

# The State of Clinical Outsourcing: 2009

Results from Avoca's 2009 Industry Survey: *What does the Future Hold for CRO-Sponsor Relationships?*

Denise Calaprice-Whitty, Ph.D.  
Executive Director, Survey Research  
and Relationship Management Programs  
The Avoca Group

June 24, 2009

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## AGENDA

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- ▶ **Key Findings from the 2009 Industry Survey:** Denise Calaprice-Whitty, Ph.D., Executive Director, Survey Research and Relationship Management Programs, The Avoca Group
- ▶ **Panel Response**
  - ◆ **Dr Adrian Otte**, Vice President, Global Development Operations, Amgen
  - ◆ **Mitchell A. Katz, PhD**, Vice President, Global Clinical Operation, Eisai Medical Research Inc.
  - ◆ **Badhri N. Srinivasan, MS**, Vice President, Enterprise Transformation Unit, Quintiles Inc.
- ▶ **Open Discussion, Q & A**



# 2009 Avoca Industry Survey: Objectives, Methodology and Respondents

## OBJECTIVES

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- ▶ Each year, The Avoca Group polls industry executives and managers to understand trends in the outsourcing of clinical research by pharmaceutical companies and other sponsors
- ▶ 2009: how outsourcing relationships were expected to change between the present and 2014, with a focus on changes related to a need for greater outsourcing efficiency
- ▶ Questions were posed about:
  - ◆ Drivers of change in sponsor-CRO relationships over the next 5 years,
  - ◆ whether and to what extent sponsors and providers feel increased pressure to become more efficient in their relationships, and
  - ◆ how this pressure would impact vendor selection priorities, outsourcing strategies, the need for measurement of vendor performance and relationships, and other aspects of outsourcing relationships
- ▶ Both multiple-choice and open-ended

## METHODOLOGY

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- ▶ Invitations to participate were emailed to selected Executives and Managers of both sponsor companies and service provider companies
- ▶ Links within the emails directed respondents to the appropriate web-based survey instruments:
  - ◆ sponsor perspective
  - ◆ provider perspective
- ▶ Respondents who completed the survey were offered the 2009 Avoca Report

## RESPONDENTS

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- ▶ 154 surveys were completed in a two-month time span in early 2009
  - ◆ 71 sponsor surveys, with representation from 51 companies
  - ◆ 83 service provider surveys, with representation from 39 companies

## Clinical Service Provider Companies Represented

AAIPharma	ExecuPharm	PharmaNet
aCROnordic	Fisher Clinical Services	Pharm-Olam
Acurian	Global Clinical Trials	PPD
AEPODIA	i3 Research	PRA
Beardsworth	ICON	Prologue Research
Biomedical Systems	iCS	PSI
Cardinal Health Research Services	INAMED Research	Quest Diagnostics
Cleartrial	IndiPharm	Quintiles
Clinical Financial Services, LLC	Kendle	RBM
Clininvent	LabConnect, LLC	REGISTRAT
COMSYS Clinical	M2S, Inc.	ResearchPoint
Copernicus Group IRB	MDS Pharma Services	Rho, Inc.
Covance	Medpace, Inc.	Strategic Outsourcing Solutions, LLC
CR, LLC	Omnicare Clinical Research	Tigermed Consulting LTD
Datatrial	Oncopartners	Worldwide Clinical Research, Inc.
Eurofins Medinet	Paragon Biomedical	
Eurorials	PAREXEL	

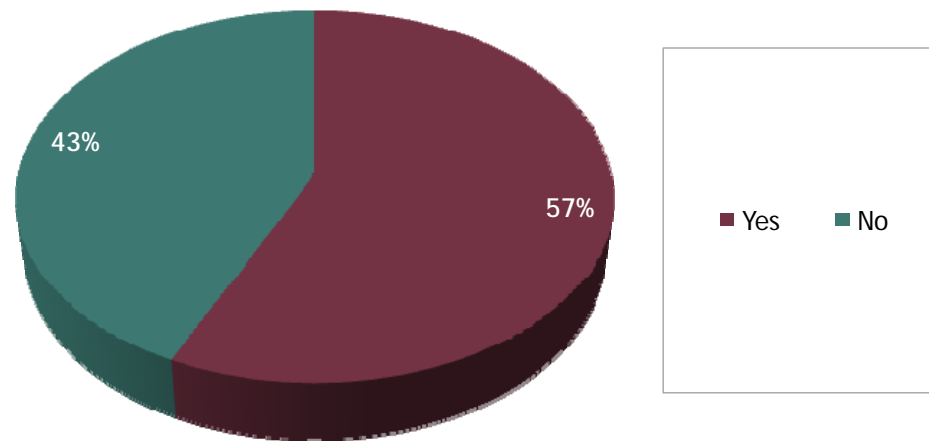
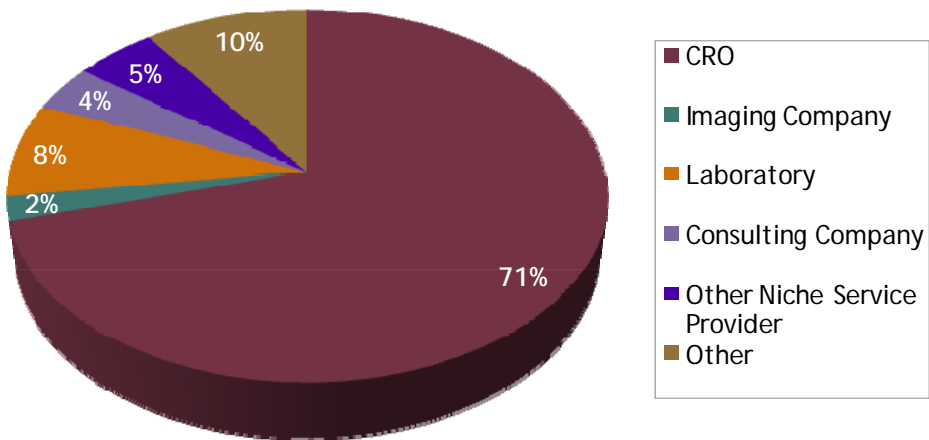
## Sponsor Companies Represented

Adnexus	Grünenthal GmbH	Neurotech USA
Allergan	GSK	NicOx
Amgen	Helsinn Healthcare	Nycomed GmbH
AstraZeneca	Hoffmann-LaRoche, Inc	OMJSA
Bayer	Hughes	Otsuka
BIAL - Portela & Co SA	Isotechnika	Pain Therapeutics, Inc.
BMS	Jennerex Inc	Pfizer
Celtic Pharma	JJPRD	Regeneron Pharmaceuticals
Chugai Pharma Europe Ltd	Johnson & Johnson	Sanofi Aventis
Cordis Corporation	Knopp Neurosciences	Schering-Plough Corporation
CR Bard	Lim	Seaside Therapeutics
Cylene Pharmaceuticals	Lundbeck	Shire
Eisai	MannKind Corporation	Solvay Pharmaceuticals
Ferring	Maxx Orthopedics	Sucampo Pharma Europe
Genentech, Inc.	Merck	Wyeth
Genzyme Corporation	Mitsubishi Tanabe Pharma Corporation	

# Provider Company Respondents

Please indicate your company type.

Is your company among the top 10 companies in revenue in your industry?

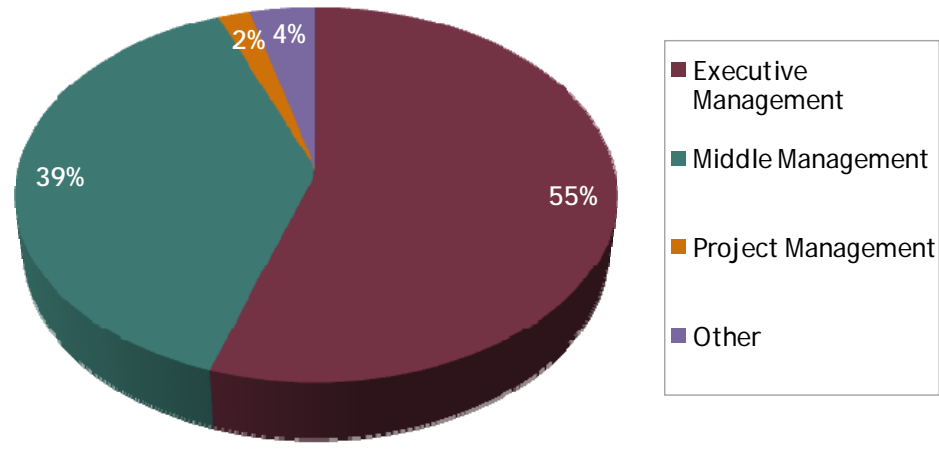
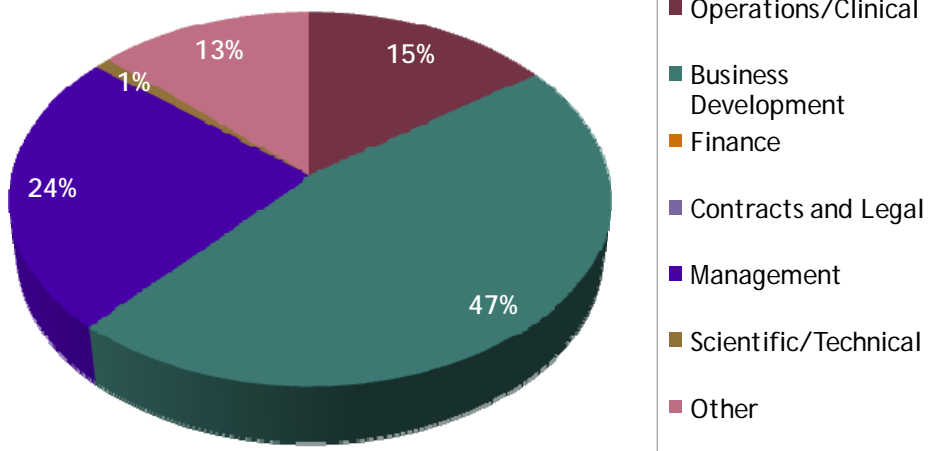


N=83

N=82

What is the functional area in which you work?

Please indicate the level of your position.



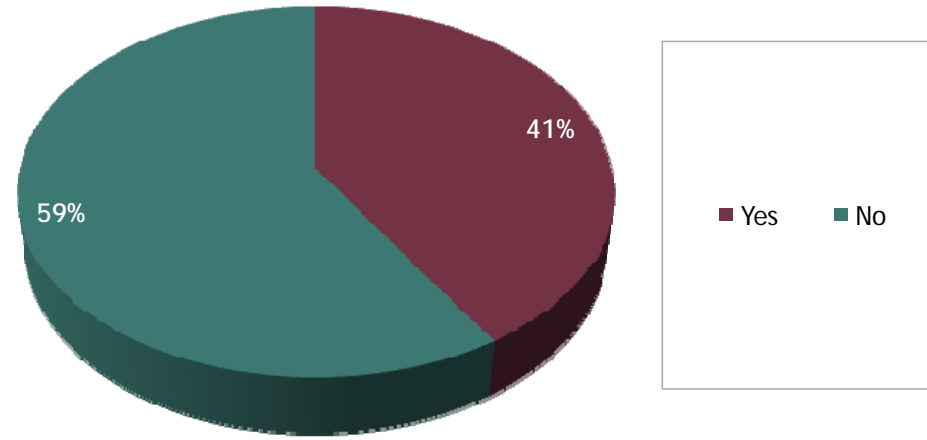
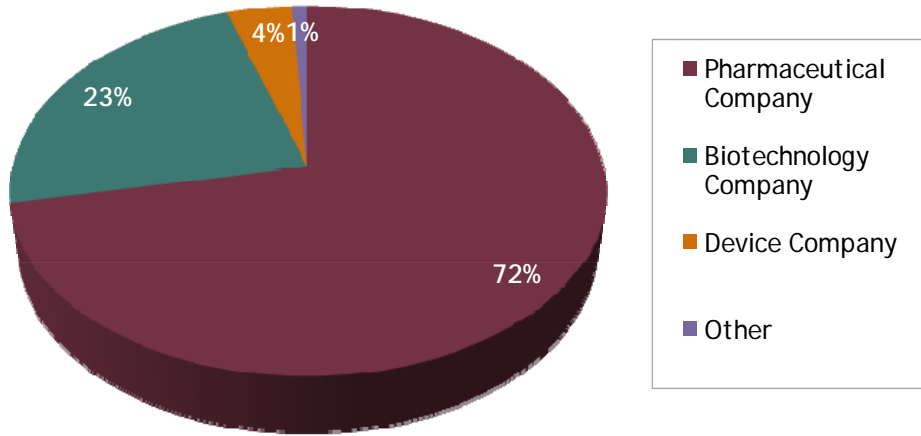
N=82

N=83

# Sponsor Company Respondents

Please indicate your company type.

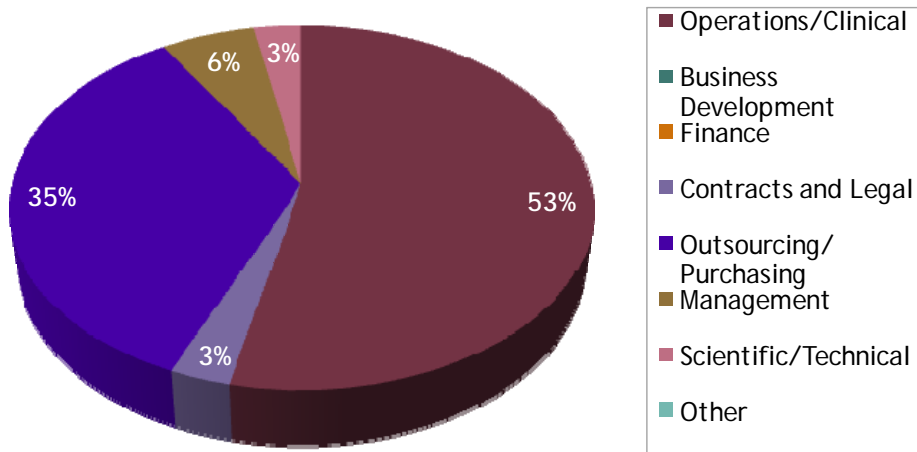
Is your company among the top 10 companies in revenue in your industry?



N=71

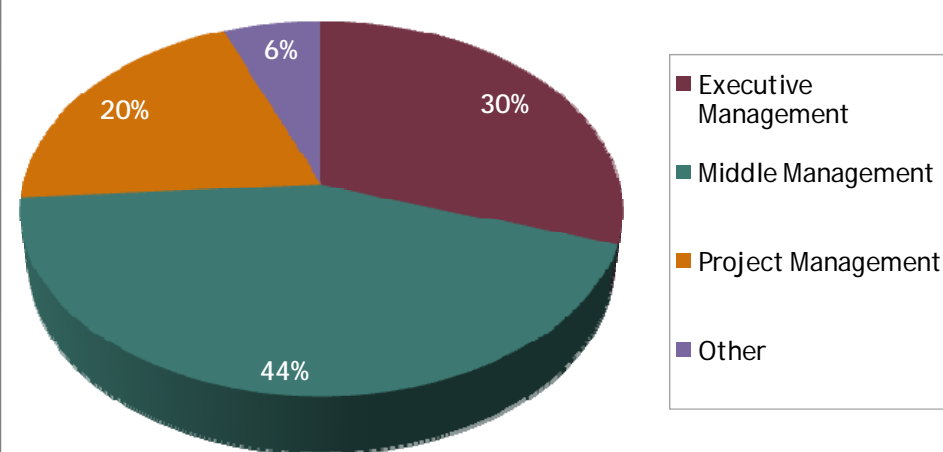
N=69

What is the functional area in which you work?



N=71

Please indicate the level of your position.



