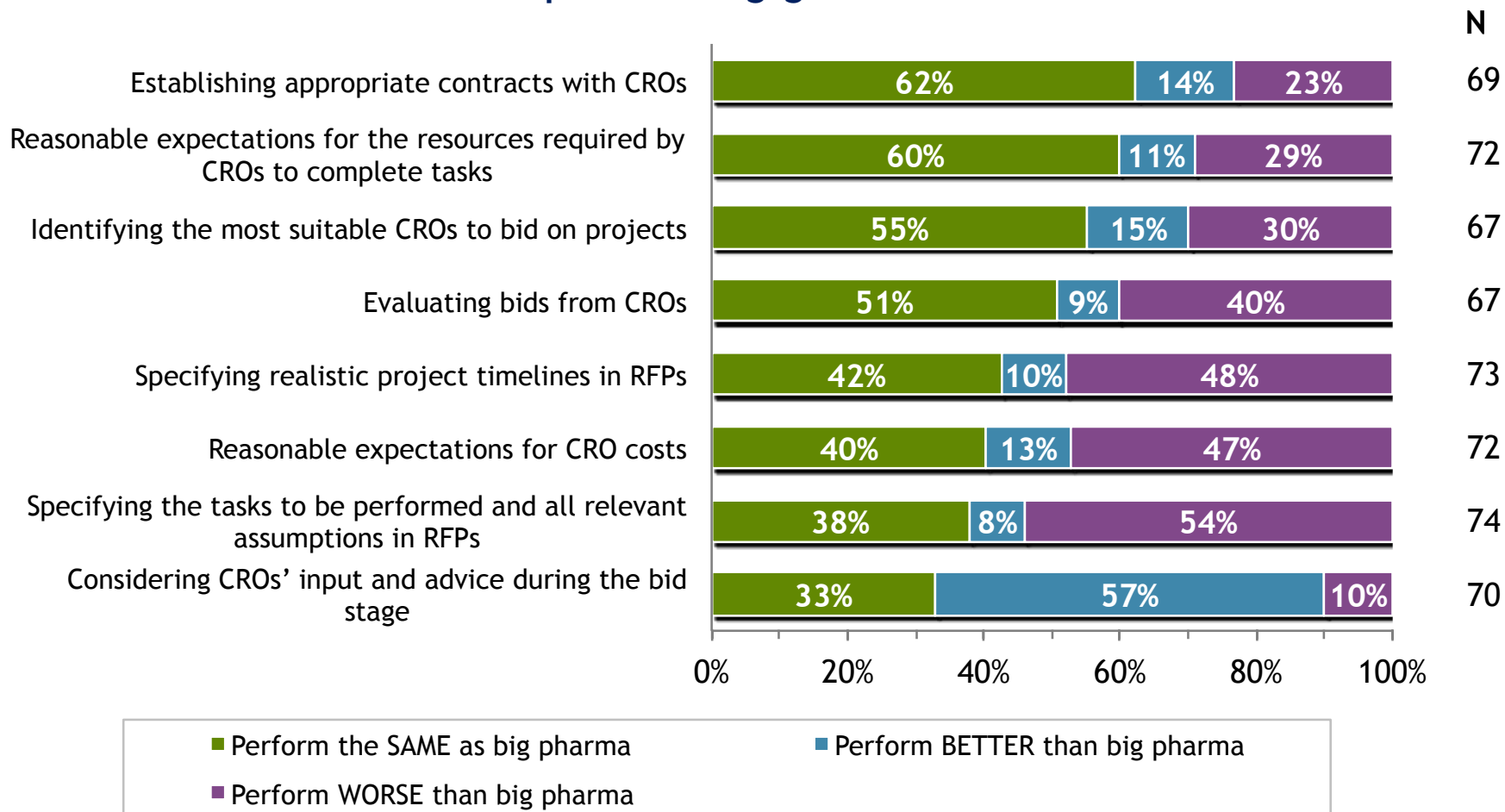
- Which sponsor company types are best at provider selection and engagement?
- Which are easiest for providers to manage, and which are best at managing providers?

Which sponsor company types are best at provider selection and engagement?

