Helping companies build, measure and manage critical business relationships.

The New Reality: Strategic Partnerships Under Scrutiny

Are They Working and How Long Does It Take?

Executive Summary of The Avoca Group's 2012 Industry Survey Research



Introduction

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.
- Over the several years leading up to 2012, there was a well-established trend whereby sponsors' outsourced clinical development work had been increasingly consolidated within a small number of strategic partnerships.
- Although the objectives and status of several of these strategic partnerships had been discussed in a variety of settings, there had been no industry-wide study of the outcomes of these partnerships and of the approaches used to their implementation and management.
- Therefore, for the topic of Avoca's 2012 Industry Survey, we chose to ask sponsor and service provider companies to share their experiences with and specific practices pertaining to strategic partnerships.
- This Executive Summary will present and summarize a selection of the data collected in this survey program.

Introduction

Introduction

- Specifically, the "Reality of Implementing New Outsourcing Strategies" survey explored respondents' experiences and views regarding:
 - Prevalence, characteristics, and maturity of existing strategic partnerships
 - Level of personal experience with strategic partnerships
 - Objectives for strategic partnerships
 - Satisfaction with the outcomes of strategic partnerships, both overall and with respect to specific objectives, including innovation
 - Tools and practices used for implementation and management of strategic partnerships, and extent to which each has been helpful
 - Prevalence and impact of risk sharing in strategic partnerships
 - Needs, issues and best practices in strategic partnering.
- In the survey, a strategic partnership was defined as "a long-term contractual commitment between two organizations that seeks to achieve specific business objectives by maximizing the effectiveness of each participant's resources. Strategic partnerships are generally characterized by process alignment, and by risk-sharing or other provisions serving to align business objectives."

Methods

Methods: 2012 Avoca Industry Survey

- The survey was web-based, with links directing respondents to the appropriate instruments:
 - Sponsor perspective
 - Provider perspective
- In addition to providing general information, each respondent was also asked to select the one "index" strategic partnership with which he/she had the most direct experience, and to report about that relationship specifically.
- Respondents who completed the survey were offered an executive summary of the survey results.
- Data was "scrubbed" of entries that were inappropriate, duplicate, etc.
 - Small consultancies and sites were excluded from this analysis.

Respondents

Characteristics of Respondents

Sponsor Respondents

- 147 respondents from 89 companies
- ▶ 72% from pharmaceutical companies, 23% biotechnology, 3% device, 2% other
- ▶ 50% from "Top 20" companies with respect to revenue

Clinical Service Provider Respondents

- 97 respondents from 84 companies
- ▶ 50% from CROs, 50% from other (specialty) providers

Respondents

List of Sponsor Companies

2C Tech Corporation	Boston Scientific	HAL Allergy	Otsuka
Actelion Pharmaceuticals	Bristol Myers Squibb	ImClone Systems Corporation	Panacea Biotec
Aeterna Zentaris	Cadence Pharmaceuticals	Incozen Therapeutics	Pfizer
Allos Therapeutics	Celgene Corporation	Inovio Pharmaceuticals	Pharmasset
Amgen	Celtic Therapeutics	Ipsen	PhaseDesign Research
Amylin Pharmaceuticals	CMC Biologics	Janssen	Purdue Pharma
Apollidon	CooperVision	Johnson & Johnson	Recordati
Apotex	Covidien	Karo Bio	Regenron
Ardea	СТІ	LEO Pharma	Rigel Pharmaceuticals
Ariad	Cubist	Lundbeck	Roche
Astellas Pharma	Cylene Pharmaceuticals	Lupin	Sandoz
Astex Pharmaceutical	Daiichi Sankyo	MAP Pharmaceuticals	Sangart
AstraZeneca	Debiopharm	MedImmune	Sanofi
Bavarian Nordic	Dr Reddy's	Merck	Shire
Baxter	Eisai	Merz Pharmaceuticals	Taiho Pharma
Bayer	Elan Pharmaceuticals	Millennium Pharmaceuticals	TARIS Biomedical
BHC Dermatology	Eli Lilly	Mitsubishi Pharma Europe	Teva Pharmaceuticals
BI Vetmedica	Endo Pharmaceuticals	Molecular Insight Pharmaceuticals	Vaccinex
Bial-Portela	Ferring Pharmaceutical	Mpex Pharmaceuticals	Valeant
Biogen Idec	Genentech	Mundipharma Research	Vertex
Biotest AG	Genzyme	Neos Therapeutics	
Blue Ocean Biomedical	Grunenthal	Noven Pharmaceuticals	
Boehringer Ingelheim	GSK	Osho Biotech Research Institute	

List of Clinical Service Provider Companies

Clinical Trials of America	ICON Clinical Research	Quintiles
Clininvent	ICON Medical Imaging	RDP Clinical Outsourcing
CoreLab Partners	ImmunoSite Technologies	Recipharm
CoreRx	INC Research	Research Across America
Covance	LabConnect	R.H. Bouchard & Associates
CRF Health	LAMA Research	Rivergate Dermatology
CRN	Makrocare Clinical Research	Ronald Fehst Research Consultants
CTB Solutions	Medpace	RPS
Delta Waves	Medscape	SMS-Oncology
Differding Consulting	MGH Translational Medicine	Spectra Clinical Research
Dimensione Ricerca	Novella Clinical	Stiris Research
Employers Health	Paragon Biomedical	Tampa Medical Group
Endign	PharmaNet/i3	The Copernicus Group
EPS USA	PharmaPM Consulting	The Smithers Group
ERT	Pharm-Olam International	TKL Research
Eurofins	PHT Corporation	Trial Runners
ExecuPharm	Pierrel Research USA	Umanis
Fisher Clinical Services	PK Consulting	Vantage BioTrials
Harrison Clinical Research	PopsiCube	Veeda
Higginbotham Group	PRA	VirtualScopics
ICON Central Labs	PSBC	WuXi AppTec
	ClininventCoreLab PartnersCoreRxCovanceCRF HealthCRNCTB SolutionsDelta WavesDifferding ConsultingDimensione RicercaEmployers HealthEndignEPS USAERTEurofinsExecuPharmFisher Clinical ServicesHarrison Clinical ResearchHigginbotham Group	ClininventICON Medical ImagingCoreLab PartnersImmunoSite TechnologiesCoreRxINC ResearchCovanceLabConnectCRF HealthLAMA ResearchCRNMakrocare Clinical ResearchCTB SolutionsMedpaceDelta WavesMedscapeDifferding ConsultingMGH Translational MedicineDimensione RicercaNovella ClinicalEmployers HealthParagon BiomedicalEndignPharmaNet/i3EPS USAPharmePM ConsultingERTPharm-Olam InternationalEurofinsPHT CorporationExecuPharmPierrel Research USAFisher Clinical ServicesPK ConsultingHarrison Clinical ResearchPopsiCubeHigginbotham GroupPRA

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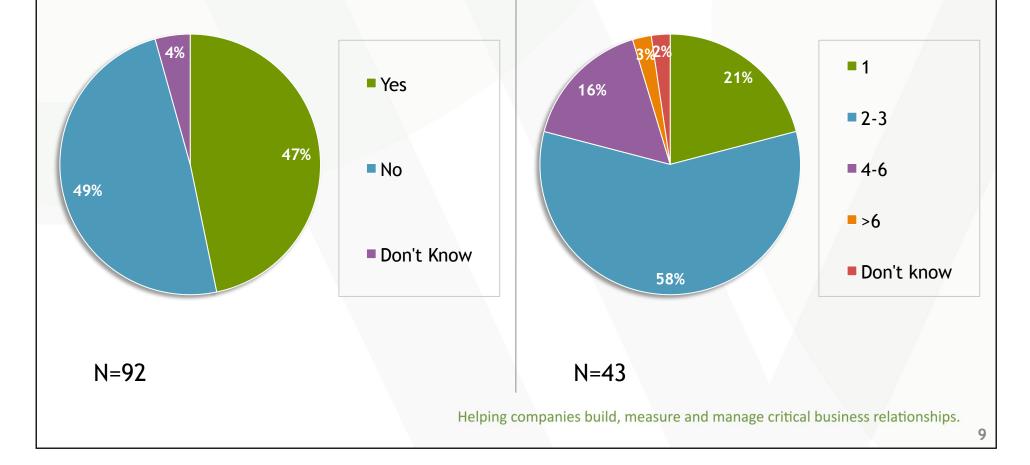
Results