N=70

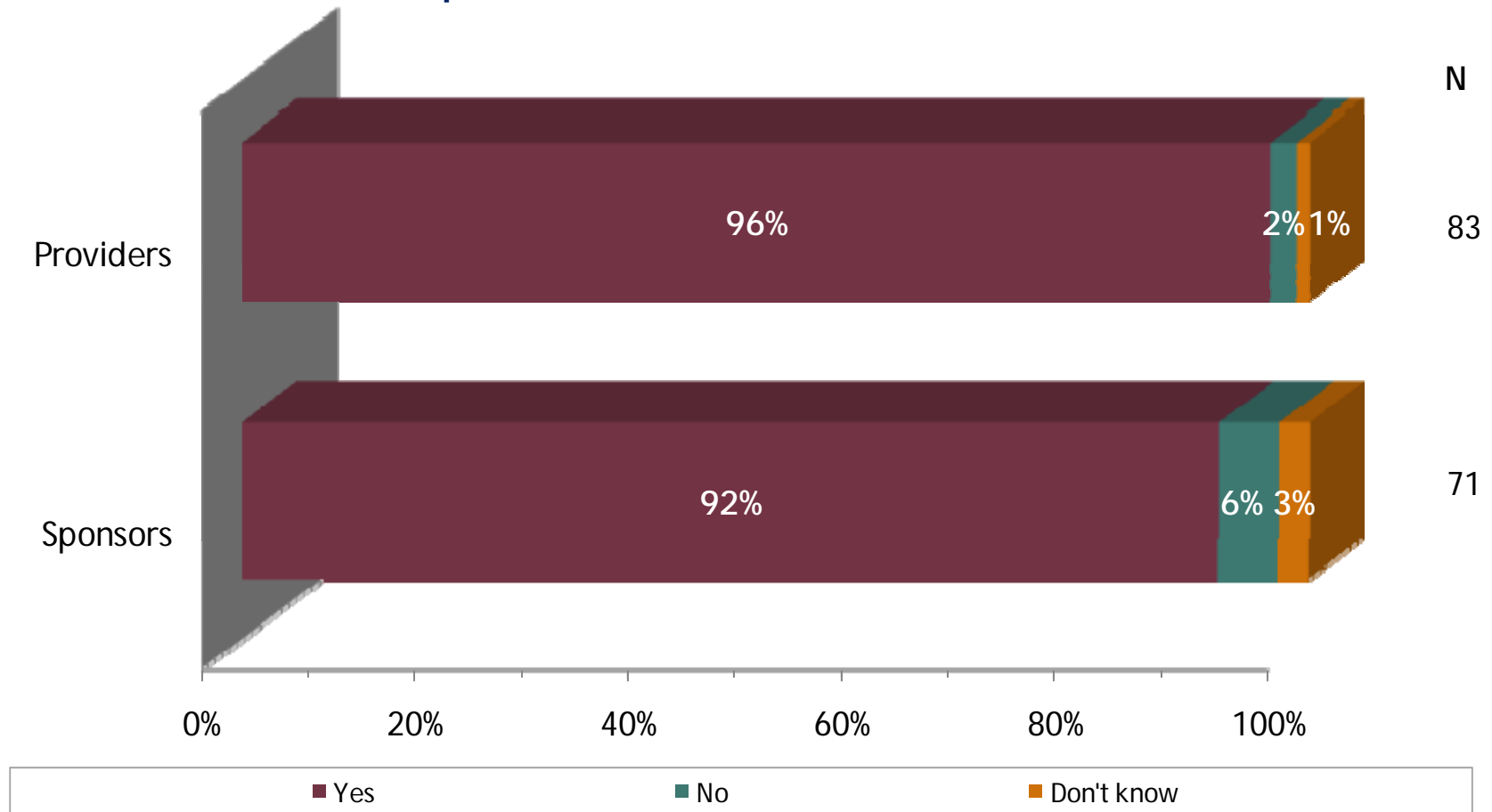


# Key Findings: The Need for Greater Efficiency

2009 Avoca Industry Survey

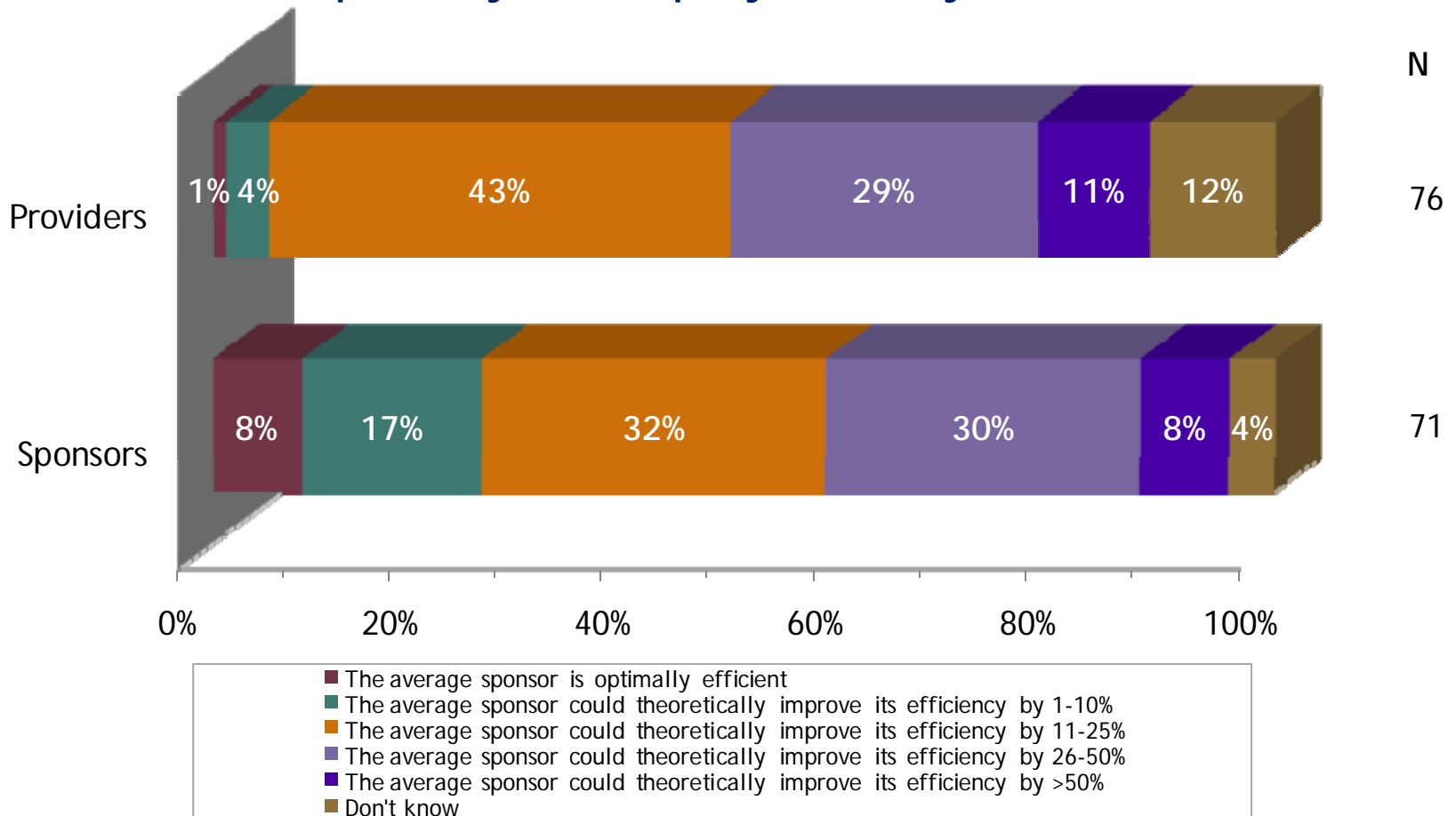
# Pressure to Achieve Increased Efficiency

Between now and 2014, do you believe that sponsors/your company will be under pressure to achieve a greater level of efficiency in their relationships with CROs and other providers of clinical research services?



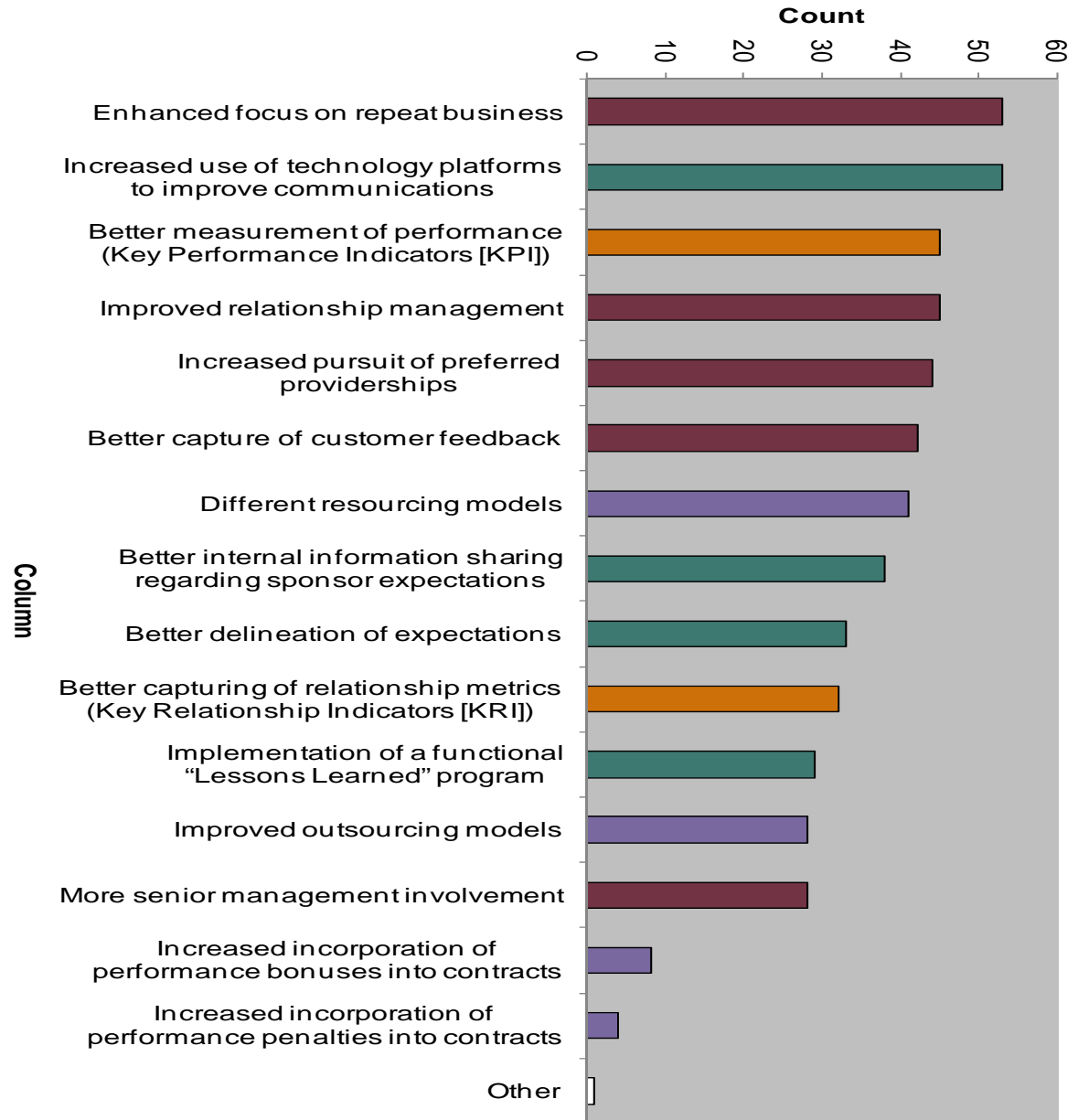
# Room for Improvement: Efficiency

In terms of the internal resources required to manage outsourced projects effectively, how much room for improvement do you think that the average sponsor/your company currently has?



# Changes that Providers Will Make to Improve Efficiency

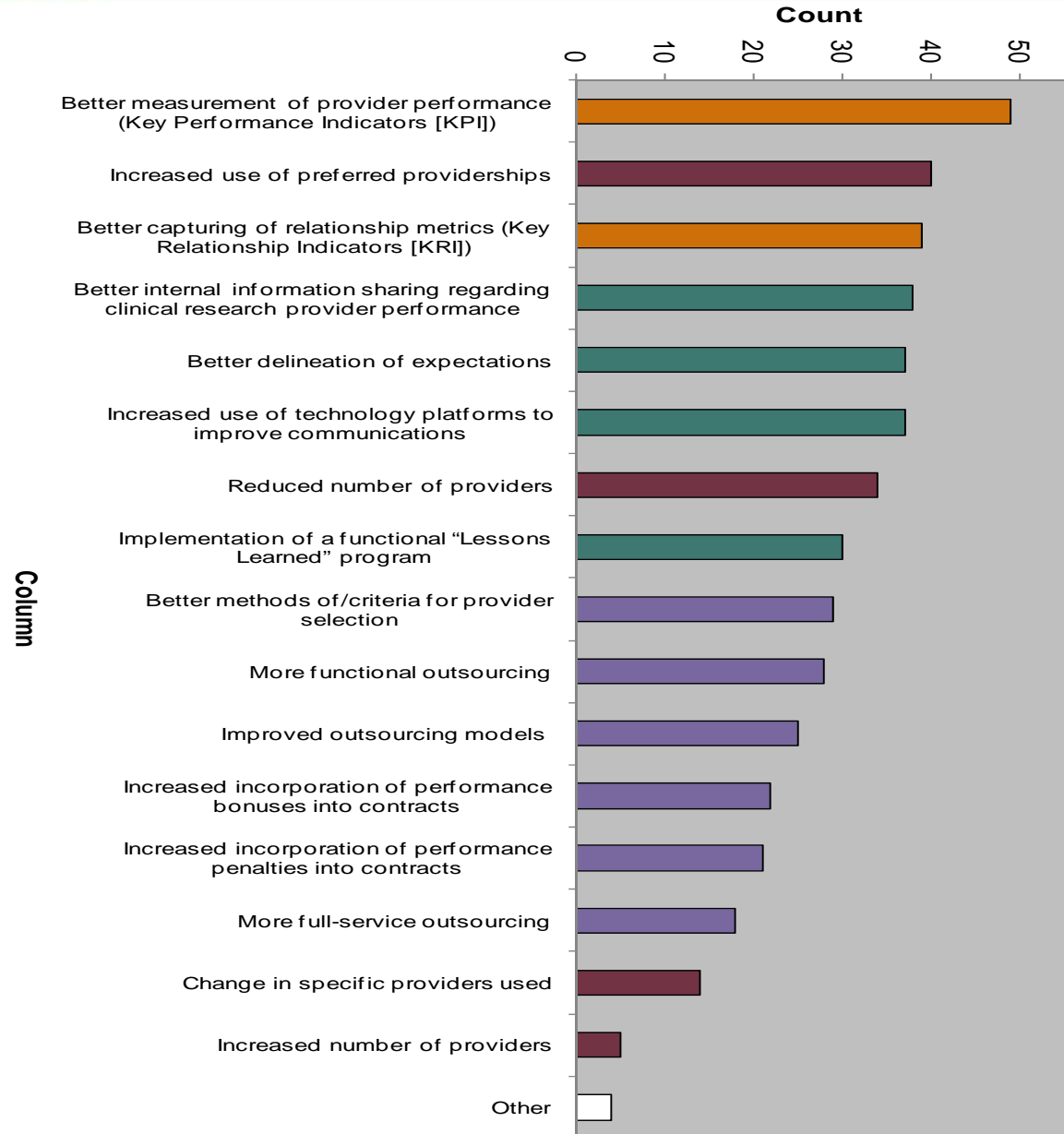
What changes, if any, do you believe your company will make in the next five years (or currently) to improve the efficiency of its work with sponsors?  
(n=83)



# Changes that Sponsors Will Make to Improve Efficiency

What changes, if any, do you believe your company will make in the next five years (or currently) to improve the efficiency of its outsourcing relationships?

(n=71)

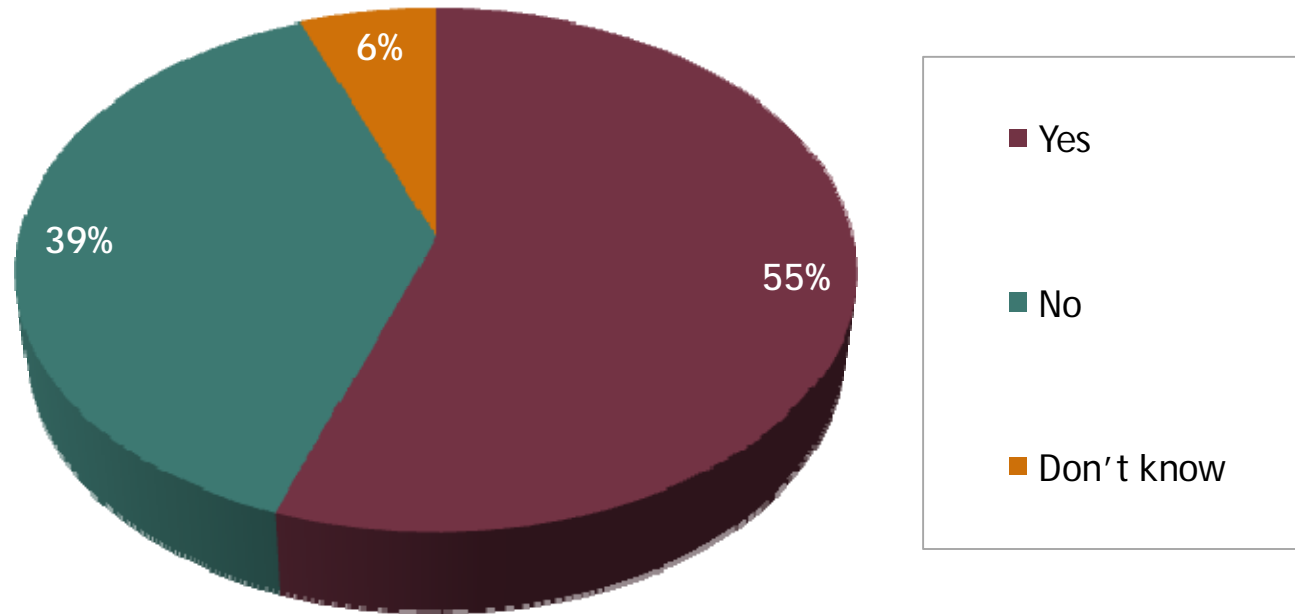




# Key Findings: Measurements of Provider Performance and Relationship Quality

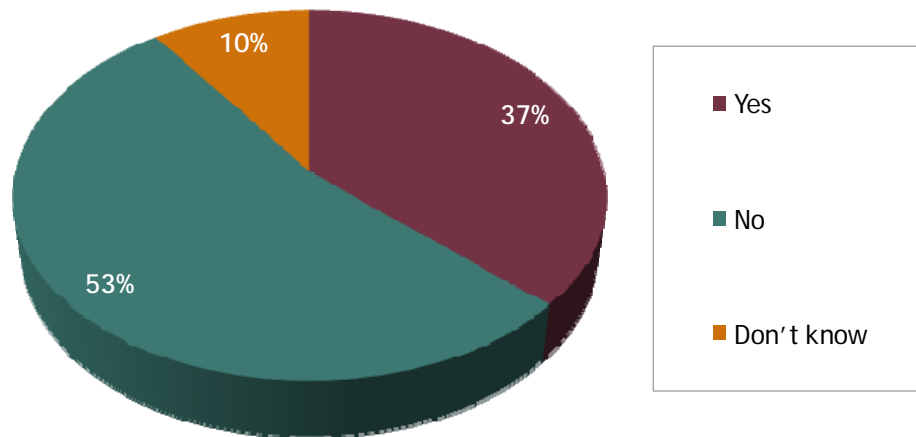
2009 Avoca Industry Survey

Does your company currently use the measurement of Key Performance Indicators (KPIs) to evaluate the performance of clinical service providers?