- ▶ The data in **Slide 30** illustrate that for several areas of provider engagement, smaller sponsor companies were seen by most provider respondents to perform just as well as did larger sponsor companies. These areas included:
 - ◆ Establishing appropriate contracts with CROs
 - ◆ Reasonable expectations for the resources required by CROs to complete tasks
 - ◆ Identifying the most suitable CROs to bid on projects
 - ◆ Evaluating bids from CROs
- ▶ Respondents who felt that sponsors of different sizes performed differently on these tasks most often felt that big pharma sponsors performed best.
- ▶ Most respondents felt that big pharma sponsors were better than smaller sponsors at specifying tasks to be performed, and all relevant assumptions, in RFPs.
- ▶ Conversely, most felt that smaller sponsors were better at considering CROs' input and advice during the bid stage.
- ▶ **Slide 31** discusses providers' points of view about the challenges associated with working with smaller sponsors during the provider selection process.

Engagement Skills by Sponsor Size

Providers: Compared to your “big pharma” clients, how well, in general, do you feel that your small to mid-sized clients perform in each of the following areas of clinical service provider engagement?



What do you feel are the biggest challenges faced by clinical service providers in providing bids to small sponsor companies?

Provider respondents most commonly discussed the following themes when asked to reflect on the question above:

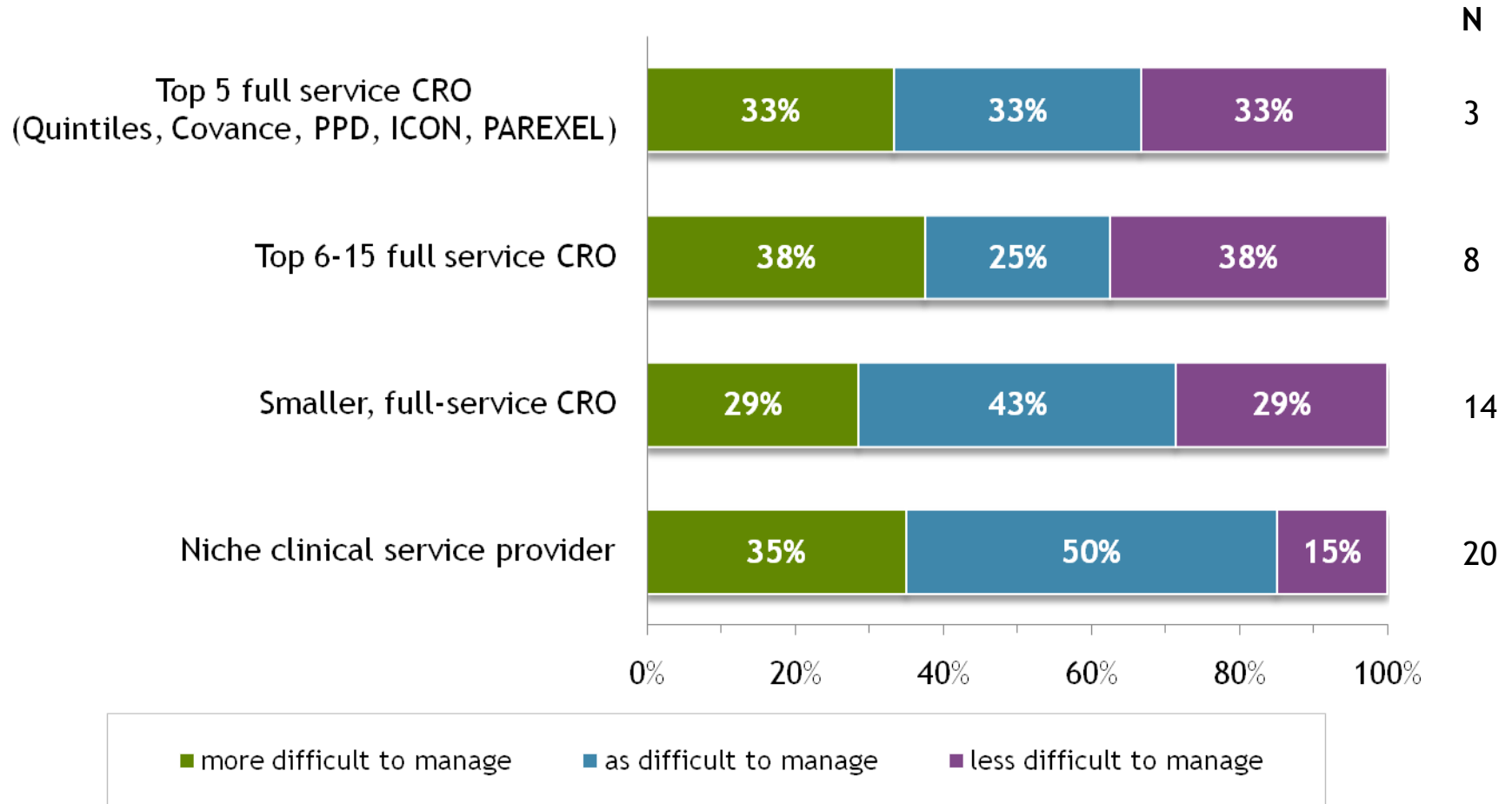
- ▶ Many smaller companies, with limited funding, may chose the provider based on absolute cost (initial price) rather than value for money, and be faced with eventual change orders.
 - ◆ “The big challenge is in dealing with a sponsor that has little or no concept of the complexity and thus true cost of clinical development.”
- ▶ Inappropriate definition of the project scope leads to great difficulty in bid comparison. Unclear and changing expectations are a persistent challenge.
- ▶ In order to manage expectations, CROs are willing to make an investment to educate sponsor companies, but Sponsors often don't provide this opportunity at a sufficiently early stage.
 - ◆ “We are generally in the position of responding to their requests and they often don't know or understand what they need. It would be much more efficient overall if the sponsors would engage the CRO earlier in the process so that we could be involved more strategically and could help them in planning their needs.”