Part One:

Prevalence of Strategic Partnerships between Sponsors and CROs

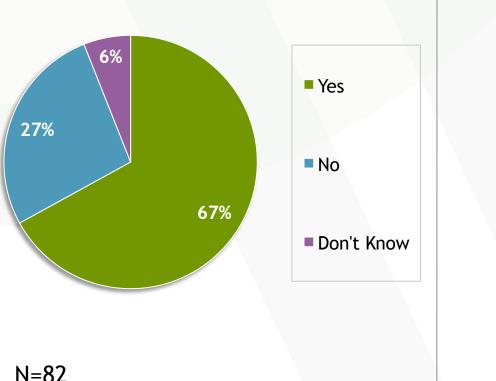


Does your current company have, or has it had, any "strategic partnerships" with clinical service providers? (one response per company) If "Yes", how many strategic partnerships does your company currently have? (one response per company)

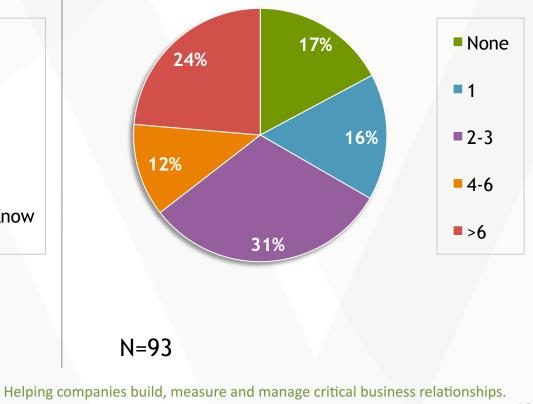


Clinical Service Provider Data

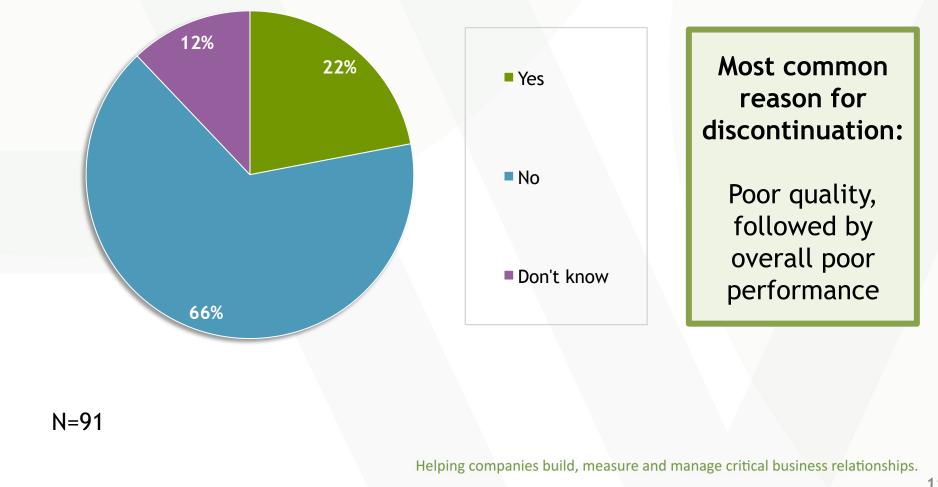
Does your current company have, or has it had, any "strategic partnerships" with sponsor companies? One response per company



With how many strategic partnerships have you personally had direct experience, either at your current company or in a previous position with a clinical service provider?



To your knowledge, has your company ever discontinued a strategic partnership? (one response per company)



Summary

Summary: Results Part One

- Forty-seven percent of the sponsor companies surveyed had had strategic partnerships with clinical service providers, and 67% of the service provider companies surveyed had had strategic partnerships with sponsors.
 - Sponsor companies were most likely (58%) to have 2 to 3 current partnerships. Twenty-one percent had only 1 such partnership, and 19% had more than 3 partnerships.
 - Most clinical service provider respondents (67%) had direct experience with at least 2 strategic partnerships. Only 17% had no direct experience with strategic partnerships.
- Twenty-two percent of sponsor companies reported having discontinued strategic relationships. Most commonly, these relationships were discontinued by sponsors because of poor quality of deliverables, followed by poor overall performance of the clinical service provider.

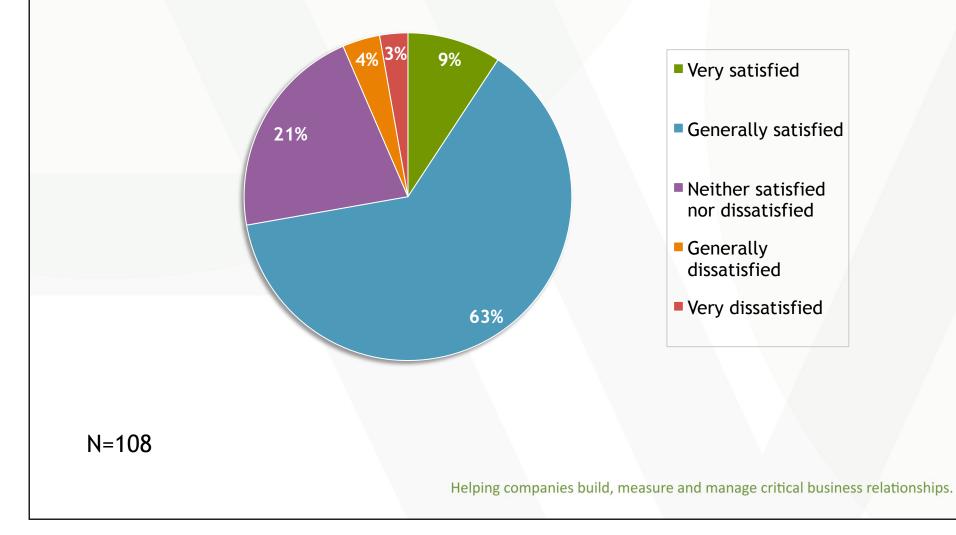
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Part Two:

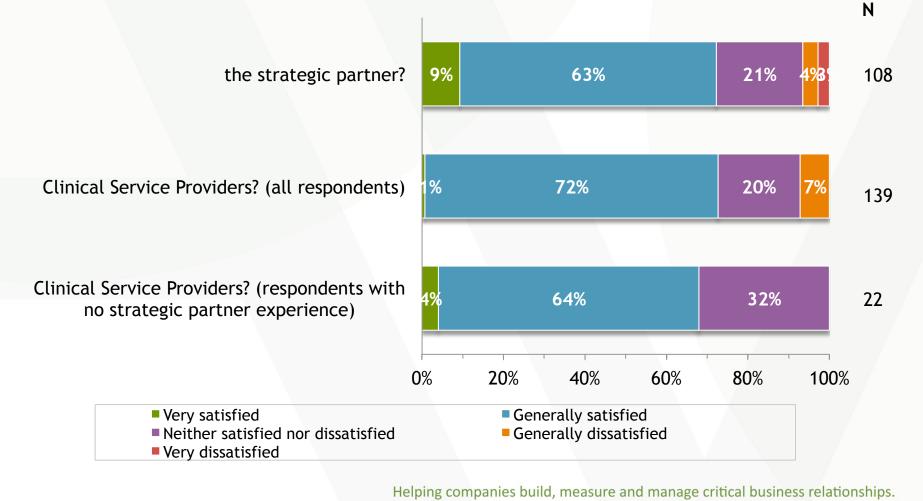
Levels of Satisfaction with Index Strategic Partnership



Overall, how satisfied are you with the work that has been done for you by the strategic partner?

