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STRATEGY GROUP

Patient-Centric Clinical Development and the Role of the Contract Research Organization (CRO)

April, 2017

About the Author

Life Science Strategy Group, LLC (LSSG) report authors draw upon extensive business, consulting and life science experience and backgrounds.

Jon Meyer, MSc, MBA
Mr. Meyer is a Founder and Principal Consultant with the Life Science Strategy Group, LLC (LSSG). With more than fifteen years of contract research services consulting experience, Mr. Meyer leads LSSG's contract research services consulting division which serves the leading global contract research organizations (CROs) across all phases of preclinical and clinical development including:

- Pre-clinical safety pharmacology, drug metabolism & bioanalytical services
- Non-clinical/GLP toxicology services
- Clinical development services (Phase I, II, III)
- Pre & post-approval services (Phase IIIb and IV)
- Clinical trial supply chain management and technologies (IVRS, IWRS, EDC, Wearable Technology)
- Chemistry, manufacturing and controls (CMC) services
- Large molecule & vaccines services

Mr. Meyer has managed consulting engagements in a variety of commercialization and market research areas including strategic planning, opportunity assessments, pricing and reimbursement analyses, forecasting, competitive benchmarking, positioning and messaging strategy and clinical trial benchmarking and analysis. Prior to LSSG, Mr. Meyer was a Director in the Life Sciences Division at Navigant Consulting, Inc. and conducted preclinical drug development in the department of inflammatory disease at Roche Bioscience. Mr. Meyer holds Masters Degrees in Biomedical Science and Business Administration.

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Source: Life Science Strategy Group, LLC

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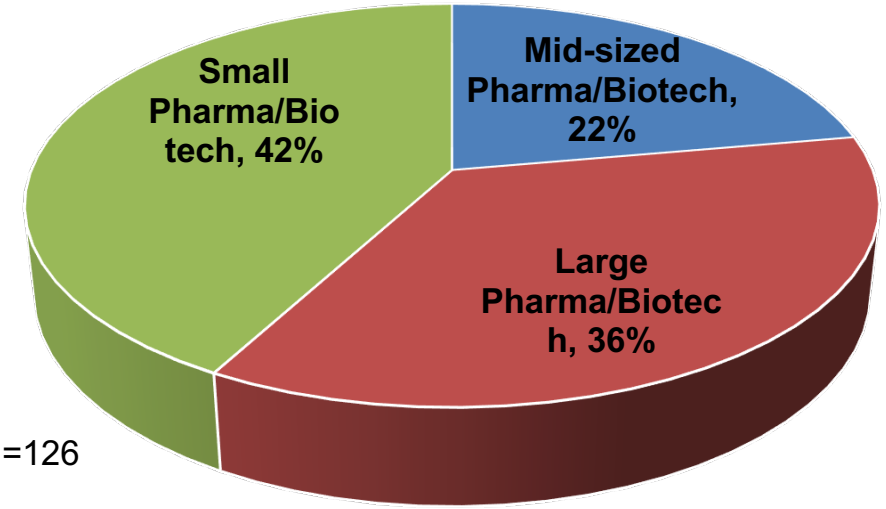
Respondent Demographics

Company Type



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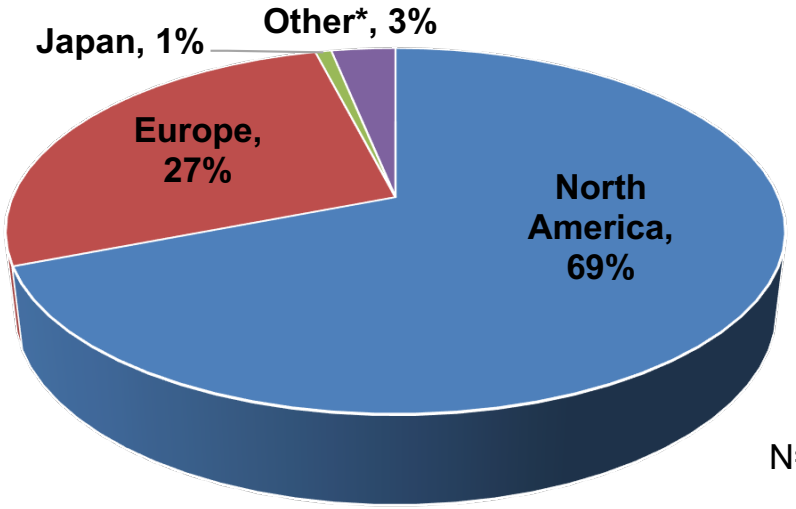
Location



N=126

*Other: India, China, Latin America

Years Experience

Average:	**15**
Min:	2
Max:	30

N=126

S2. Where are you located?
S3. What type of company do you work for?
S5. How many years of industry experience do you have in your current role?