Which sponsor company types are best at provider management?

- ▶ The data in Slide 33 illustrate that from the provider point of view, there was no clear pattern relating the size of the sponsor company to the overall level of difficulty associated with project management.
- ▶ The data in Slide 34 illustrate that for several areas of provider management, smaller sponsor companies were seen by most provider respondents to perform just as well as did larger sponsor companies. These areas included:
 - ◆ Respect of provider team members
 - ◆ Overall team leadership
 - ◆ Adherence to own commitments
 - ◆ Communication
 - ◆ Appropriate level of management
- ▶ For respect and communication, respondents who felt that sponsors of different sizes performed differently most often felt that smaller sponsors performed best. Small pharma sponsors were also felt to be relatively strong with respect to accessibility and decision-making.
- ▶ For overall team leadership and appropriate level of management, respondents who felt that sponsors of different sizes performed differently most often felt that **larger** sponsors performed best.

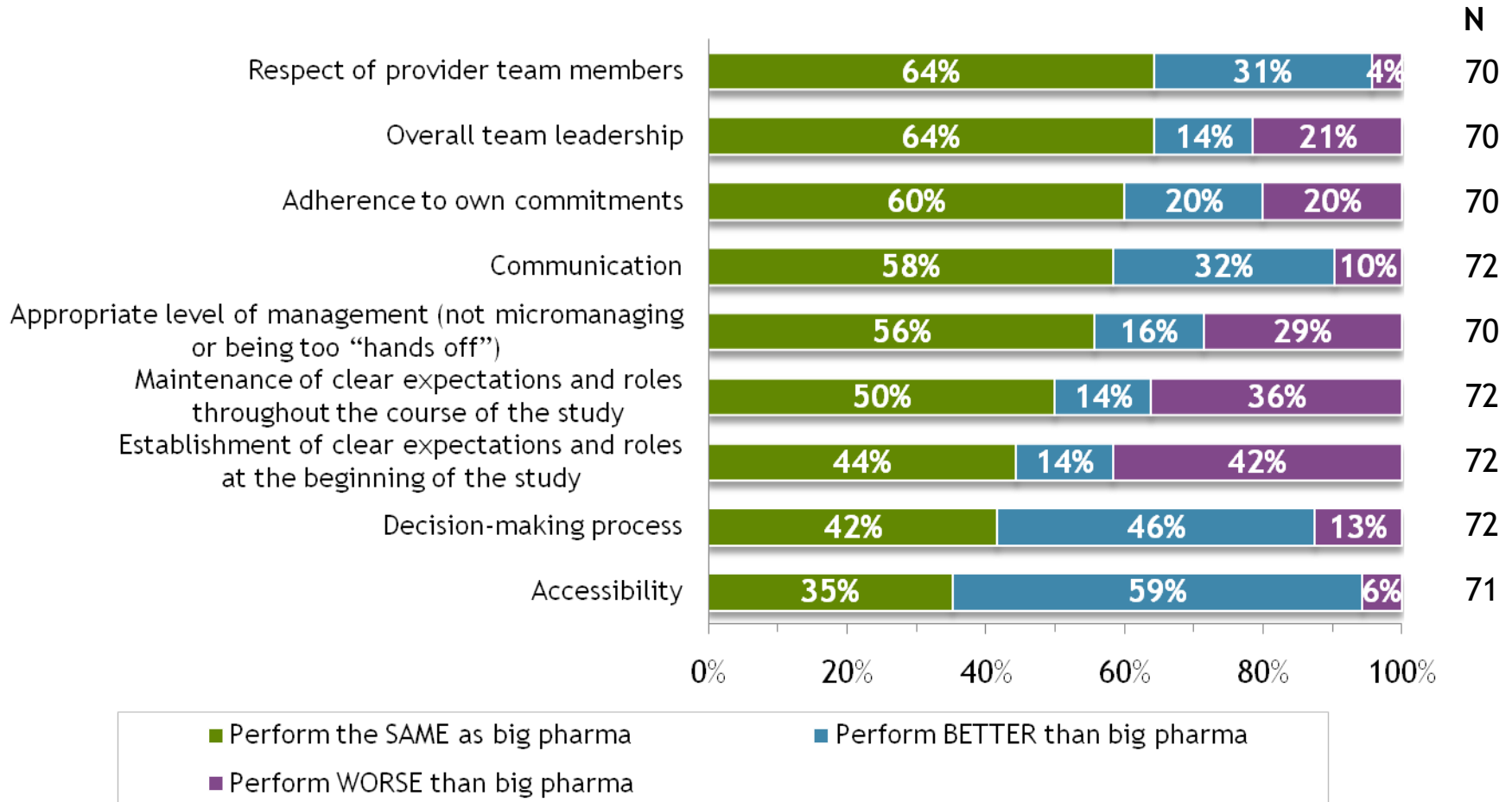
Vendor Management Skills by Sponsor Size