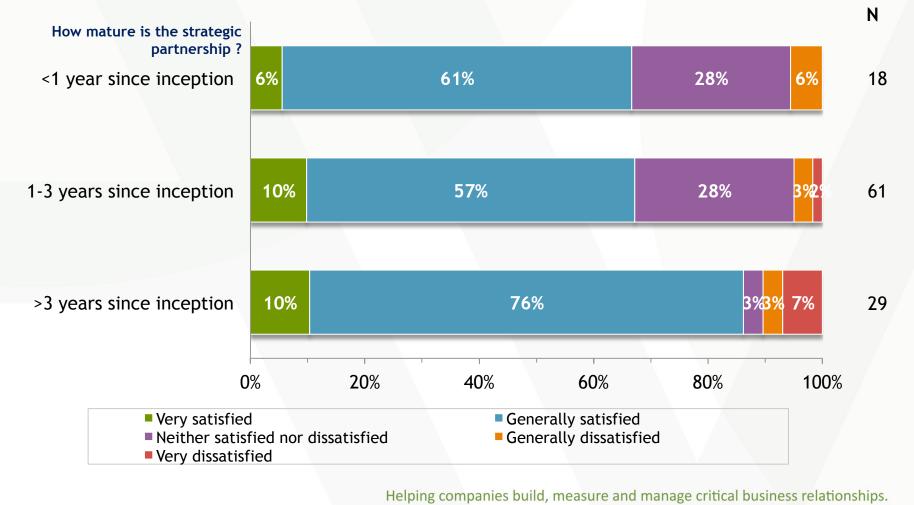


Overall, how satisfied are you with the work that has been done for you by...

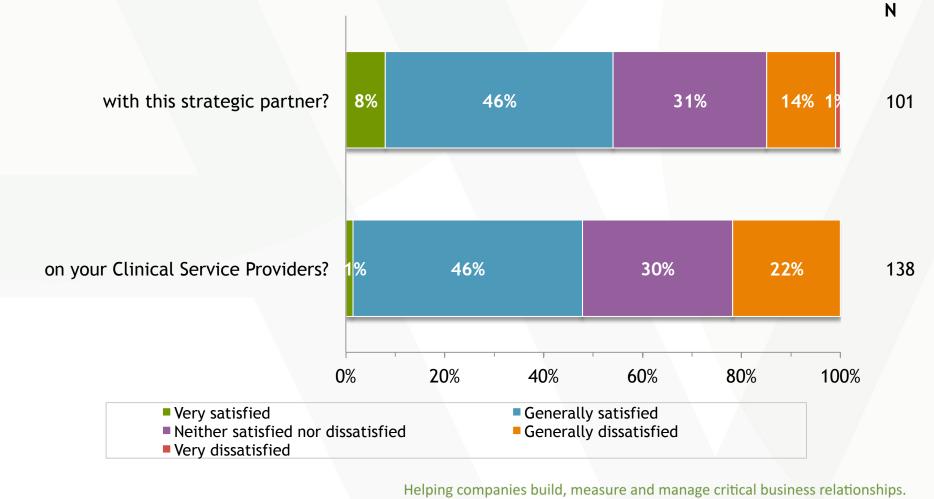


15

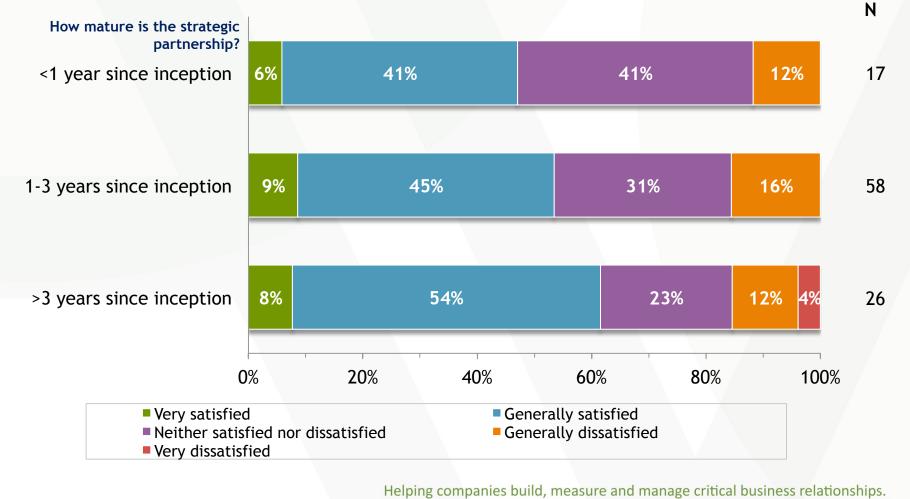
Overall, how satisfied are you with the work that has been done for you by the strategic partner?



In general, how satisfied are you with the value that you have received for the money spent...

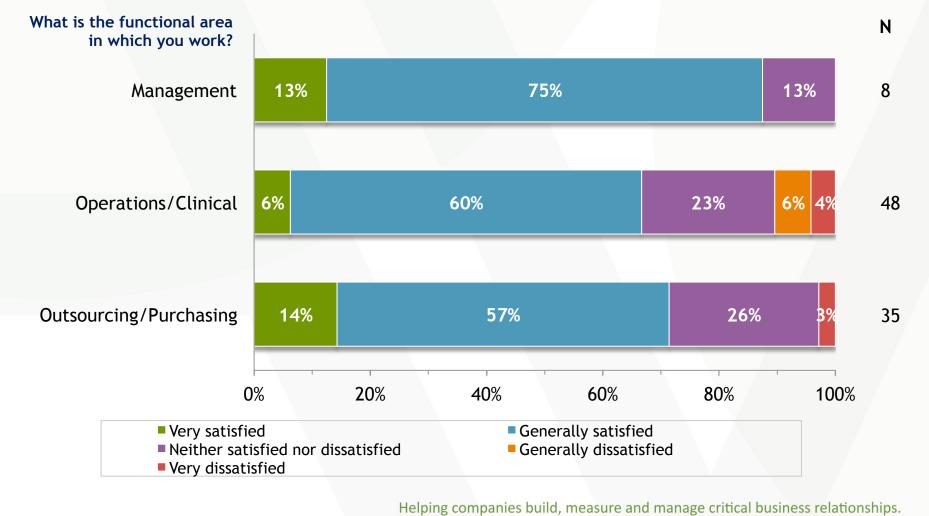


In general, how satisfied are you with <u>the value that you have received for the</u> <u>money spent</u> with this strategic partner?