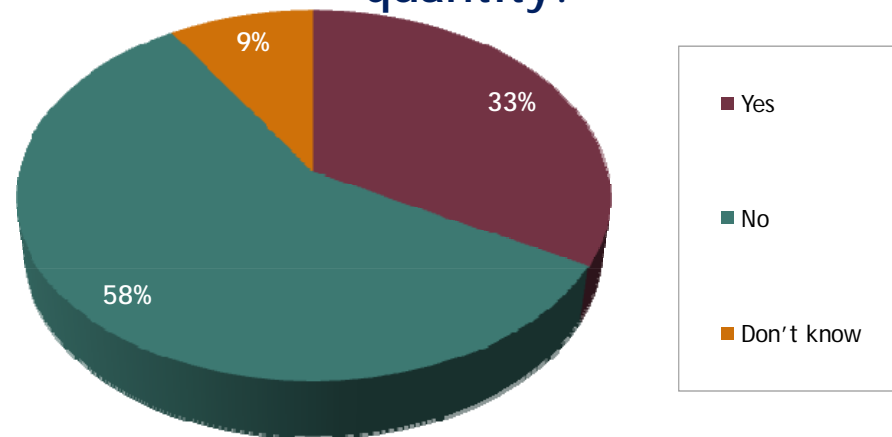
N=70

If "Yes", do you feel that your company's KPIs provide an adequate reflection of the true performance of providers?



N=41

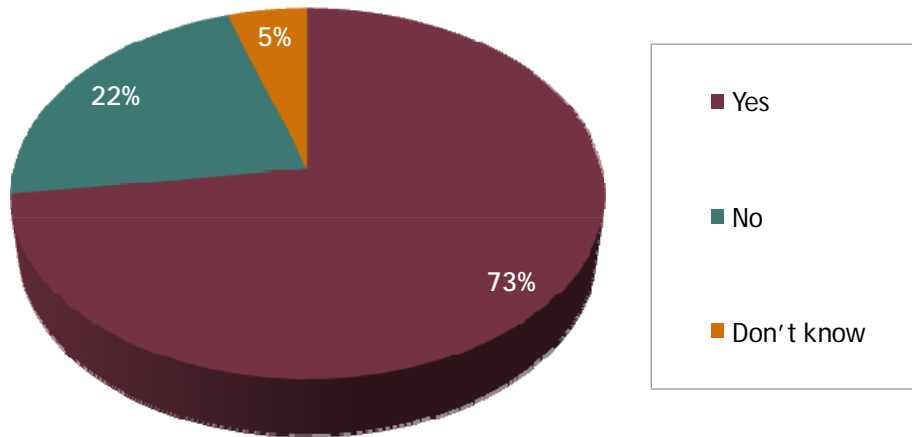
Do you feel that your company's KPIs take sufficiently into account the QUALITY of deliverables (e.g. evaluability of subjects, cleanliness of data), as opposed to the timing and quantity?



N=45

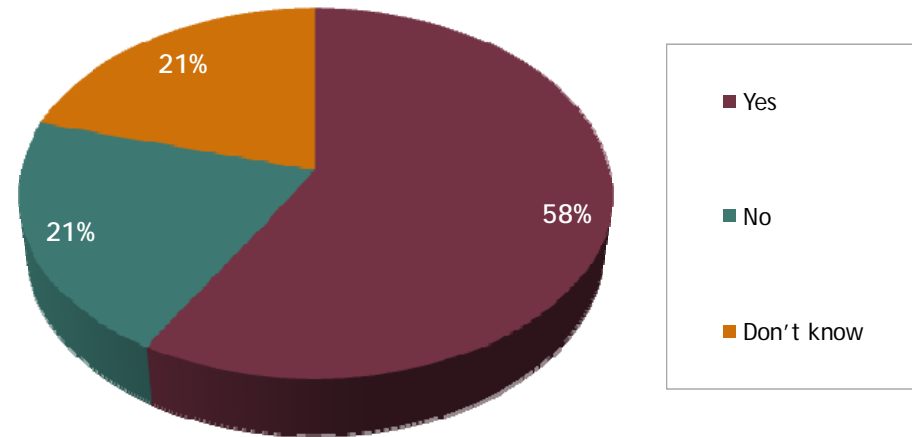
# Provider Company Results: KPIs

Does your company currently use the measurement of Key Performance Indicators (KPIs) to evaluate your own performance?



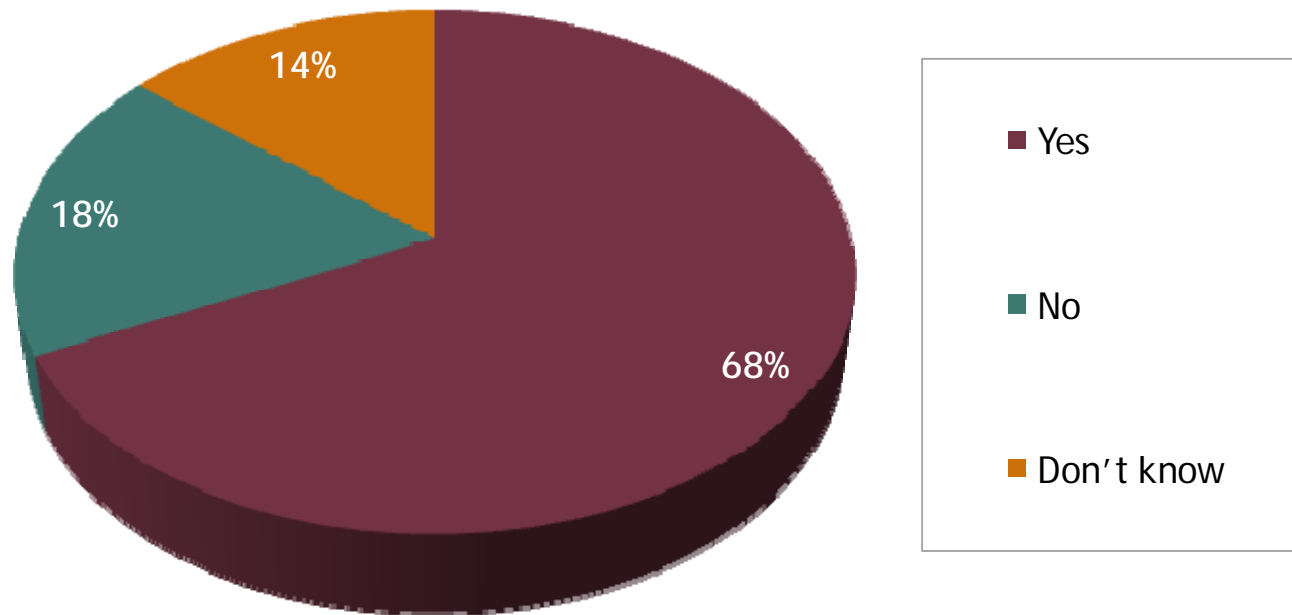
N=77

If "Yes", do you feel that your company's KPIs provide an adequate reflection of your true performance?



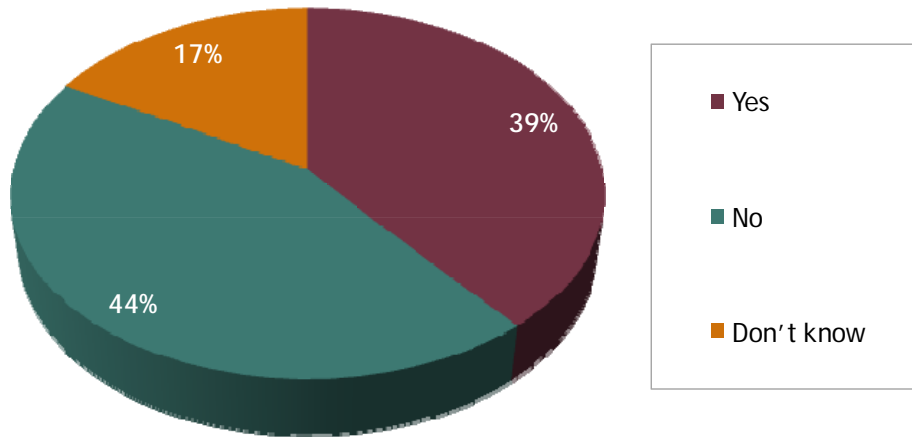
N=58

Are you aware of sponsors that have used a defined set of KPIs to evaluate your company's performance?



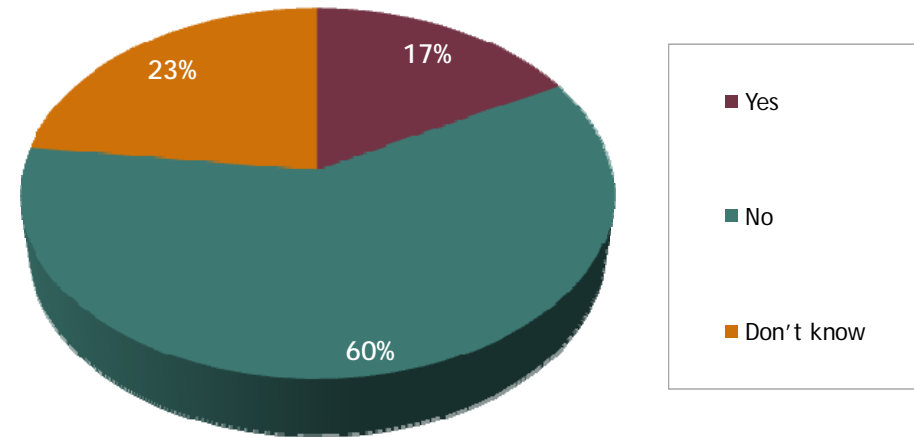
N=77

If "Yes", do you feel that sponsors' KPIs generally provide an adequate reflection of your true performance?



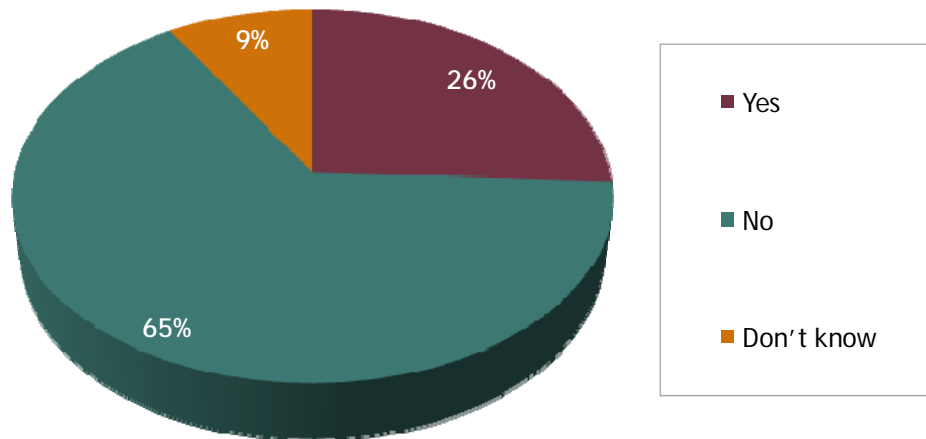
N=54

Do you feel that the sponsor's KPIs take sufficiently into account the QUALITY of deliverables (e.g. evaluability of subjects, cleanliness of data), as opposed to the timing and quantity?



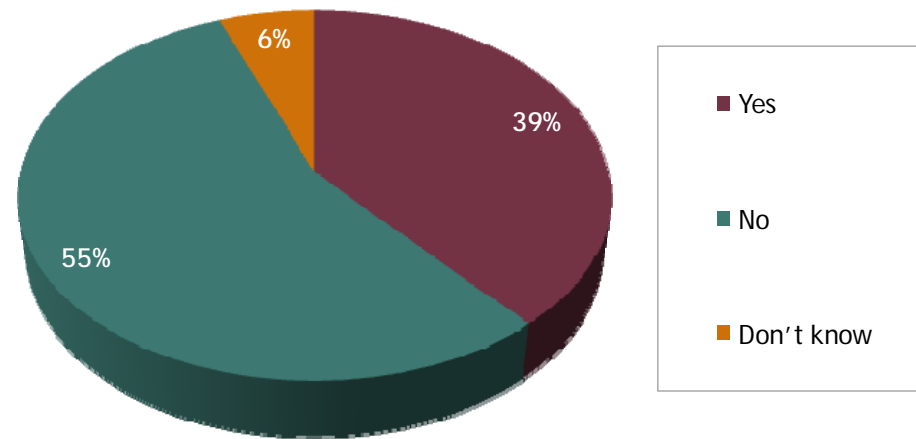
N=65

Does your company currently use a formal set of relationship metrics to evaluate your relationships with clinical service providers (Key Relationship Indicators [KRIs])?



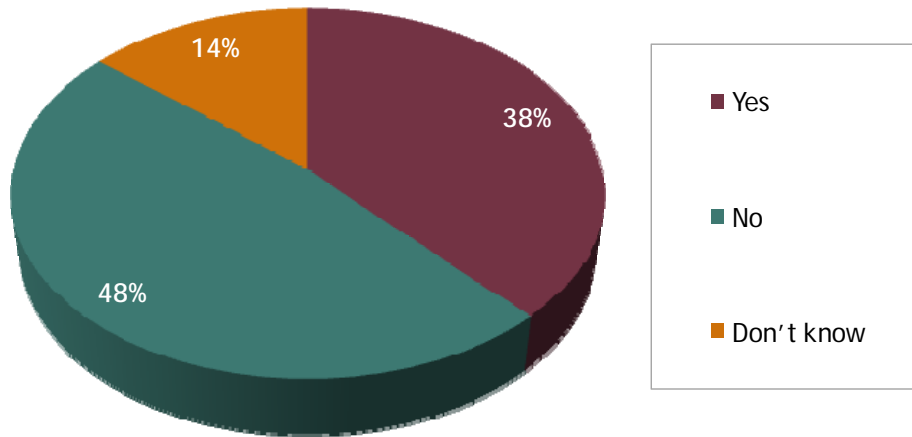
N=70

If "Yes", do you feel that your company's KRIs provide an adequate reflection of the actual quality of relationships with providers?



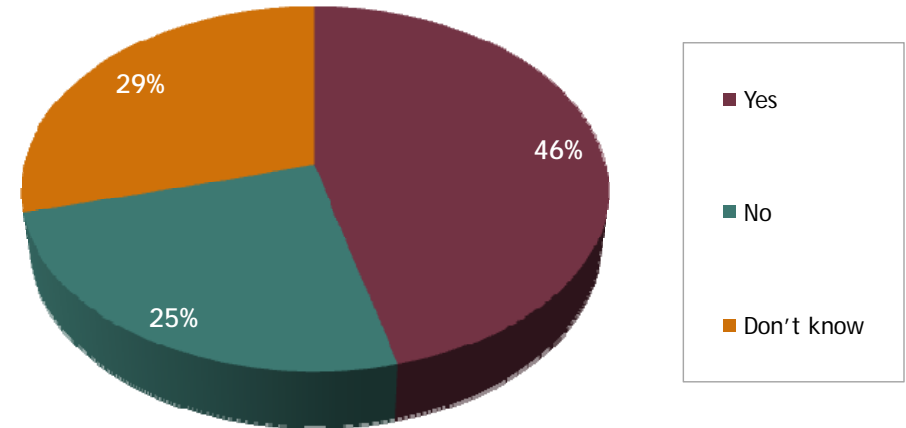
N=18

Does your company currently use a formal set of relationship metrics to evaluate your relationships with sponsors (Key Relationship Indicators [KRIs])?