Providers: Compared to the projects your company executes for “big pharma”, the projects your company executes for small to mid-sized biotechnology and pharmaceutical companies are generally...



Vendor Management Skills by Sponsor Size

Compared to your “big pharma” clients, how well, in general, do you feel that your small to mid-sized clients perform in each of the following areas of clinical service provider management?



Which sponsor company types are the best clients?

- ▶ **Slides 36 through 38** describe, from the provider point of view, the pros and cons of managing projects for each size of sponsor company.
- ▶ Data was also collected from Sponsors about specific strengths and weaknesses in managing CROs. This data is not presented here, but is available as part of the full report.

Compared to the projects your company executes for “big pharma”, the projects your company executes for small to mid-sized biotechnology and pharmaceutical companies are generally: **Comments**

- ▶ More difficult to manage:
 - ◆ Staff is less experienced and tends to micro-manage
 - ◆ These companies face budgetary and overall resource restrictions
 - ◆ “They are more difficult due to the lack of SOPs and process.”
 - ◆ “When the small company requires us to provide cross-functional services, we must utilize a greater amount of project management resources to coordinate efforts between third party firms. Also, smaller companies may require a greater amount of consultation for the drug development activities. This may result in additional manpower spent to plan programs and greater communications.”

Compared to the projects your company executes for “big pharma”, the projects your company executes for small to mid-sized biotechnology and pharmaceutical companies are generally: **Comments**

- ▶ As difficult to manage:
 - ◆ “There are exceptions in both directions, but the complexity of the projects is a function of the country, the therapeutic indication and the location for the study (hospital, private practice). An inexperienced sponsor contact can make it more complicated... Large pharma often have more bureaucratic hoops to jump through. Small pharma tend not to know what they really want and sometimes are not willing to pay for expert advice.”

Compared to the projects your company executes for “big pharma”, the projects your company executes for small to mid-sized biotechnology and pharmaceutical companies are generally: **Comments**

- ▶ Less difficult to manage:
 - ◆ “Typically...you are working directly with key decision makers and there is no middle man communications, which streamlines the productivity.”
 - ◆ More flexibility with process and approach
 - ◆ “Most times, we are using our processes, our systems...”
 - ◆ Projects are of smaller scale

What do you feel are the biggest challenges faced by clinical service providers in managing relationships with less-experienced sponsor companies?

- ▶ Frequent and clear communication was cited as essential. This can be improved by the addition of communication and escalation plans.
- ▶ Regular reporting will add to the success of the relationship. Suggestions include metric-based reporting and site feedback to the sponsor.
- ▶ Many challenges can be overcome by gaining the trust and confidence of the sponsor. Suggestions include illustrating a proven track record.
- ▶ Many of the less-experienced sponsors do not have a complete understanding of Regulatory requirements.
- ▶ “Educating them. We will and have pulled together training programs to teach the 510(k) process, IDE requirements, PMA requirements, auditing benefits, etc. and this has helped them to understand the need for some of the activities we indicate are required for their projects.”
- ▶ Other tools employed include proactively establishing a contingency plan and data-driven planning.
- ▶ “To me the biggest challenge is managing an outcome where the project is successful but the study result is not. Less experienced sponsors do not understand the failure rate inherent in research.”

4.