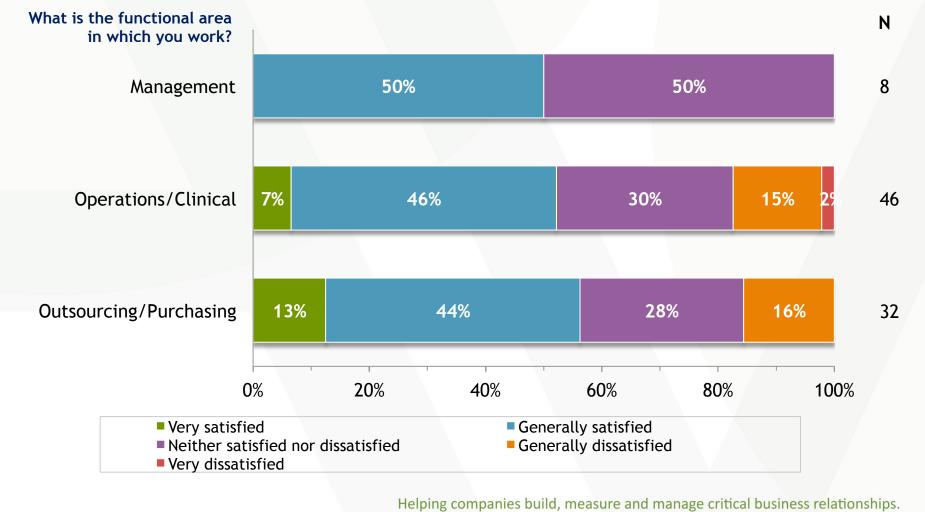


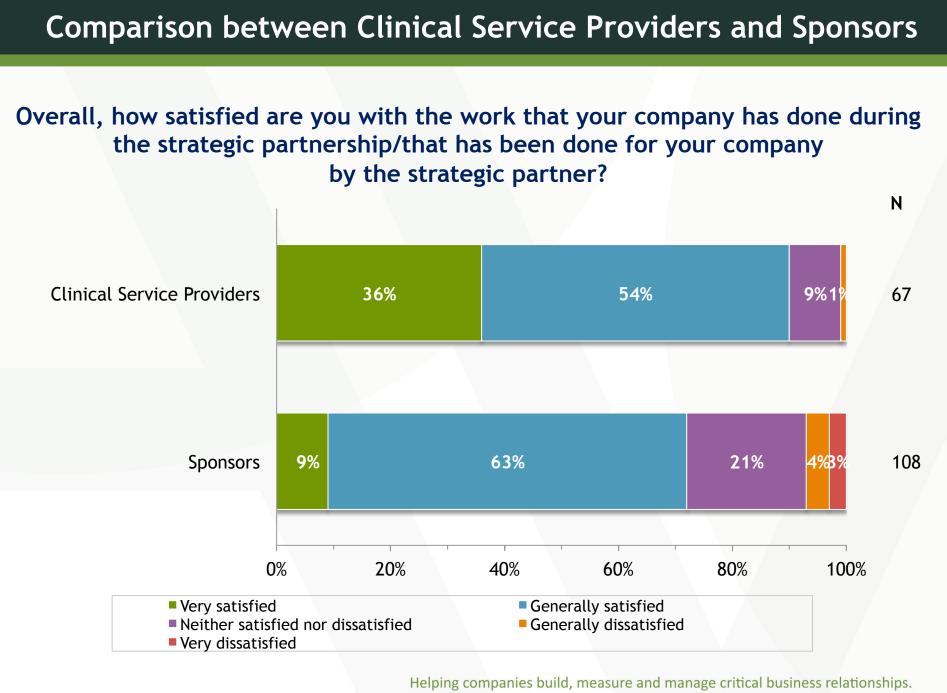
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Overall, how satisfied are you with the work that has been done for you by the strategic partner?



In general, how satisfied are you with the value that you have received for the money spent with this strategic partner?





Clinical Service Provider Data

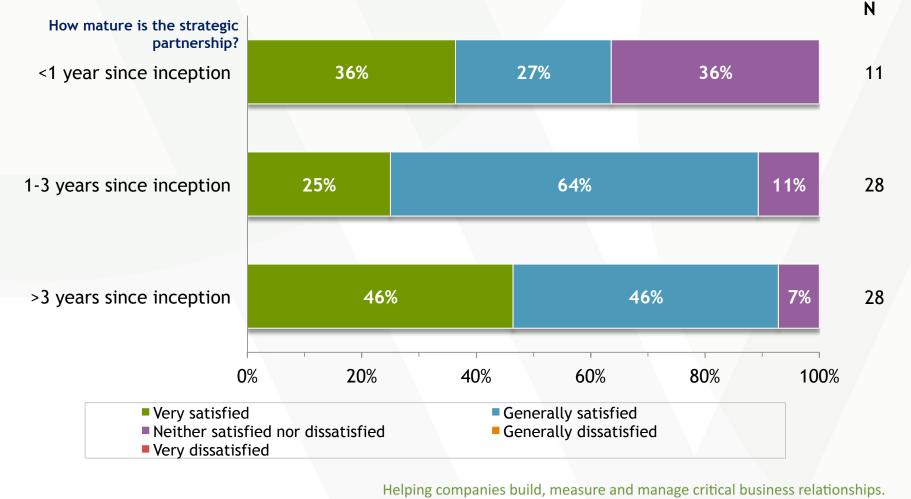
In general, how satisfied are you with the <u>profit</u> that has been generated for your company by the strategic partnership?



22

Clinical Service Provider Data

Overall, how satisfied have you been with the quality of the work that has been delivered to the sponsor during the strategic partnership?



Summary

Summary: Results Part Two

- Overall, 72% of the sponsor respondents were very (9%) or generally (63%). satisfied with the work performed for their companies by their (index) strategic partner, and 7% were dissatisfied. This rate of satisfaction was similar to that reported by sponsor respondents for clinical service providers in general.
 - Among sponsors, overall satisfaction with the work performed by strategic partners appeared to increase with the duration of the partnership; 86% of those reporting on strategic partnerships of duration >3 years were satisfied, compared to only 67% of those reporting on strategic partnerships of duration 0-3 years.
- Fifty-four percent of the sponsor respondents were very (8%) or generally (46%)satisfied with the value received for the money spent with their index strategic partners, and 15% were dissatisfied. This rate of satisfaction was slightly higher, and the rate of dissatisfaction was slightly lower, than reported by sponsor respondents for clinical service providers in general.
 - Again, satisfaction with value appeared to increase with the duration of the partnership; 62% of those reporting on strategic partnerships of duration >3 years were satisfied, compared to only 47% of those reporting on strategic partnerships of duration <1 year, and 54% of those reporting on partnerships of duration 1-3 years.

Summary

Summary: Results Part Two

- Among sponsors, management personnel were more likely to be satisfied overall with the work done by strategic partners (88%) than were personnel from operations/ clinical (66%) or outsourcing/purchasing (71%). However, they were no more likely to be satisfied with the value received.
- Clinical service providers were much more likely than were sponsors to be satisfied with the work performed by their companies during their strategic partnerships (36% very satisfied, 54% generally satisfied).
- Among clinical service providers, overall satisfaction with the profit generated by their strategic partnerships appeared to increase with the duration of the partnership; 71% of those reporting on strategic partnerships of duration >3 years were satisfied and none were dissatisfied, whereas only 60% of those reporting on strategic partnerships of duration 0-3 years were satisfied, and 20% were dissatisfied.
- Among clinical service providers, overall satisfaction with the quality of the work performed by their companies in the context of strategic partnerships also appeared to increase with the duration of the partnership; 92% of those reporting on strategic partnerships of duration >3 years were satisfied (including 46% who were very satisfied), whereas only 63% of those reporting on strategic partnerships of duration <1 year were satisfied.</p>

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Part Three:

Objectives of Entering into (Index) Strategic Partnerships and Evaluation of Whether Objectives Were Met



What were your company's main objectives in launching the strategic partnership?

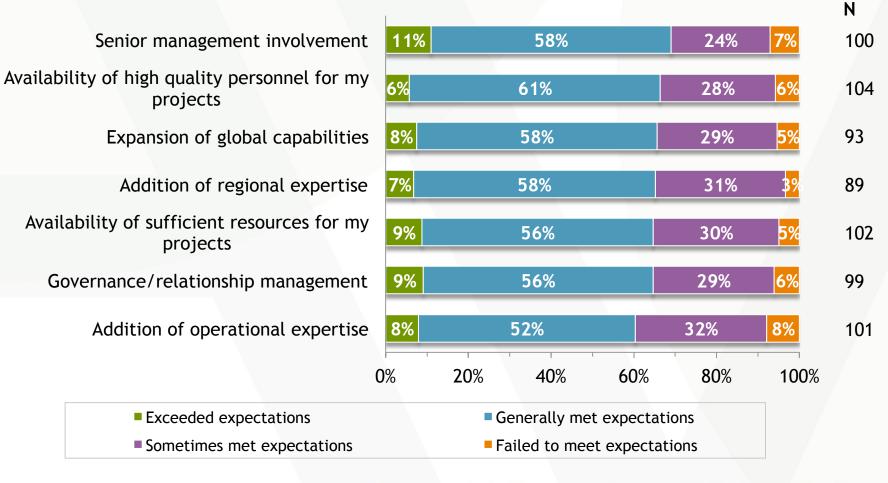
(one respondent per company, current company relationships only)