N=77

If "Yes", do you feel that your company's KRIs provide an adequate reflection of the actual quality of relationships with sponsors?



N=24

Is the use of an adequate set of KPIs and/or KRIs associated with greater satisfaction with provider performance and/or with greater outsourcing efficiency?

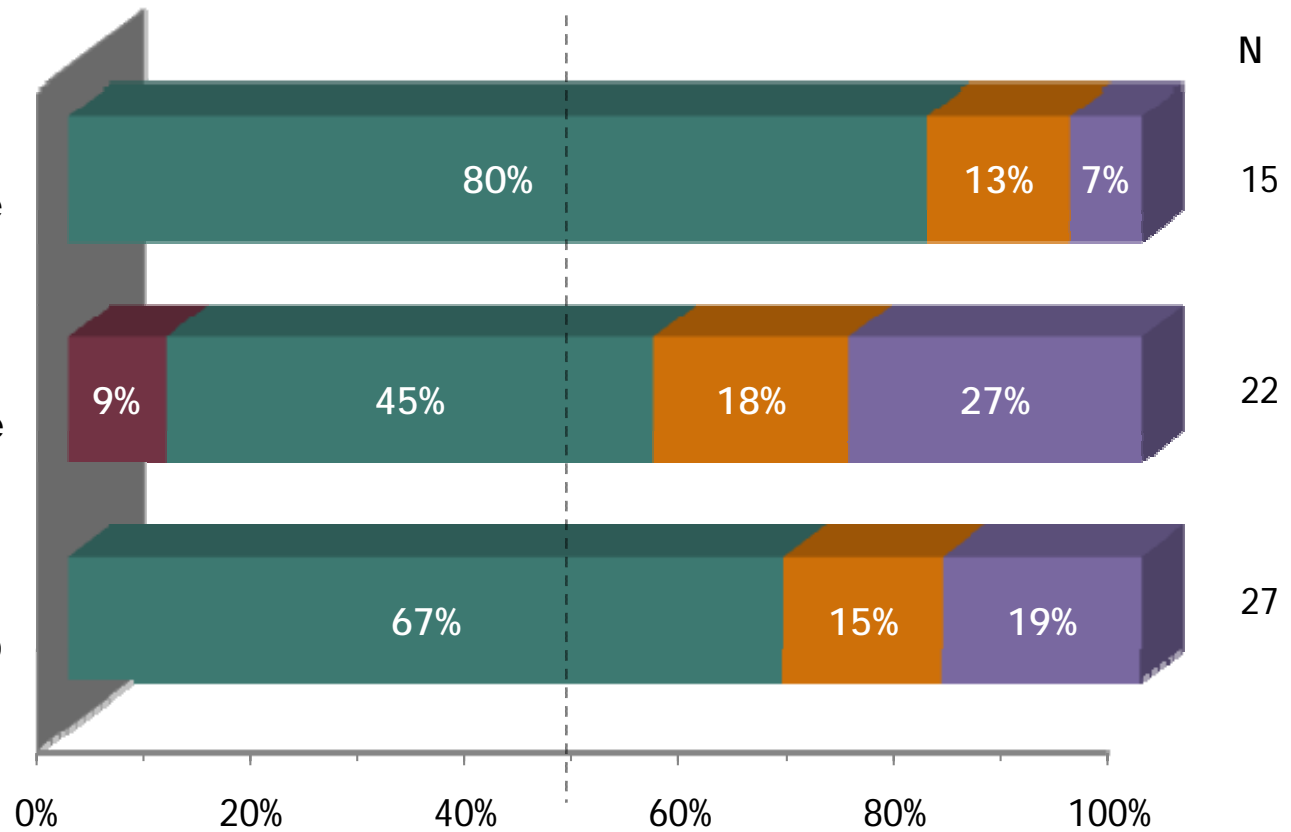
In general, how satisfied are you with the work that has been done for you by clinical service providers?

Does your company currently use the measurement of Key Performance Indicators (KPIs) to evaluate the performance of clinical service providers?

Yes, and adequate

Yes, but not adequate

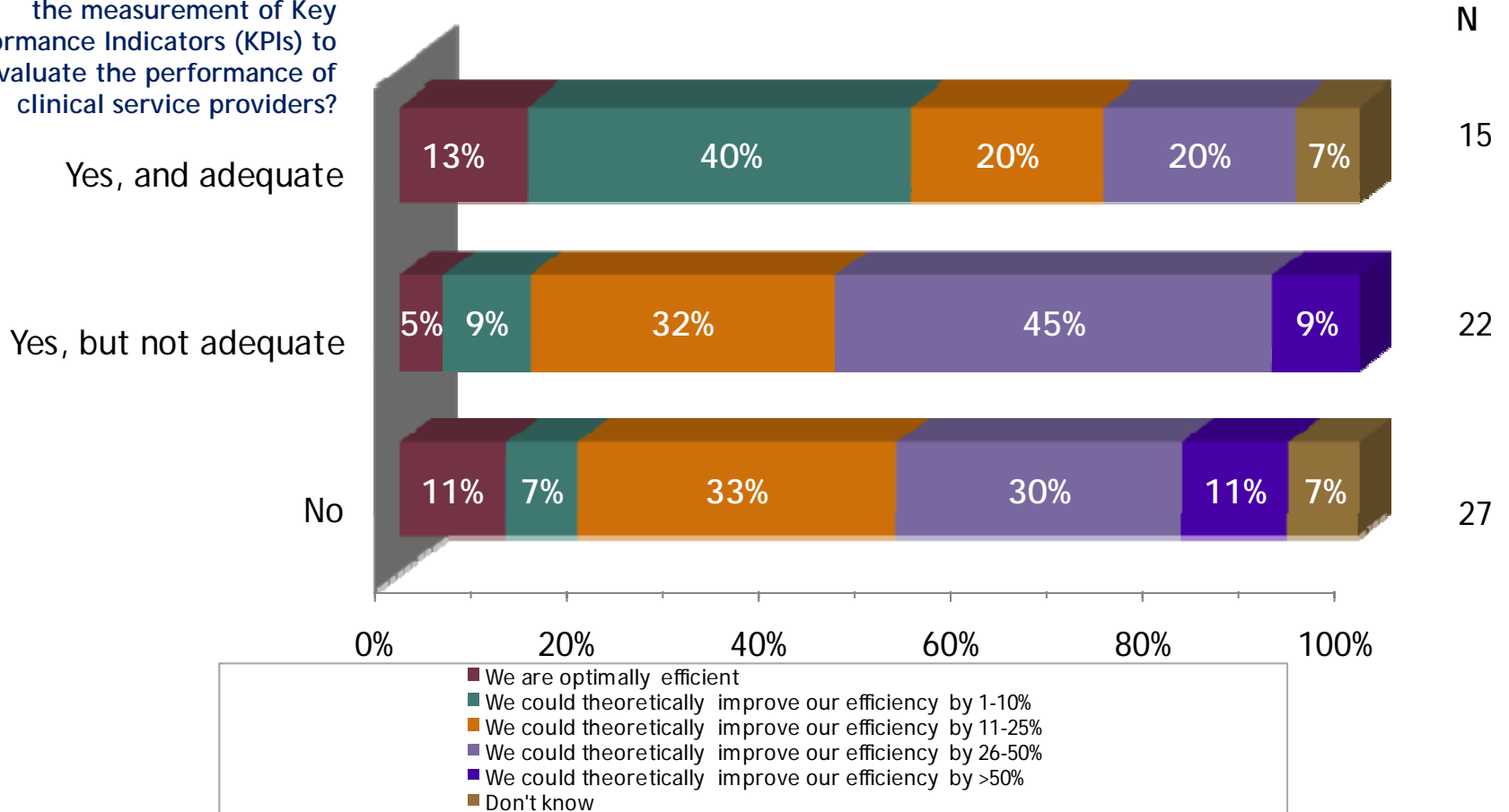
No



Very satisfied Somewhat satisfied Neither satisfied nor dissatisfied Somewhat dissatisfied Very dissatisfied

In terms of the internal resources required to manage outsourced projects effectively, how much room for improvement do you feel that your company has?

Does your company currently use the measurement of Key Performance Indicators (KPIs) to evaluate the performance of clinical service providers?



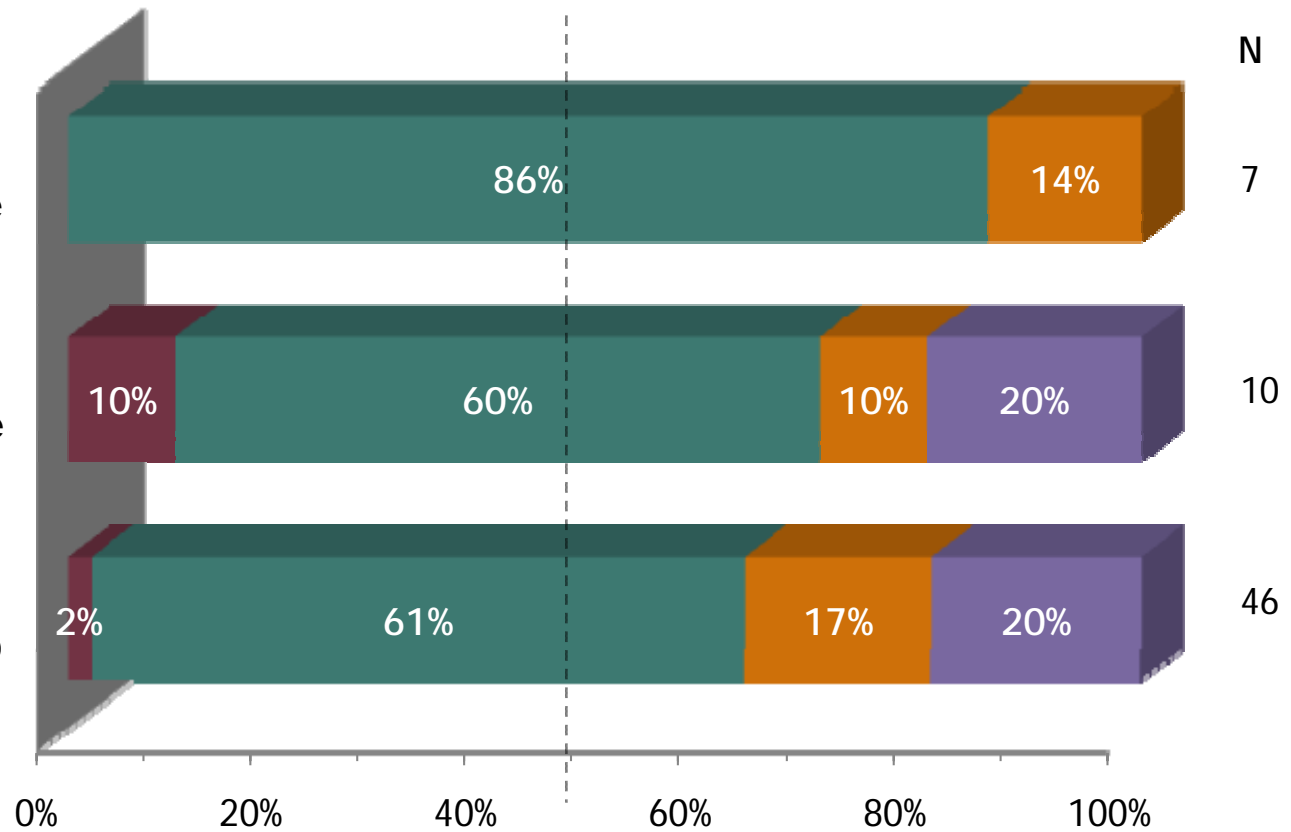
In general, how satisfied are you with the work that has been done for you by clinical service providers?

Does your company currently use a formal set of relationship metrics to evaluate your relationships with clinical service providers (Key Relationship Indicators [KRIs])?

Yes, and adequate

Yes, but not adequate

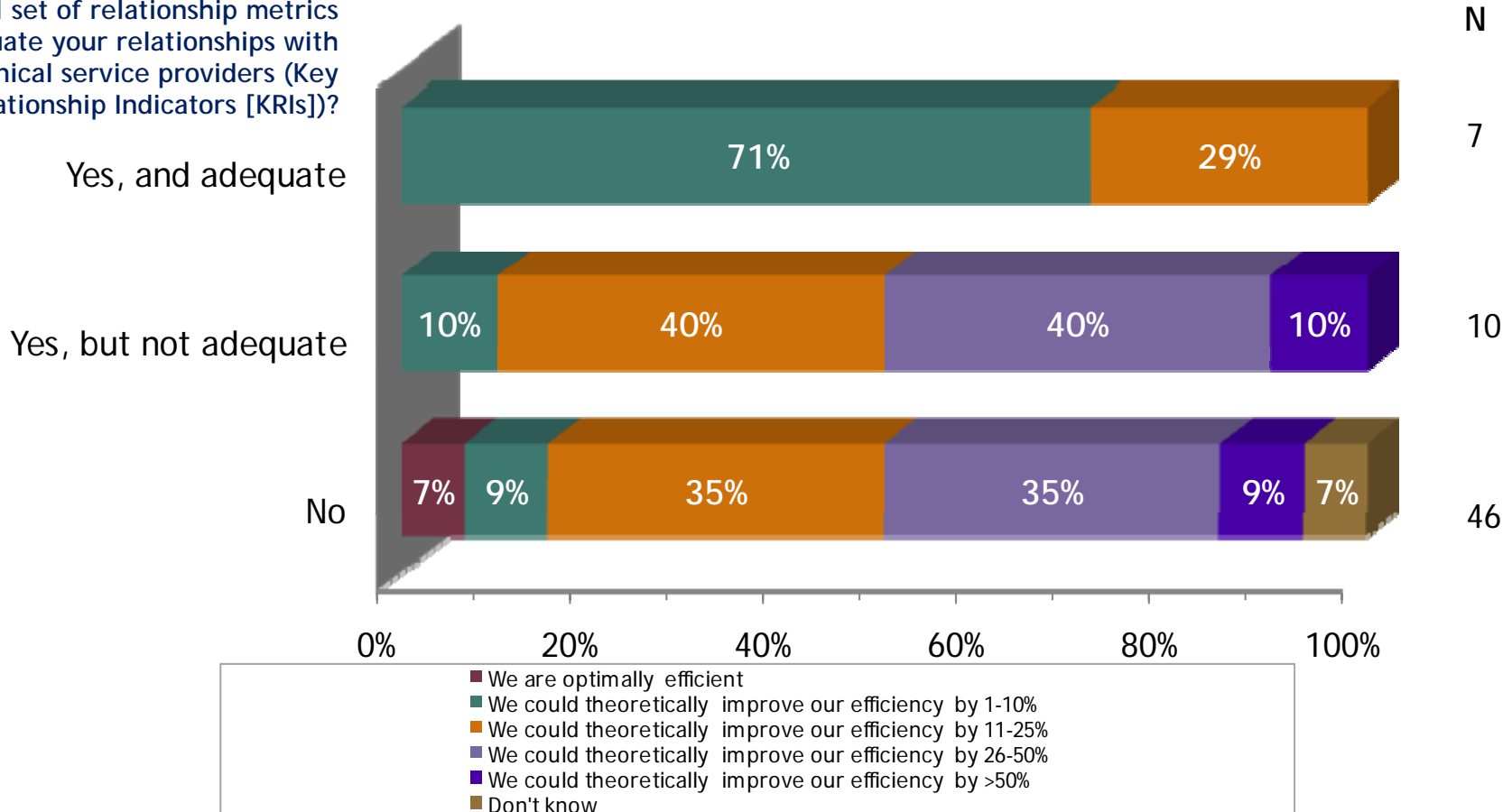
No



Very satisfied Somewhat satisfied Neither satisfied nor dissatisfied Somewhat dissatisfied Very dissatisfied

In terms of the internal resources required to manage outsourced projects effectively, how much room for improvement do you feel that your company has?

Does your company currently use a formal set of relationship metrics to evaluate your relationships with clinical service providers (Key Relationship Indicators [KRIs])?