Is outsourcing equally beneficial for all sizes of sponsor companies? Does one size fit all in terms of the benefits/costs of different outsourcing models?

Provider Viewpoint

- ▶ Nearly all providers felt that the **highest quality clinical trial execution could be achieved by outsourcing rather than by performing clinical trials in house**. Few ($\leq 4\%$) felt that performing trials using internal staff would result in the highest quality for sponsors of any size.
 - ◆ For small-mid-sized sponsors, providers were most likely to feel that full-service outsourcing to CROs would result in the highest quality (43%).
 - ◆ For “big pharma” sponsors, providers were most likely to feel that a mixture of full service and functional outsourcing would result in the highest quality (47%).

Sponsor Viewpoint

- ▶ Sponsors for the most part agreed with Providers.
 - ◆ Among large company sponsors, only **13% felt that the best quality could be achieved by using internal staff**. Among small, revenue-generating companies, this figure was 7%.
 - ◆ Pre-revenue company respondents most often felt that full-service outsourcing led to the best quality result, largely due to lack of the infrastructure required to manage FSP or other models.
 - ◆ Most sponsor respondents from all other company sizes felt that a **mixture of full service and functional outsourcing lead to the best quality result**.

- ▶ Most provider companies think that full-service outsourcing is **as cheap or cheaper** than internal clinical development for both small-mid-sized sponsors (73%) and big Pharma companies (77%).
- ▶ Sponsor respondents disagree. 100% of the small company sponsor respondents, 50% of mid-sized sponsor respondents, and 61% of big Pharma respondents felt that full-service outsourcing was **more expensive** than performing clinical trials in-house.
- ▶ Many felt that a mixed model of full-service and functional outsourcing was most cost-effective.

Conclusions

Conclusions

- ▶ The data from the 2011 Avoca State of Clinical Outsourcing Survey suggest that there is a close association between the size of a sponsor company and the size of clinical service provider selected to perform clinical trials.
- ▶ The data further suggest that this association is largely rational:
 - ◆ Most respondents felt that larger sponsor companies are best served by mid-sized to large CROs, whereas smaller sponsor companies are best served by small to mid-sized providers.
 - ◆ Analyses of actual satisfaction rates by % of outsourcing spend allocated to the largest CROs support this perception.
 - ◆ The associations that exist appear to result in similar overall outsourcing satisfaction levels for different sponsor sizes.
- ▶ The existing association also appears to benefit providers.
 - ◆ Providers are most likely to be satisfied with client relationships with correspondingly-sized clients.

Conclusions

- ▶ For several areas of provider engagement, smaller sponsor companies were seen by most provider respondents to perform just as well as did larger sponsor companies. These areas included:
 - ◆ Establishing appropriate contracts with CROs
 - ◆ Reasonable expectations for the resources required by CROs to complete tasks
 - ◆ Identifying the most suitable CROs to bid on projects
 - ◆ Evaluating bids from CROs
- ▶ Respondents who felt that sponsors of different sizes performed differently on these tasks most often felt that big pharma sponsors performed best.
- ▶ Most respondents felt that big pharma sponsors were better than smaller sponsors at specifying tasks to be performed, and all relevant assumptions, in RFPs. Conversely, most felt that smaller sponsors were better at considering CROs' input and advice during the bid stage.

Conclusions

- ▶ From the provider point of view, there was no clear pattern relating the size of the sponsor company to the overall level of difficulty associated with project management.
- ▶ For several specific areas of provider management, smaller sponsor companies were seen by most provider respondents to perform just as well as did larger sponsor companies. These areas included:
 - ◆ Respect of provider team members
 - ◆ Overall team leadership
 - ◆ Adherence to own commitments
 - ◆ Communication
 - ◆ Appropriate level of management
- ▶ Small pharma sponsors were felt to be strong relative to larger sponsors when it came to accessibility and decision-making.
- ▶ Sponsors and providers of all sizes agreed about the quality benefits to be gained by outsourcing. In general, smaller to mid-sized sponsors were perceived to benefit most from full-service outsourcing, whereas mid-sized to larger sponsors were perceived to benefit most from a mix of full-service and functional outsourcing.

Thank you

- ▶ Once again, The Avoca Group offers its thanks for your participation in the industry survey. More data on this topic is available from Avoca on a custom report basis.

- ▶ We look forward to your participation in Avoca's industry survey in 2012.



Avoca

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Improving the Health of Critical Business Relationships

Thank you

Contact Avoca at:

(609) 252-9020

www.theavocagroup.com

info@theavocagroup.com

179 Nassau Street

Suite 3A

Princeton, NJ 08542