Top five responses:

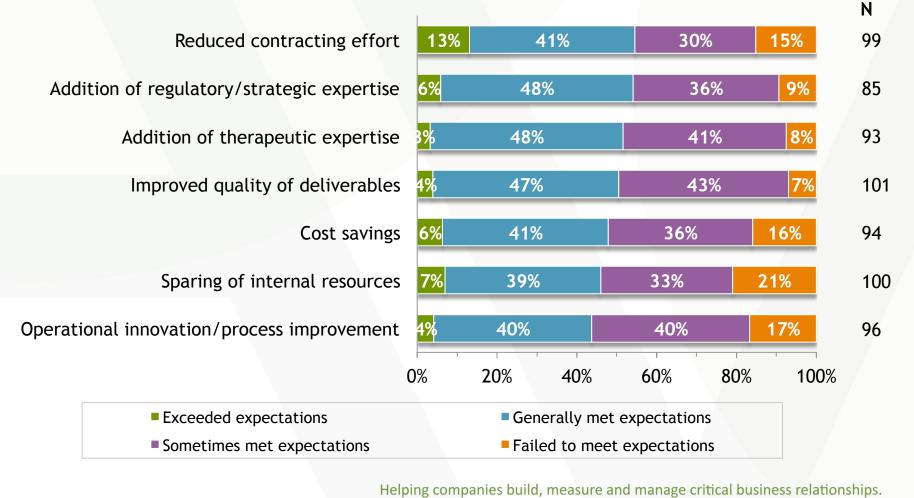
- 1. Reduced costs (53%)
- 2. Improved quality (43%)
- 3. Improved efficiency in use of internal staff (43%)
- 4. Access to operational expertise (43%)
- 5. Process improvement (30%)

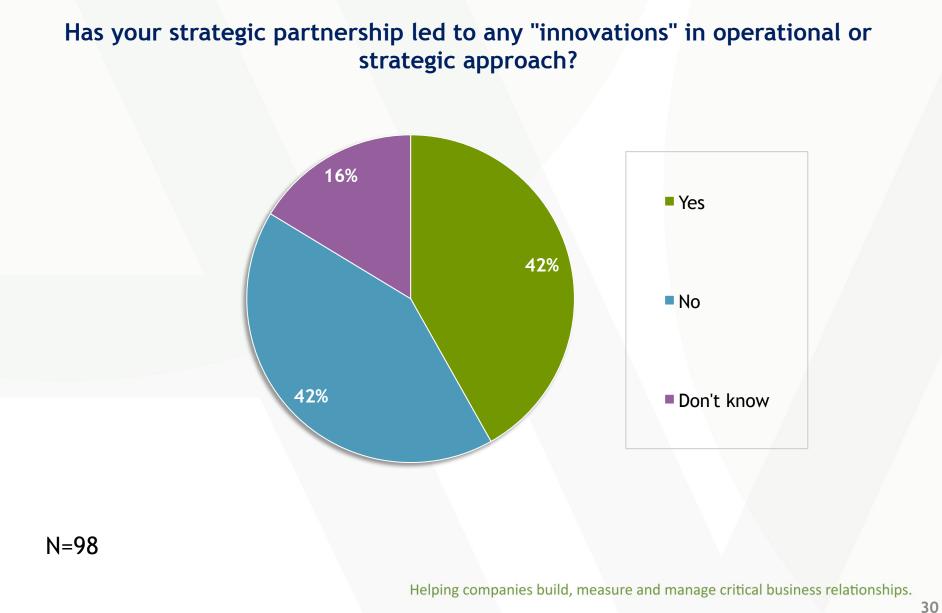


For each of the following, to what extent has the strategic partnership met your expectations? (slide 1 of 2)

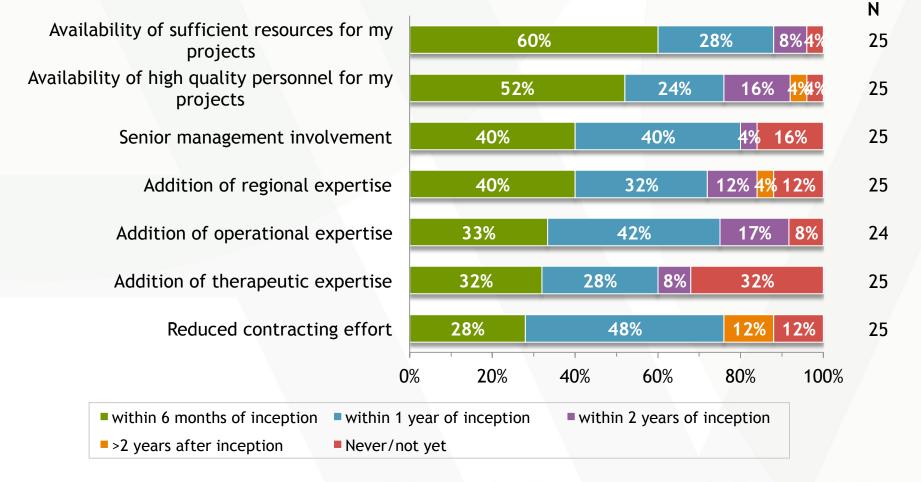


For each of the following, to what extent has the strategic partnership met your expectations? (slide 2 of 2)