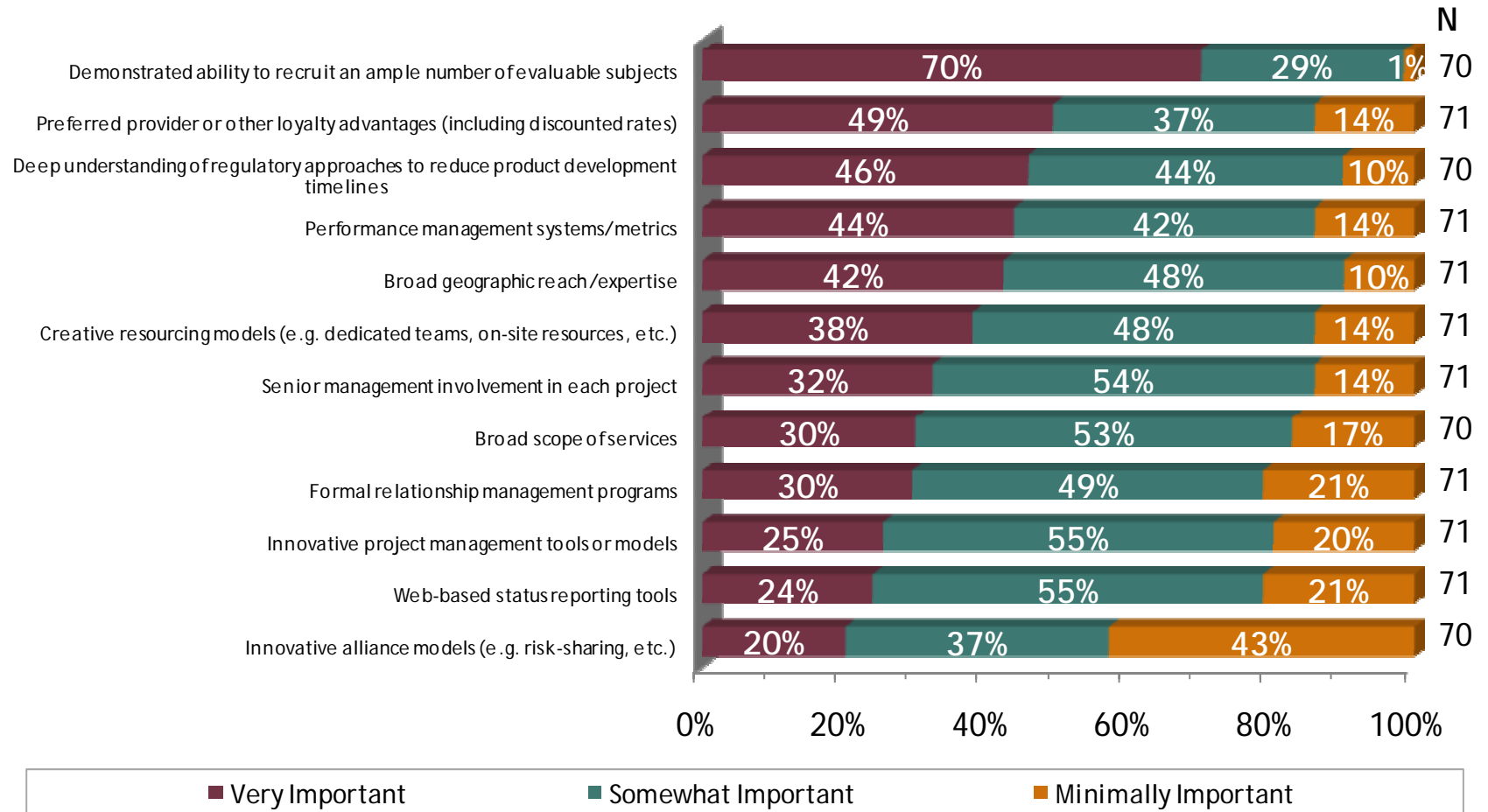




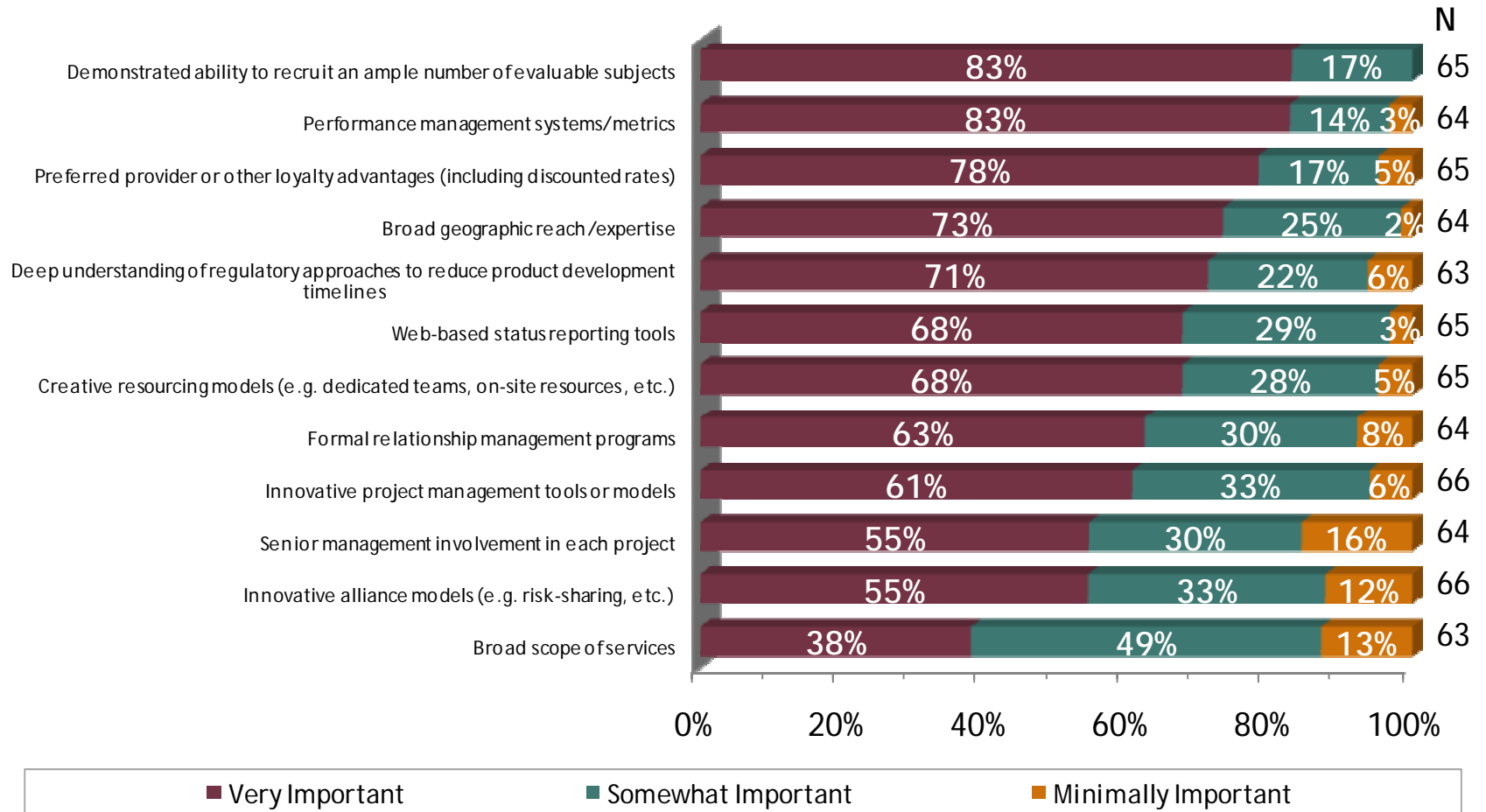
# Key Findings: New Priorities in the Choice of Providers

2009 Avoca Industry Survey

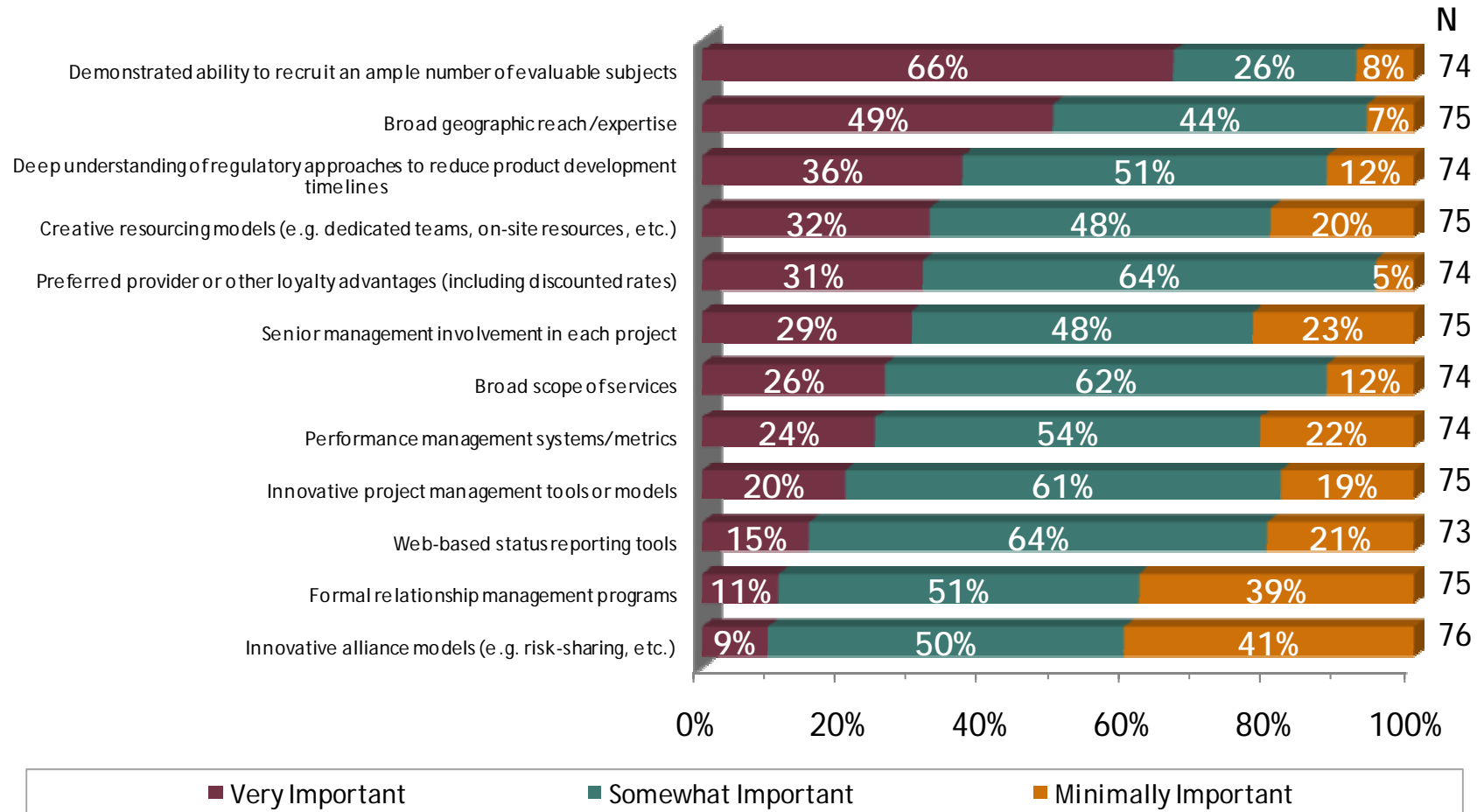
## Importance in Evaluating Prospective Providers: Past



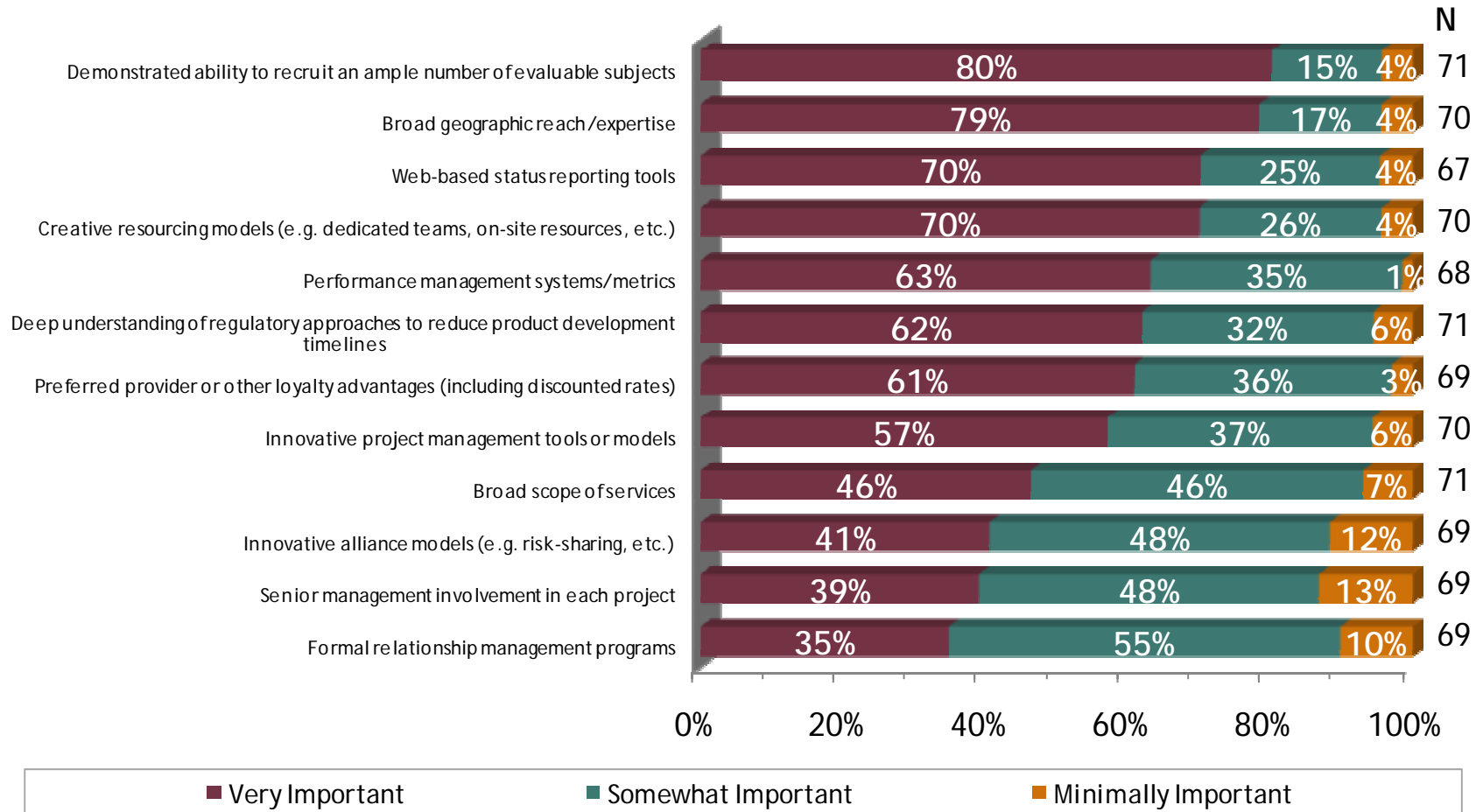
## Importance in Evaluating Prospective Providers: Future



## Importance to Sponsors in Evaluating Prospective Providers: Past

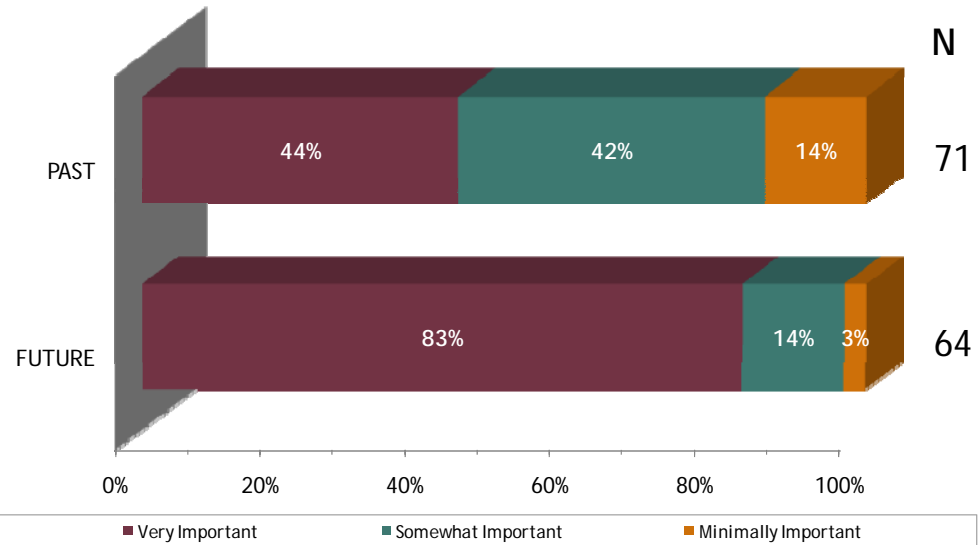


## Importance to Sponsors in Evaluating Prospective Providers: Future

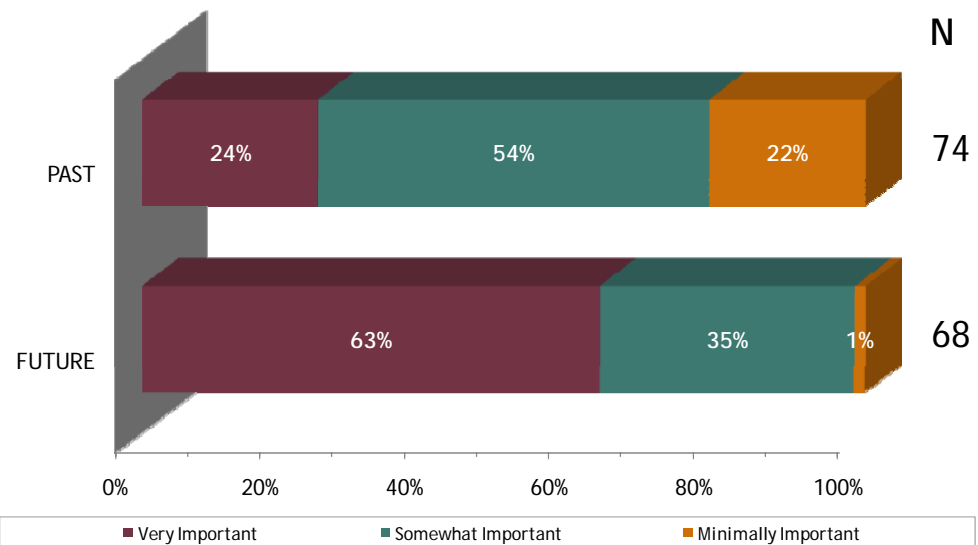


## Performance management systems/metrics

Importance in Evaluating Prospective Providers:

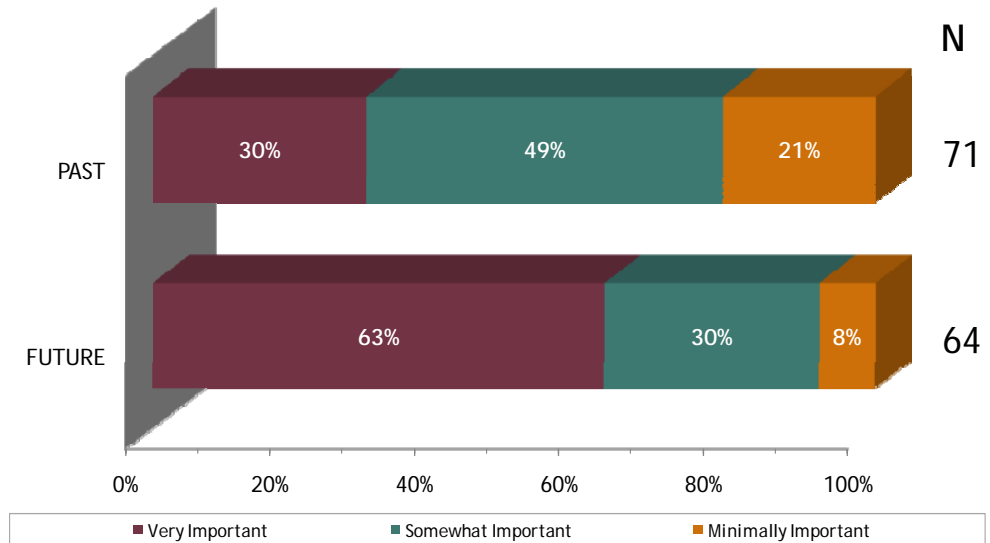


Importance Sponsors Gave/Will Give in Evaluating Prospective Providers:

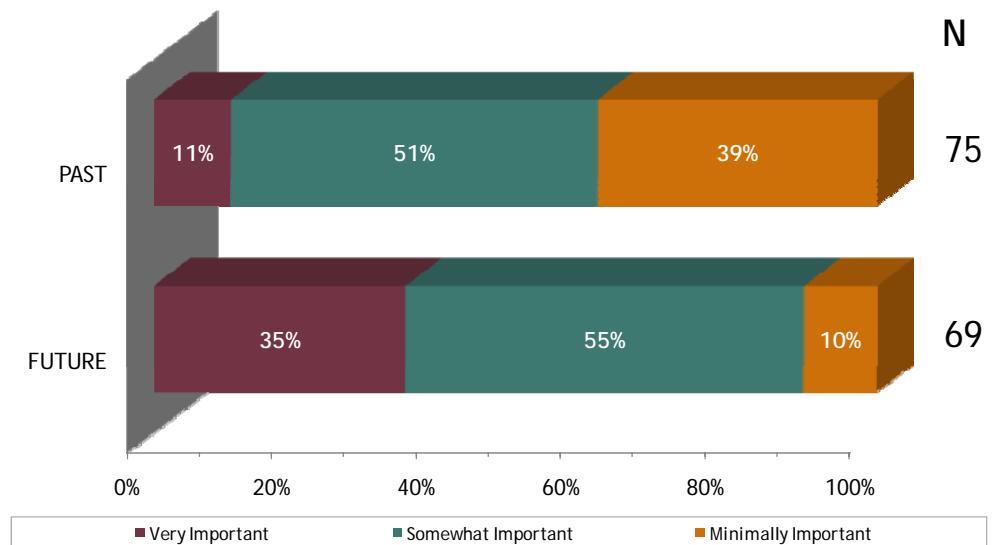


## Formal relationship management programs

Importance in  
Evaluating Prospective  
Providers:

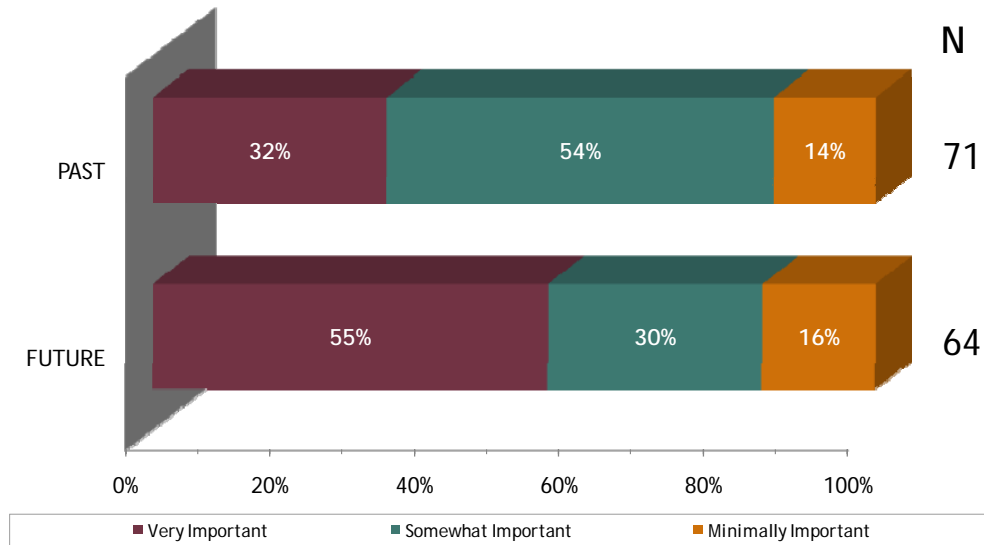


Importance Sponsors  
Gave/Will Give in  
Evaluating Prospective  
Providers:

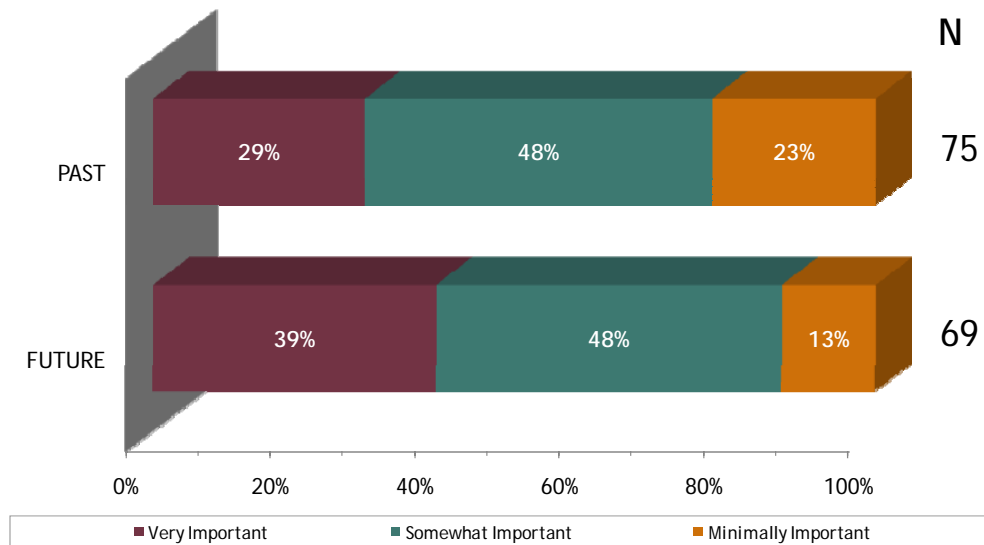


## Senior management involvement in each project

Importance in Evaluating Prospective Providers:



Importance Sponsors Gave/Will Give in Evaluating Prospective Providers:



What will be the best ways for providers to differentiate themselves, increase market share, and gain loyal customers over the next 5 years?

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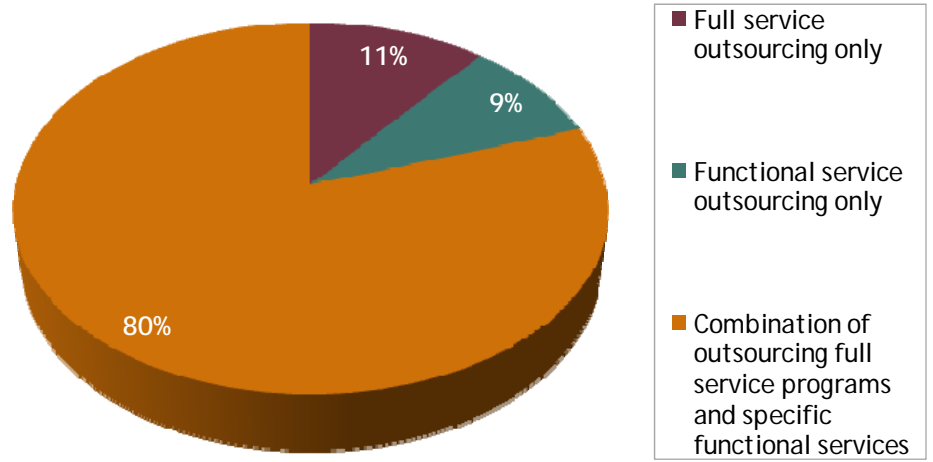
- ▶ Higher caliber of personnel
- ▶ Better personnel retention
- ▶ Less focus on BD, more focus on data demonstrating reliable performance record, customer satisfaction data
- ▶ Formal relationship management programs
- ▶ Flexibility in resourcing models
- ▶ Ability to partner starting with early stage development
- ▶ Niche/regional specialization, desire for smaller, more focused providers
- ▶ Truly innovative technology solutions for information sharing
- ▶ Ability to help sponsors clarify expectations at award stage
- ▶ Transparency, demonstration of commitment to success
- ▶ Desire for more personalized attention, less transactional

# Key Findings: Outsourcing Models

2009 Avoca Industry Survey

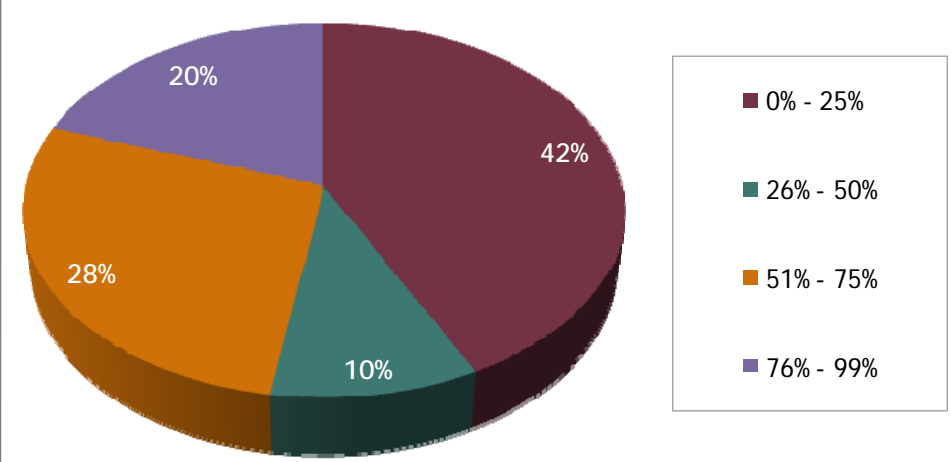
# Sponsor Results: FSP vs. Full-Service Outsourcing

What approach or model do you currently use when outsourcing clinical projects?



N=70

If a combination of outsourcing approaches, what approximate percentage of your outsourced projects are full service programs?

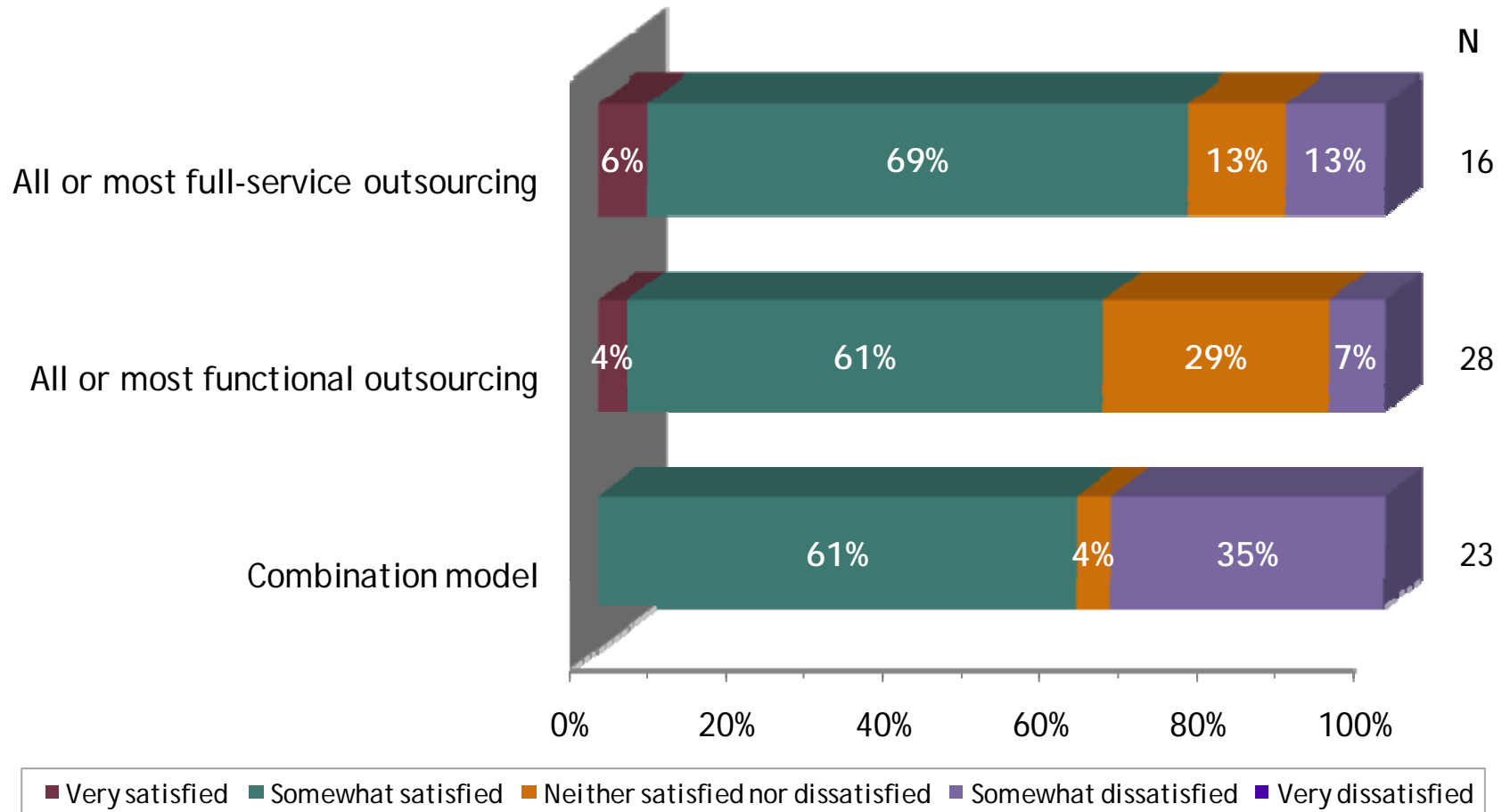


N=61

Is the use of functional service outsourcing associated with greater satisfaction with provider performance and/or with greater outsourcing efficiency?