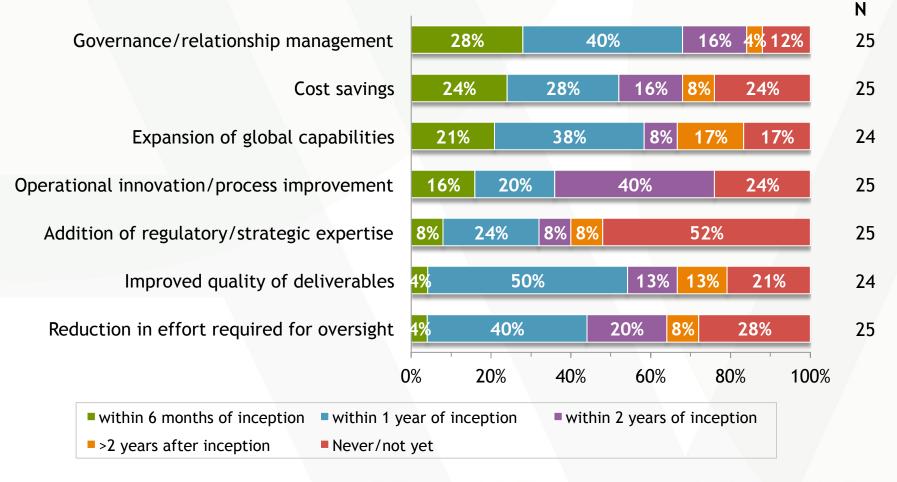


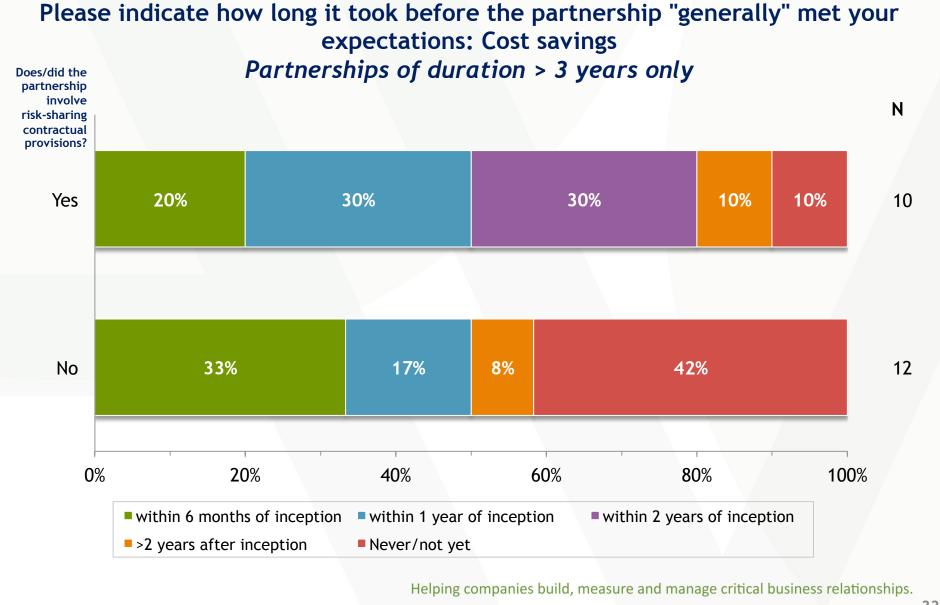


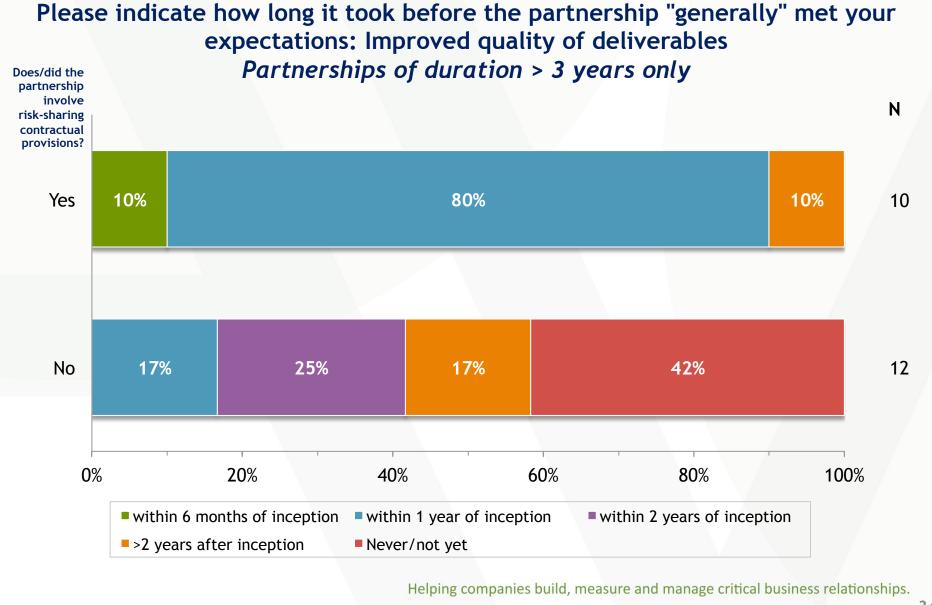
For each of the areas listed below, please indicate how long it took before the partnership "generally" met your expectations. (slide 1 of 2) Partnerships >3 years since inception only

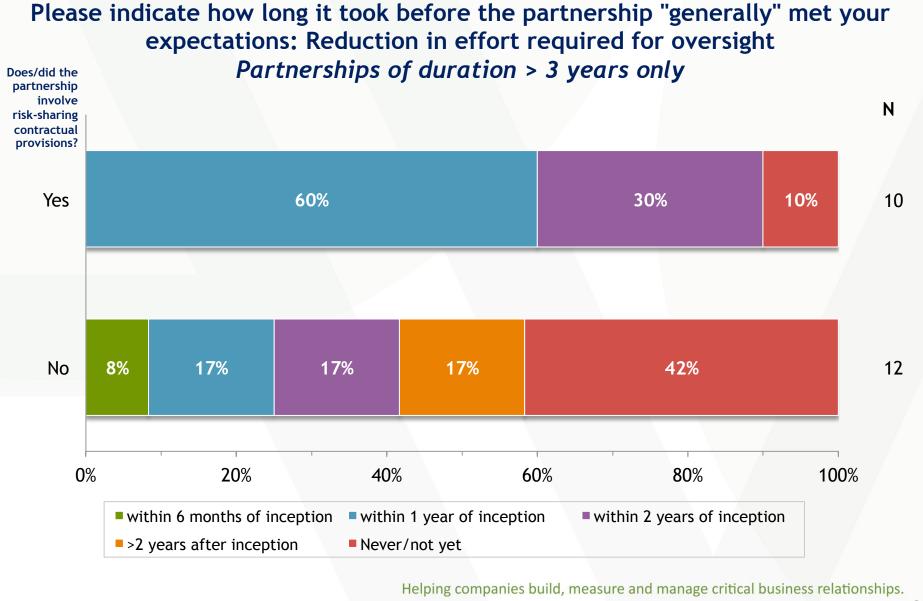


For each of the areas listed below, please indicate how long it took before the partnership "generally" met your expectations. (slide 2 of 2) Partnerships >3 years since inception only









Clinical Service Provider Data

What were your company's main objectives (e.g. Top 3) in launching the strategic partnership?

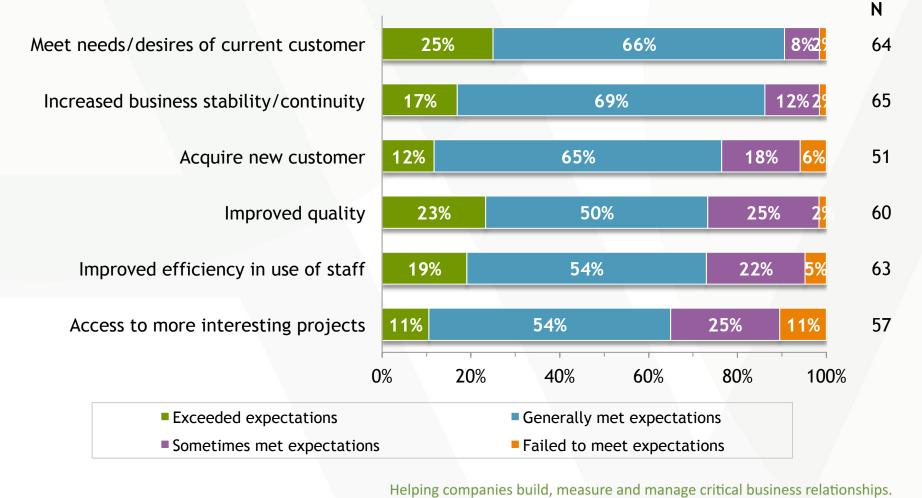
(one respondent per company, current company relationships only)

Top five responses:

- 1. Increased business stability/continuity (80%)
- 2. Improved efficiency in the use of staff (39%)
- 3. Increased profit (36%)
- 4. Access to more interesting projects (36%)
- 5. Meet needs/desires of current customers (34%)



Please describe the extent to which the strategic partnership has met your expectations with respect to each of the following, to date. *(slide 1 of 2)*



Please describe the extent to which the strategic partnership has met your expectations with respect to each of the following, to date. *(slide 2 of 2)*



For each of the areas listed below, please indicate how long it took before the partnership "generally" met your expectations. Partnerships >3 years since inception

Meet needs/desires of current customer Increased business stability/continuity Access to more interesting projects Reduced contracting effort Process improvement Increased profitability Improved quality Improved staff retention Improved efficiency in use of staff Reduced business development effort Access to incentives for high performance

within 6 months of inception

>2 years after inception

	1							Ν
stomer	32%		48%			8% 17	2%	25
tinuity	289	%	32%		32%		<mark>%1%</mark>	25
ojects	20%	36%		12%	12% 16%		%	25
effort	17%	50%			8% 8%		6	24
ement	17%	29%		38	%	13%	4%	24
ability	16%	36%		28%		16%	4%	25
quality	13%	46%		25%		8%	8%	24
ention	12%	48%			20%			25
of staff	12%	40%		32%		12%	4%	25
effort	8%	38%		13% 1	% 17%			24
mance	<mark>4% 2</mark> 1	% 13	% <mark>8</mark> %		54%			24
(0%	20%	40%	60%	80	%	100%	
within	1 year of	inception	■ wit	nin 2 years	s of incep	otion		
Never/not yet								