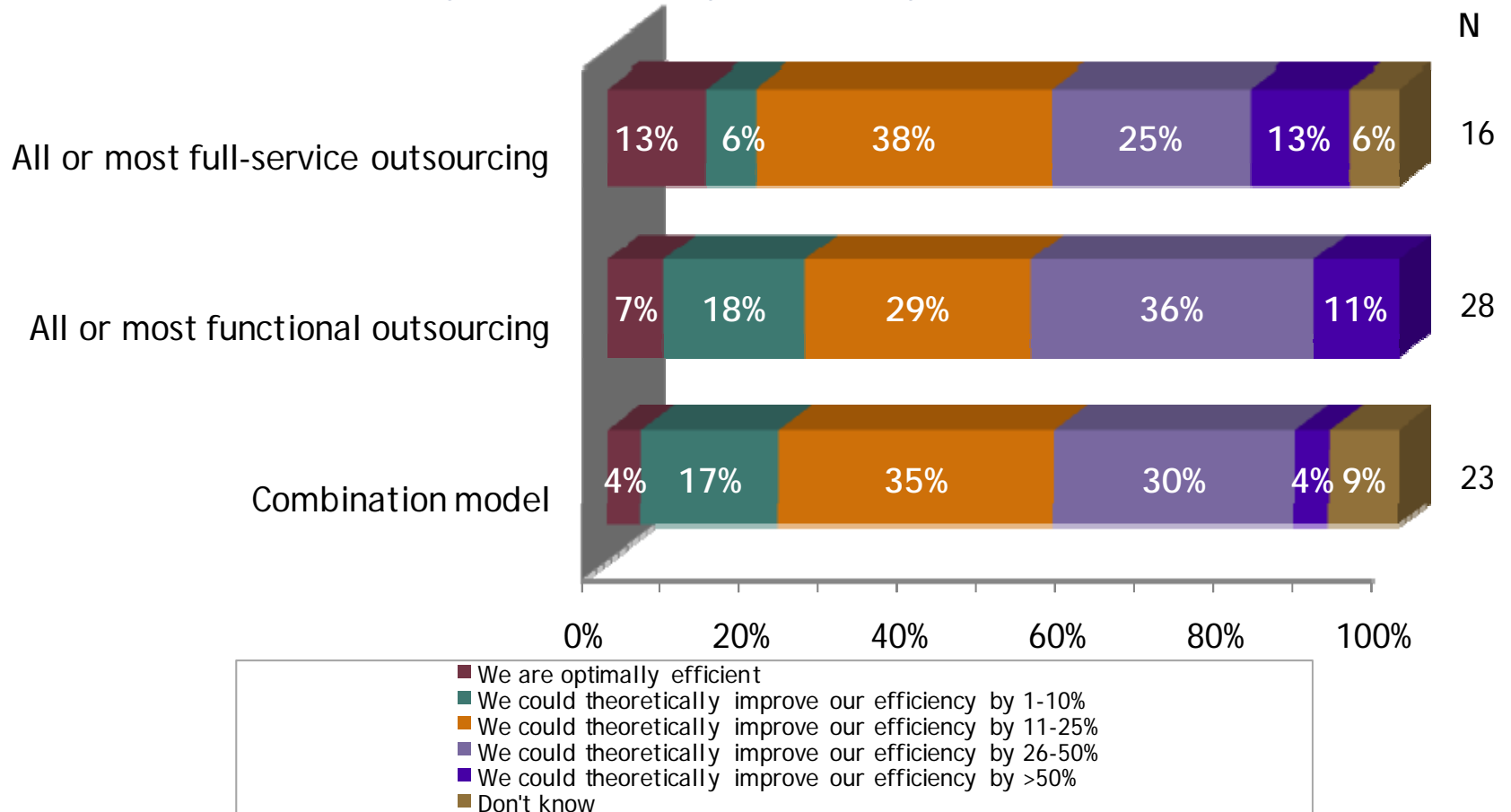
# Satisfaction by Outsourcing Model: Sponsors

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



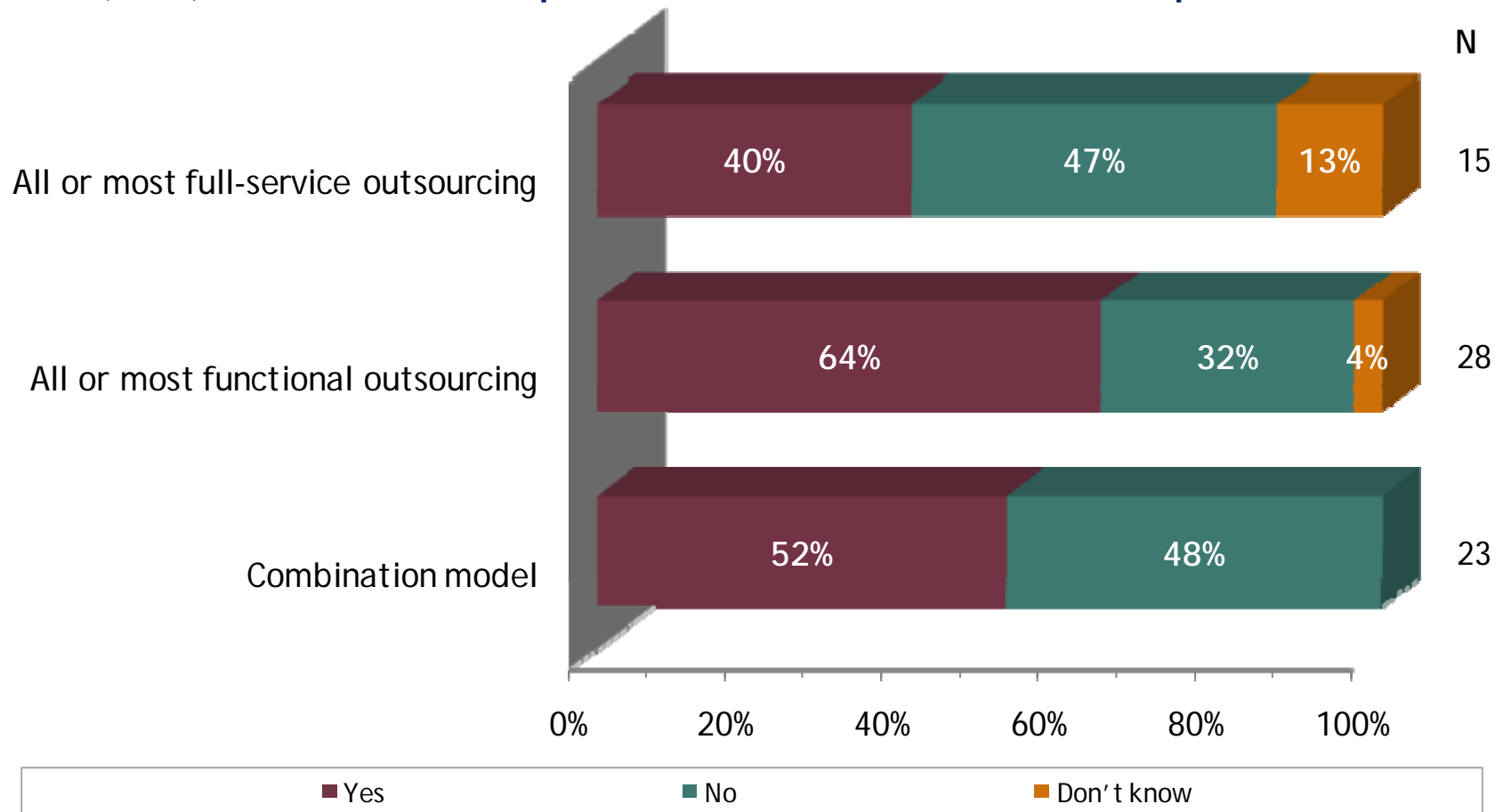
# Efficiency by Outsourcing Model: Sponsors

In terms of the internal resources required to manage outsourced projects effectively, how much room for improvement do you think your company currently has?



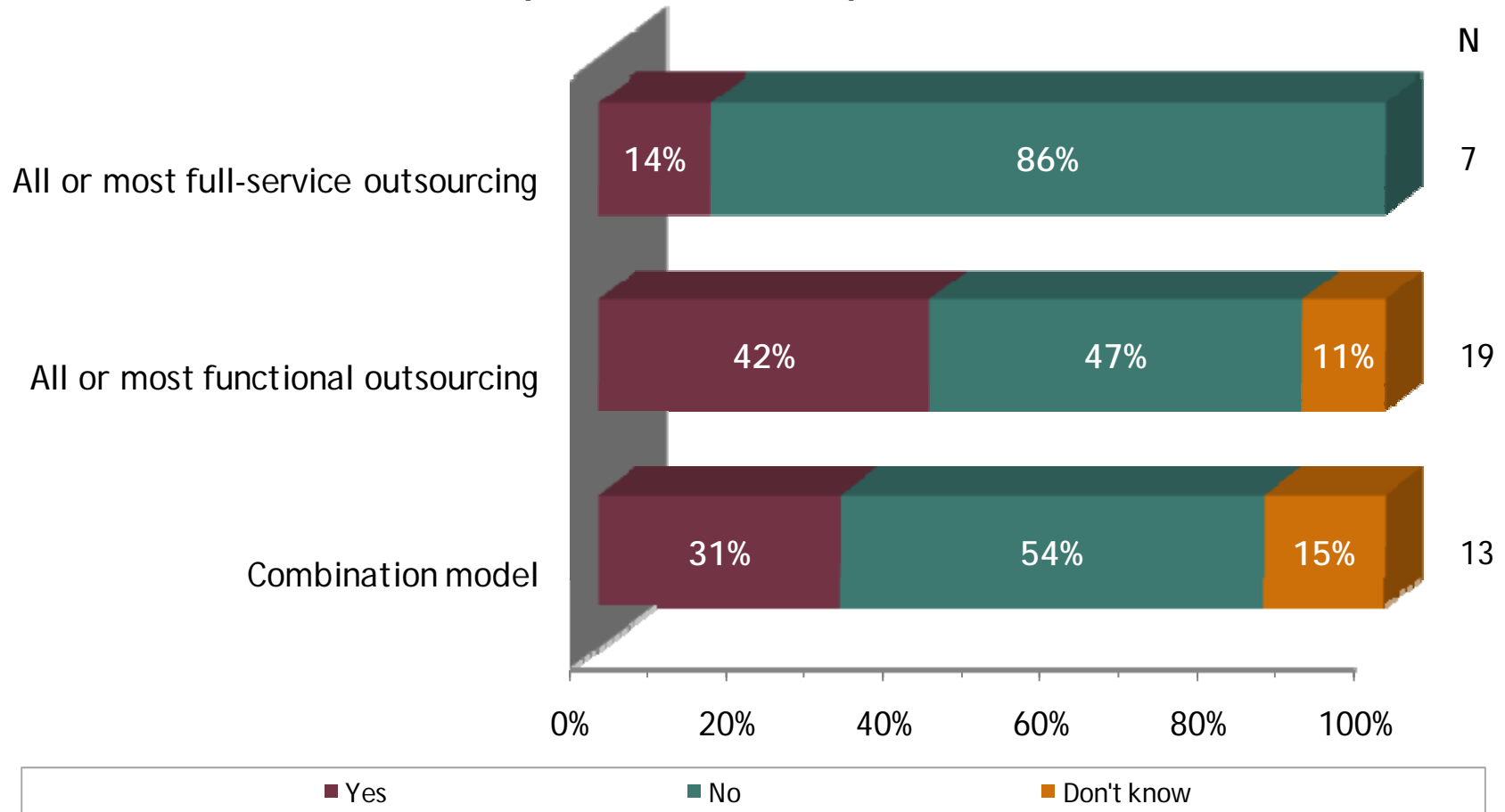
# Use of KPIs by Outsourcing Model: Sponsors

Does your company currently use the measurement of Key Performance Indicators (KPIs) to evaluate the performance of clinical service providers?



# Adequacy of KPIs by Outsourcing Model: Sponsors

If "Yes", do you feel that your company's KPIs provide an adequate reflection of the true performance of providers?





# Key Findings: Considerations for Smaller Sponsor Companies

2009 Avoca Industry Survey

# Sponsor Results by Company Size

Between now and 2014, do you believe that your company will be under pressure to achieve a greater level of efficiency in your relationships with CROs and other providers of clinical research services?

Is your company among the top 10 companies in revenue in your industry?

N

28

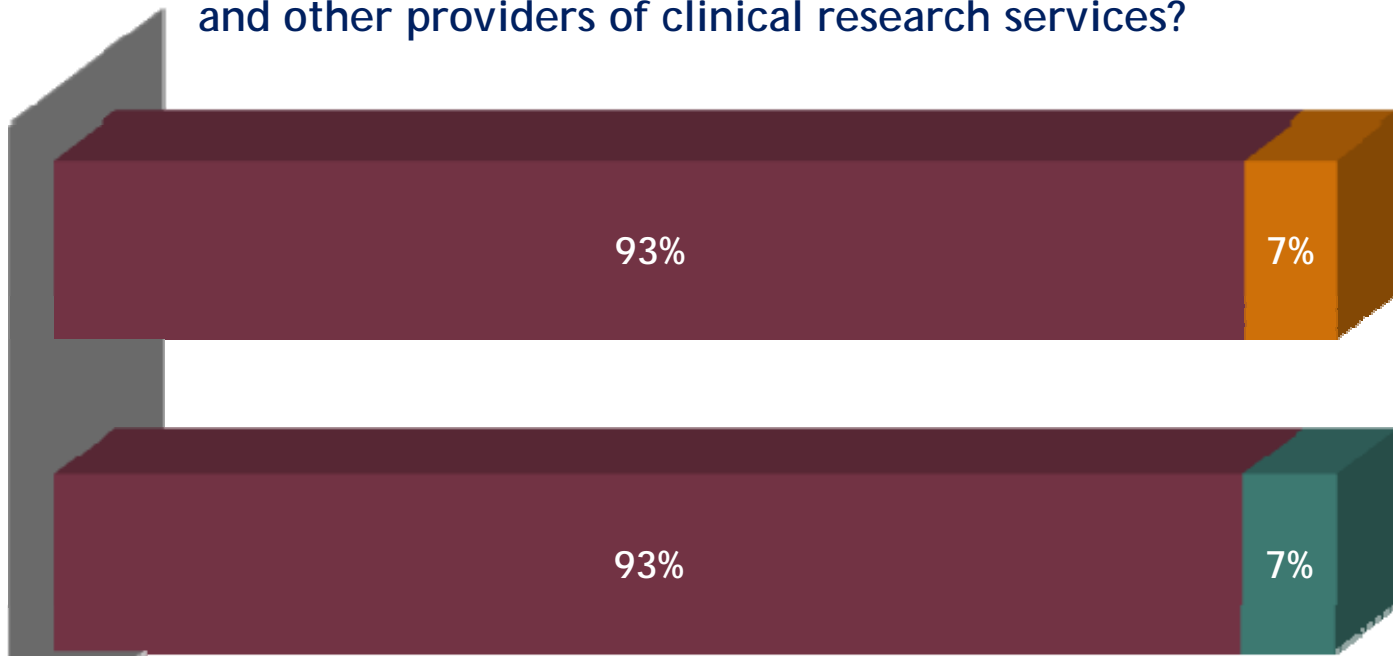
41

Yes

No

0% 20% 40% 60% 80% 100%

■ Yes ■ No ■ Don't know



# Sponsor Results by Company Size

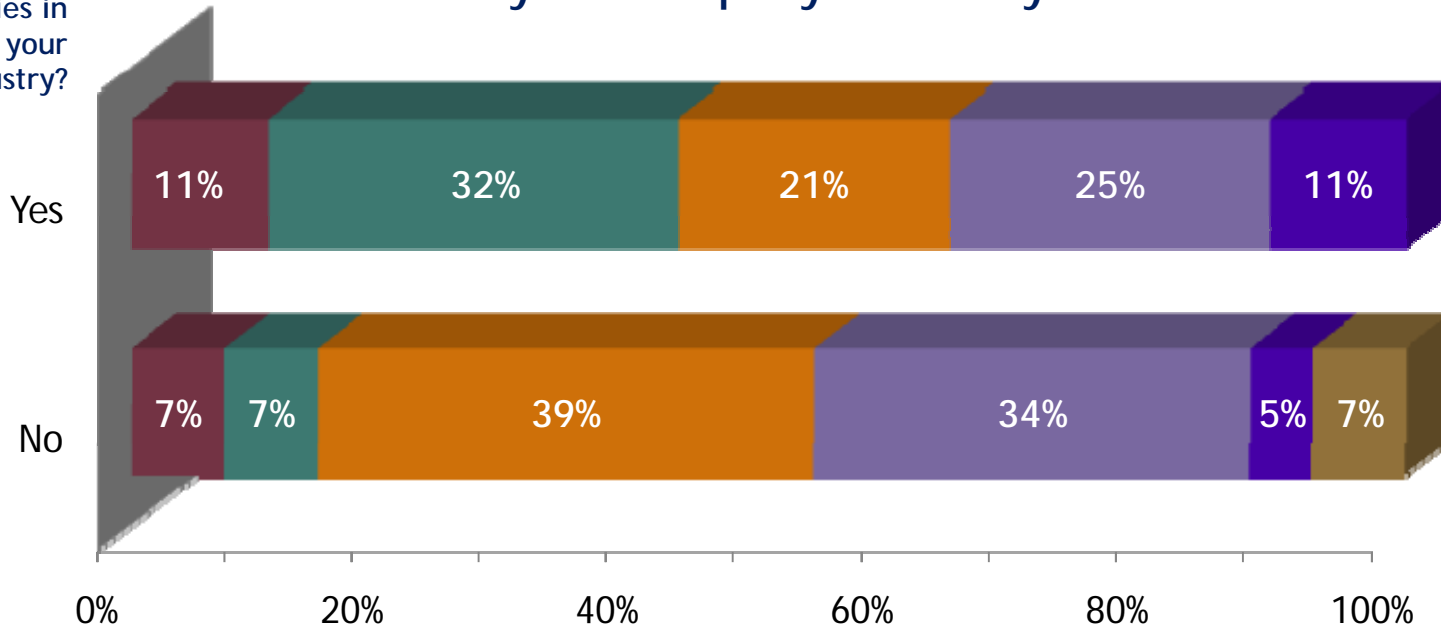
In terms of the internal resources required to manage outsourced projects effectively, how much room for improvement do you think your company currently has?

Is your company among the top 10 companies in revenue in your industry?

N

28

41



- We are optimally efficient
- We could theoretically improve our efficiency by 1-10%
- We could theoretically improve our efficiency by 11-25%
- We could theoretically improve our efficiency by 26-50%
- We could theoretically improve our efficiency by >50%

# Sponsor Results by Company Size

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

Is your company among the top 10 companies in revenue in your industry?

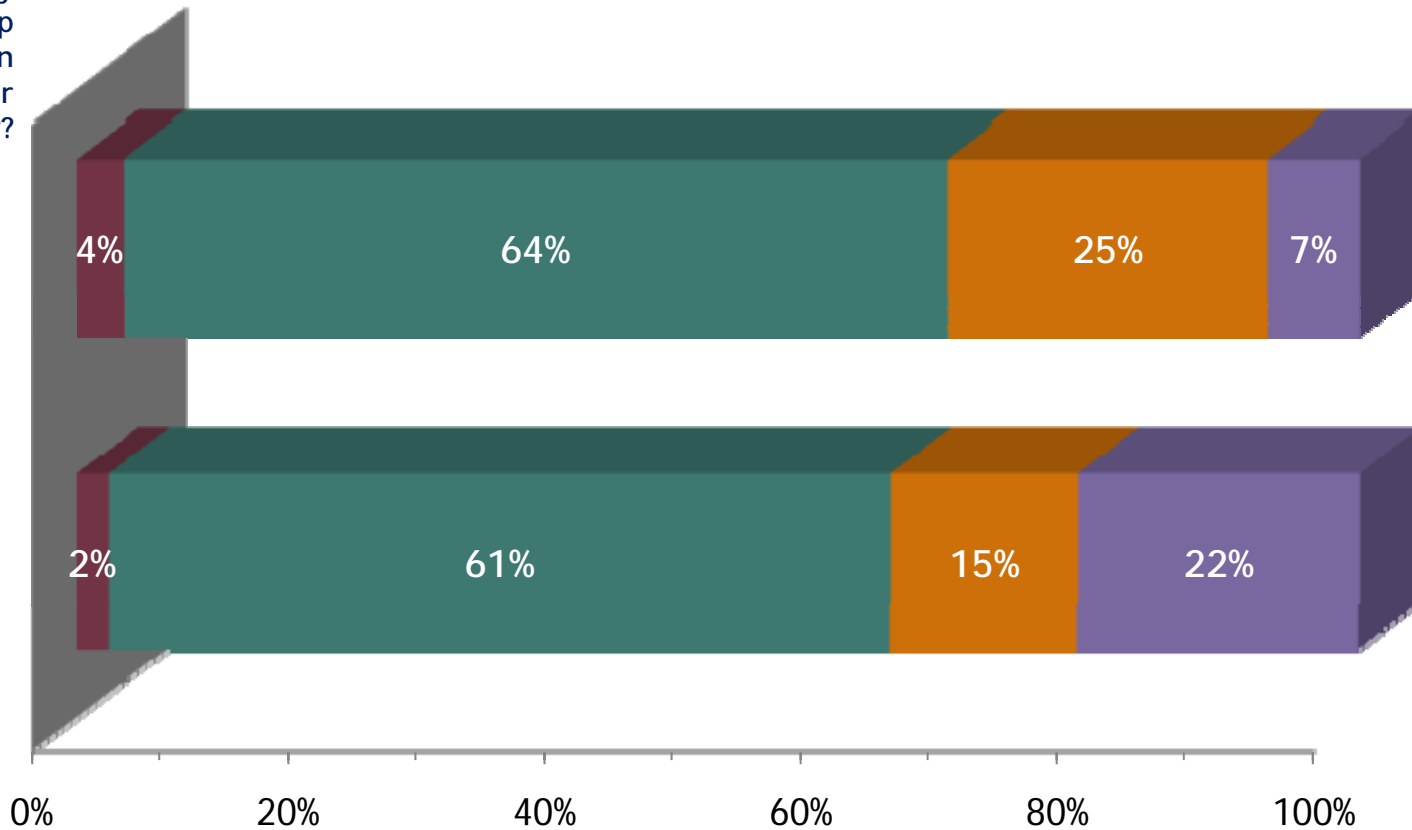
N

28

41

Yes

No



Very satisfied Somewhat satisfied Neither satisfied nor dissatisfied Somewhat dissatisfied Very dissatisfied

# Sponsor Results by Company Size

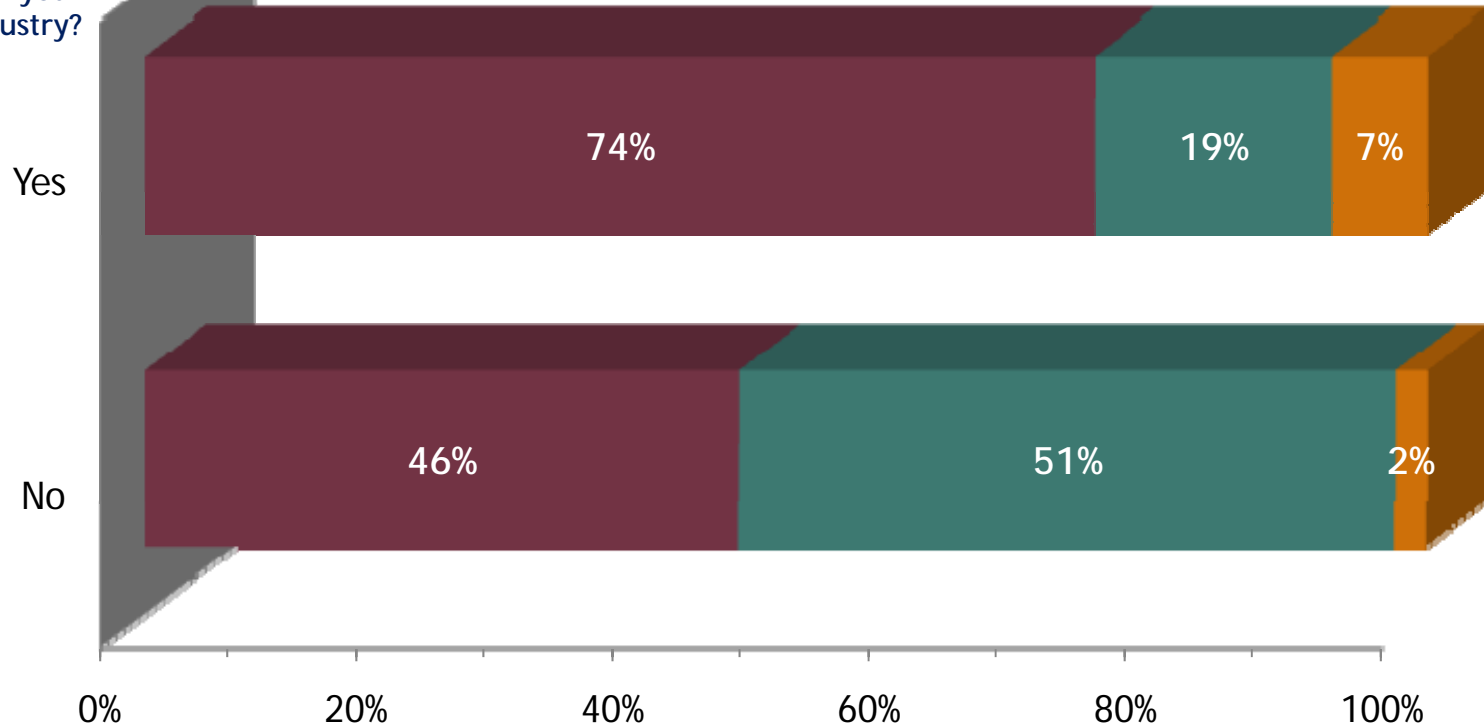
Does your company currently use the measurement of Key Performance Indicators (KPIs) to evaluate the performance of clinical service providers?

Is your company among the top 10 companies in revenue in your industry?

N

27

41



# Sponsor Results by Company Size

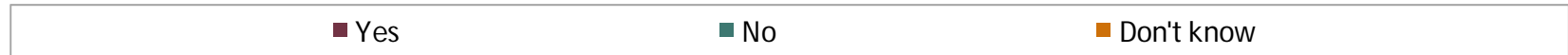
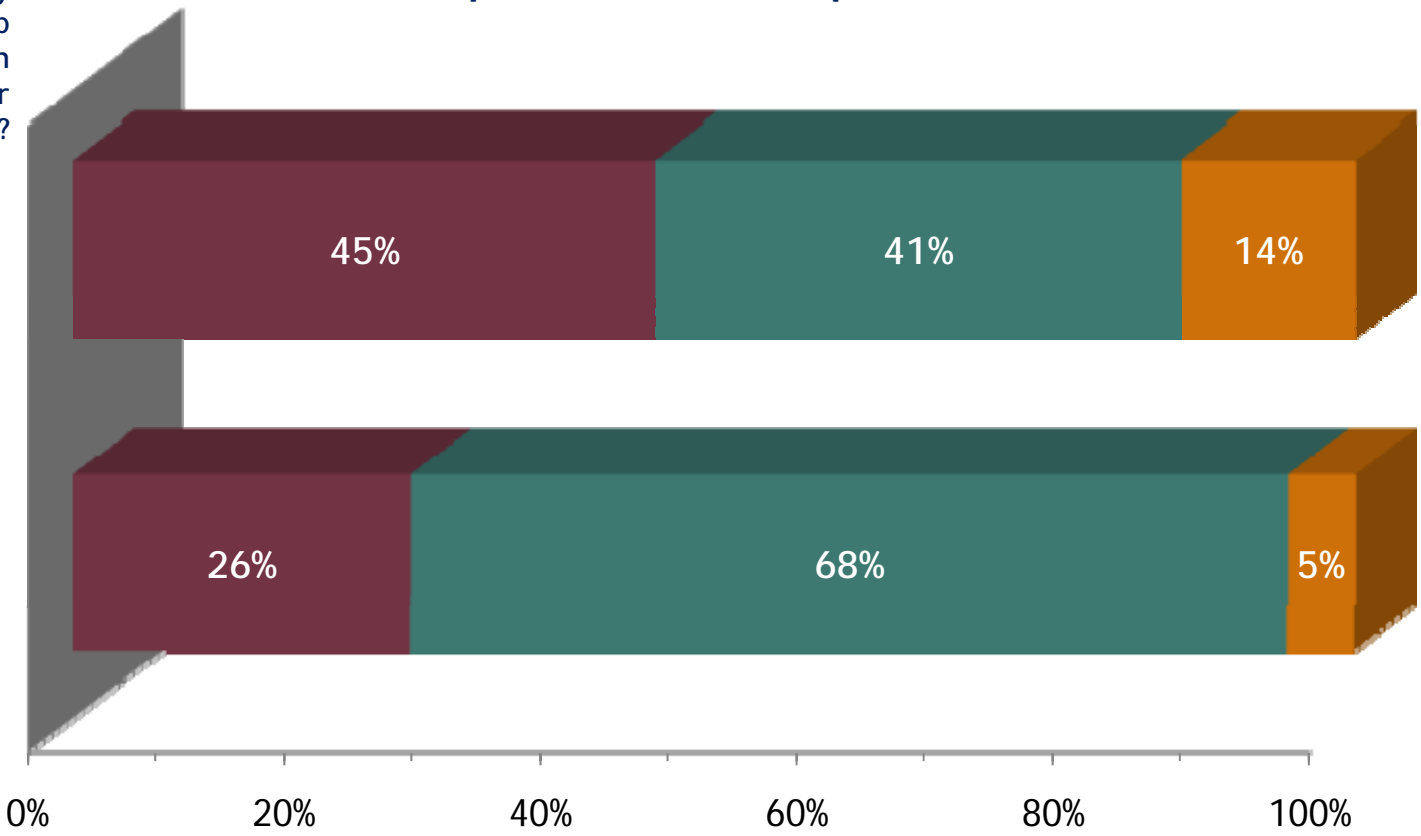
If "Yes", do you feel that your company's KPIs provide an adequate reflection of the true performance of providers?

Is your company among the top 10 companies in revenue in your industry?

N

22

19



# Sponsor Results by Company Size

## Does your company currently use a formal set of relationship metrics to evaluate your relationships with clinical service providers (Key Relationship Indicators [KRIs])?

Is your company among the top 10 companies in revenue in your industry?

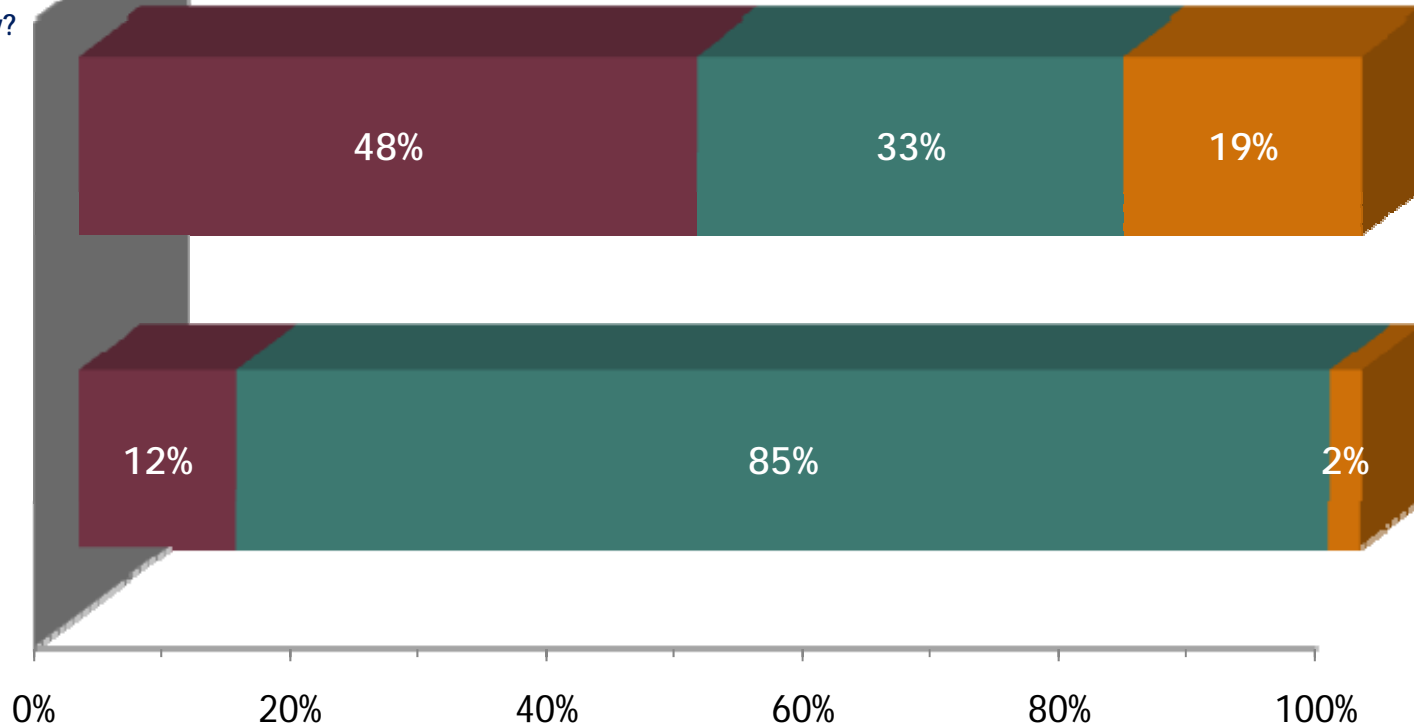
N

27

41

Yes

No



Yes

No

Don't know

## CONCLUSIONS

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- ▶ The pressure to achieve a greater level of efficiency in outsourced clinical development activities is widespread throughout the industry.
- ▶ Nearly all sponsor and provider respondents to the survey were able to name concrete changes that their companies plan to make to their outsourcing strategies over the next 5 years, with the hope of achieving greater efficiency.
- ▶ A key and promising focus of these efforts will be on better measurement of provider performance and relationship quality. Currently, providers appear to be doing this more satisfactorily than are sponsors, and sponsors are looking to providers to supply such measurements.
- ▶ Sponsors are becoming more discerning and data-focused in the selection of providers, and are demanding more evidence of provider investment in the relationship.
- ▶ Many sponsor companies intend to define their outsourcing strategies more explicitly, particularly when it comes to the use of full-service vs. functional service outsourcing. Currently, a mix of approaches is often used and the data suggest a widespread lack of refinement in approach.
- ▶ Implementation of strategies and tactics aimed at greater outsourcing efficiency will be a particular challenge for smaller sponsor companies.

# Panel Perspectives

2009 Avoca Industry Survey

# Open Discussion: Q & A

2009 Avoca Industry Survey

The Avoca Group, Inc.

*Improving the Health of Critical Business Relationships*

Thank you

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