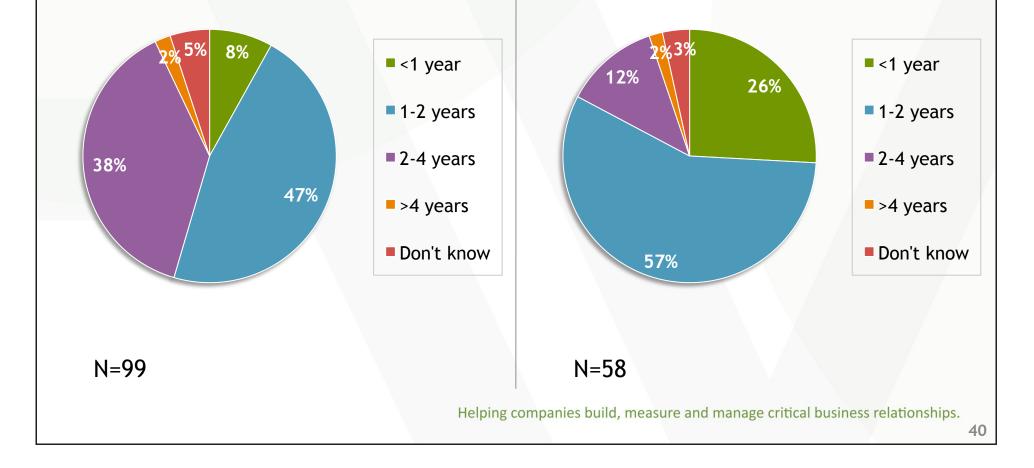
Comparison between Clinical Service Providers and Sponsors

Sponsor Data

In your experience, how long does it take for most sponsor project teams to adapt their styles to working under a strategic partnership?

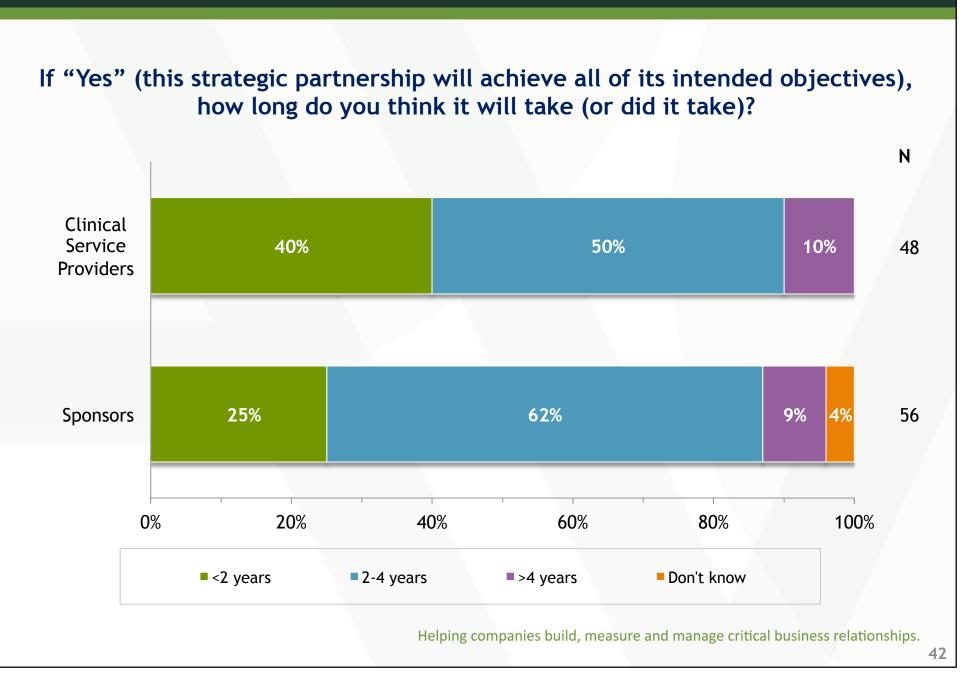
Clinical Service Provider Data

In your experience, how long does it take for most clinical service provider project teams to adapt their styles to working under a strategic partnership?



Do you feel that ultimately, this strategic partnership will achieve all of its intended objectives? Ν Clinical Service 79% 10% 11% 61 **Providers** Sponsors 55% 24% 21% 103 0% 20% 40% 60% 80% 100% Yes No Don't know Helping companies build, measure and manage critical business relationships.

41



Summary: Results Part Three

- Among sponsors, the most common objectives for launching strategic partnerships included reduced costs (53%), improved quality (43%), improved efficiency in use of internal staff (43%), access to operational expertise (43%), and process improvement (30%).
- For most of the objectives about which sponsors were asked, at least half of the respondents felt that their strategic partnerships met their expectations at least "generally." However, with respect to the critical objectives of reduced costs and sparing of internal resources, only 47% and 46% (respectively) of respondents felt that their partnerships at least generally met their expectations and 16% and 21% (respectively) felt that they failed to meet expectations.
- Forty-two percent of sponsor respondents stated that their strategic partnerships had led to "innovations" in operational or strategic approach.

Summary: Results Part Three

- Among sponsor respondents whose relationships spanned a period of >3 years, there was considerable variability in the time it took for expectations to be met. For example:
 - **Reduced costs:** A little more than half of the respondents achieved cost savings in one year or less; however, almost a quarter of the respondents reported never achieving cost savings.
 - Improved quality: 54% of respondents indicated improved quality within one year; however, 21% reported never achieving improved quality.
 - Improved efficiency: Less than half of the respondents felt that efficiency and the reduction in effort for oversight was achieved within one year; 28% said it was never achieved.
 - **Process improvement:** Only 36% saw process improvement within 1 year; however 40% reported that their expectations with respect to process improvement were met between 1 and 2 years. Almost one quarter of this group said that their expectations in this area were never met.
- The existence of risk-sharing contractual provisions appeared to accelerate the time needed for strategic relationships to meet sponsors' expectations in these areas.

Summary: Results Part Three

- Among clinical service providers, the most common objectives for launching strategic partnerships included increased business stability/continuity (80%), improved efficiency in the use of staff (39%), increased profit (36%), access to more interesting projects (36%), and meeting needs/desires of current customers (34%).
- For nearly all of the objectives about which clinical service providers were asked, at least half of the respondents felt that their strategic partnerships met their expectations at least "generally". With respect to the critical objective of increased business stability/continuity, 86% of respondents felt that their partnerships at least generally met their expectations.

Summary: Results Part Three

- Among clinical service provider respondents whose relationships spanned a period of >3 years, there was considerable variability in the time it took for expectations to be met:
 - Increased business stability/continuity: 60% achieved this in one year or less;
 32% said that it took between one and two years.
 - Improved efficiency in the use of staff: 52% of respondents indicated improved efficiency within one year; 32% said that it took between one and two years.
 - Increased profit: 52% of respondents reported increased profitability within one year; 28% said it took between 1 and 2 years; 16% reported that it took longer than two years; and a small percentage indicated that this was never achieved.
 - Access to more interesting projects: a little over half of the respondents reported access to more interesting projects within one year and 16% said that this was never achieved.
 - Meet needs and desires of current customers: the majority of respondents (80%) indicated that customers' needs and desires were met within one year.

Summary: Results Part Three

- Most often, both sponsor and service provider respondents felt that it took between 1 and 2 years for project teams to adapt their styles to working in a strategic partnership. Clinical service providers were more likely than were sponsors to feel that their teams could adapt within 1 year (26% vs. 8%), whereas sponsors were more likely than were clinical service providers to feel that their teams would need 2-4 years to adapt (38% vs. 12%).
- Clinical service provider respondents were more likely than were sponsor respondents to feel that ultimately, their strategic partnerships would achieve all of their intended objectives (79% vs. 55%).
- As a group, clinical service provider respondents were also more optimistic than were sponsors about the time it would take for their strategic partnerships to achieve all of their intended objectives: 40% of provider respondents, but only 25% of sponsor respondents, felt that this would happen within 2 years of inception.

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Part Four:

Implementation Strategies and Tools for Managing Strategic Partnerships: Index Partnerships



Sponsor Data

Please indicate whether your company used each of the following tools for or approaches to implementing its strategic partnership, and if so, the degree to which it was helpful in ensuring successful implementation.

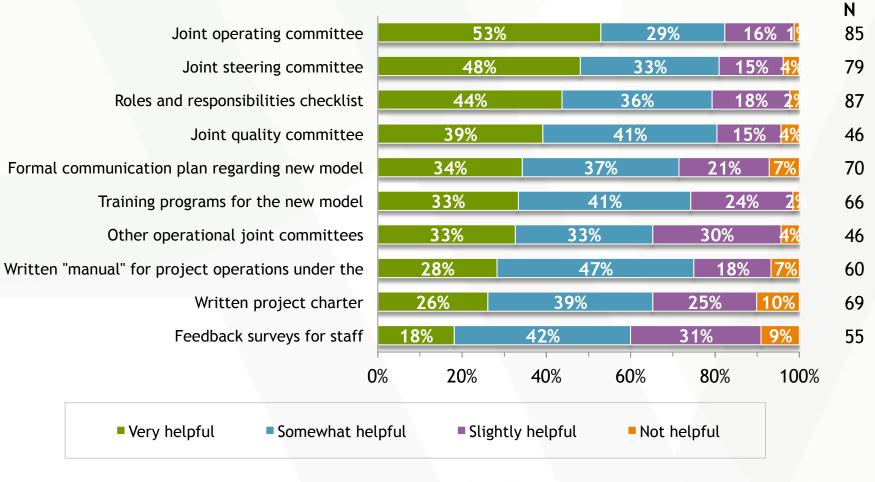
Top responses:

- 1. Roles and responsibilities checklist (95%)
- 2. Joint operating committee (89%)
- 3. Joint steering committee (83%)
- 4. Formal communication plan regarding new model (80%)
- 5. Written project charter (75%)



Sponsor Data

Please indicate the degree to which each was helpful in ensuring successful implementation.



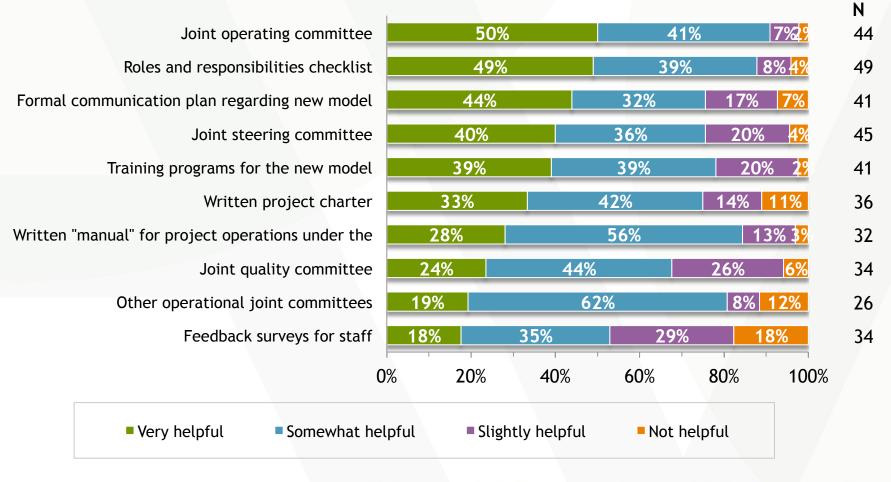
Please indicate whether your company used each of the following tools for or approaches to implementing its strategic partnership, and if so, the degree to which it was helpful in ensuring successful implementation.

Top responses:

- 1. Roles and responsibilities checklist (90%)
- 2. Joint steering committee (81%)
- 3. Joint operating committee (79%)
- 4. Training programs for the new model (78%)
- 5. Formal communication plan regarding the new model (75%)



Please indicate the degree to which it was helpful in ensuring successful implementation.



Sponsor Data

What went well during the implementation phase?

- The most frequently cited theme was ongoing and open communication between teams including face-to-face time and clear communication pathways.
- Sense of collaboration and trust
- Governance structure and CRO Partnership Manual
- Definition of Roles and Responsibilities
- Senior management support
 - "Getting senior management to support initiative and whenever possible had presentations by internal Outsourcing Sr. Management to present strategy and company wide meetings."
- Training programs
 - "Hired an outside group to help develop communication and training programs for the internal organization as well as the CRO."

What went well during the implementation phase?

- The two most frequently cited themes:
 - Smoothness of transition including collaboration of sponsor and provider partner teams and transfer of operational responsibilities
 - Establishment of clear expectations including definition of strategy and strategic alignment.
- Open communication is the third most common theme cited. This includes the mention of a face-to-face meeting with the entire project team from both sides of the relationship.

Sponsor Data

What you would have done differently during the implementation phase?

- ▶ The most frequently cited verbatim themes cited need for enhanced training.
 - "Provide tailored training to staff at sponsor, alliance partner and CRO on how to optimally use the business model and improve working interactions."
 - "Have more time set aside to on board the organization from a training perspective. Usually it was either JIT or a mass training session and not a continuous one which would have helped folks that learn better through exposure over time."
- Improved clarity relating to Roles and Responsibilities
- Upfront and continued involvement by Senior Management (Sponsor and CRO)
 - "Required more upfront involvement of leadership for show of support and reinforcing importance of this process/partner change."
- Establishment and management of common expectations
 - "Greater management of expectations and development of sponsor skill set prior or at the same time as the model change."
- Communication improvement

What you would have done differently during the implementation phase?

- The most frequently cited verbatim themes offered suggestions surrounding robustness of communication.
 - "Encouraged communication at all levels between sponsor and CRO, to enable escalations to be minimized."
 - "Improved communication on roles and responsibilities of sponsor's affiliates."
- Establishment of common expectations and improvement in advance planning also received multiple mentions.
 - "Implemented Roles and Responsibilities sooner along with SOPs."
 - "More fully reviewed expectations, down to details. Or created a plan for reviewing and redefining these on a more regular basis."



Summary: Results Part Four

- Sponsors reported using a wide variety of tools for, and approaches to, implementing their strategic partnerships. The tools most commonly used included roles and responsibilities checklists (95%), joint operating committees (89%), joint steering committees (83%), formal communication plans regarding the new model (80%), and written project charters (75%).
- All of the tools and approaches listed were felt by the majority of sponsor respondents to be at least somewhat helpful. Joint committees (operating, steering, and quality) and roles and responsibilities checklists were most likely to be considered "very helpful".
- Clinical service providers also reported using a wide variety of tools for, and approaches to, implementing their strategic partnerships. The tools most commonly used among this group included roles and responsibilities checklists (90%), joint steering committees (81%), joint operating committees (79%), training programs for the new model (78%), and formal communication plans regarding the new model (75%).
- Again, all of the tools and approaches listed were felt by the majority of provider respondents to be at least somewhat helpful. Joint committees (operating and steering), roles and responsibilities checklists, and formal communication plans regarding the new model were most likely to be considered "very helpful".

Summary: Results Part Four

- When they were asked, in an open-ended manner, to describe what went well during the implementation phases of their relationships, sponsor and clinical service provider respondents most commonly mentioned open and frequent communication and collaboration (including face-to-face), and establishment of clear expectations, often through written documents.
- When they were asked, in an open-ended manner, to describe what they would have done differently during the implementation of their relationships, sponsor and clinical service provider respondents most commonly mentioned the need to set more clear and common expectations for the new relationships. Specifically, the documentation of roles and responsibilities and communicating expectations through the use of enhanced training programs was cited. The need for enhanced communication and the importance of senior management support was also often mentioned.

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Thank you

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