Source: Life Science Strategy Group, LLC; Web Surveys

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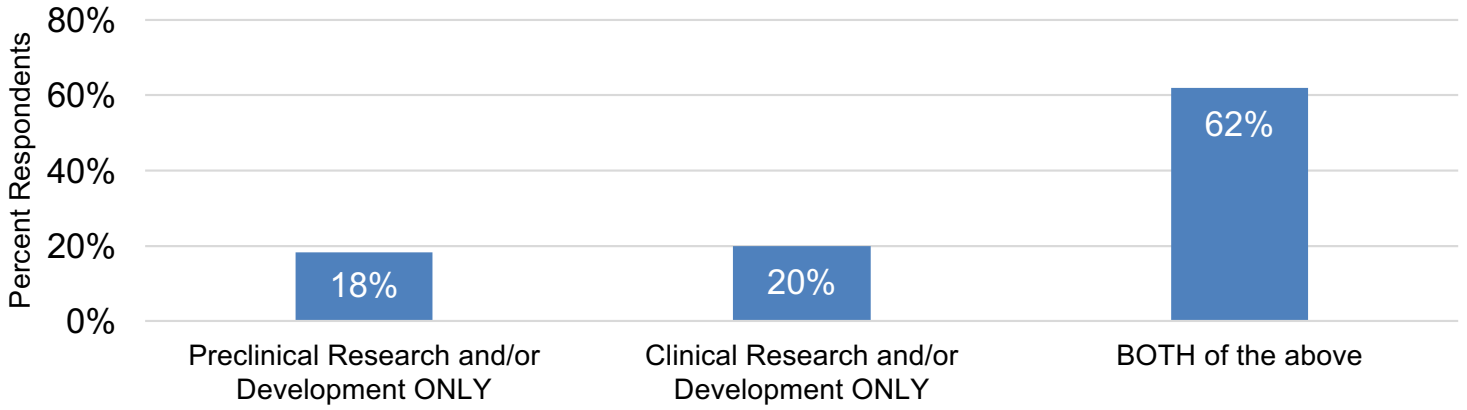
Respondent Demographics

Area of Responsibility



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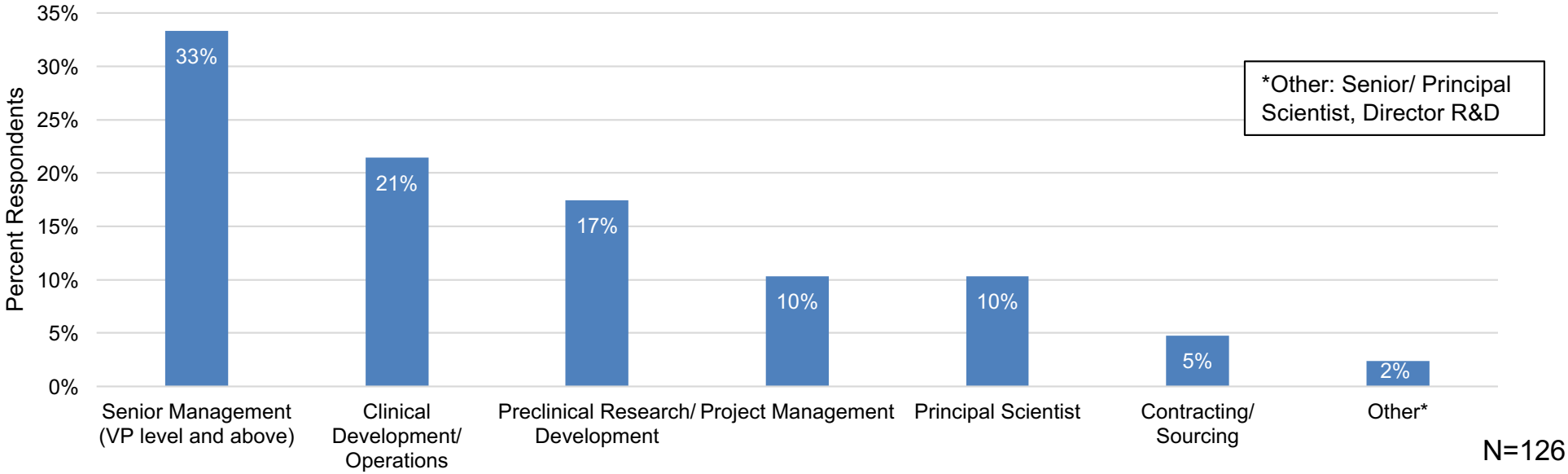
Role



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S1. Please indicate your functional area(s) of responsibility related to research and development at your company. Please select the best fitting area of responsibility
S4. What best describes your functional role at your company?
Source: Life Science Strategy Group, LLC; Web Surveys

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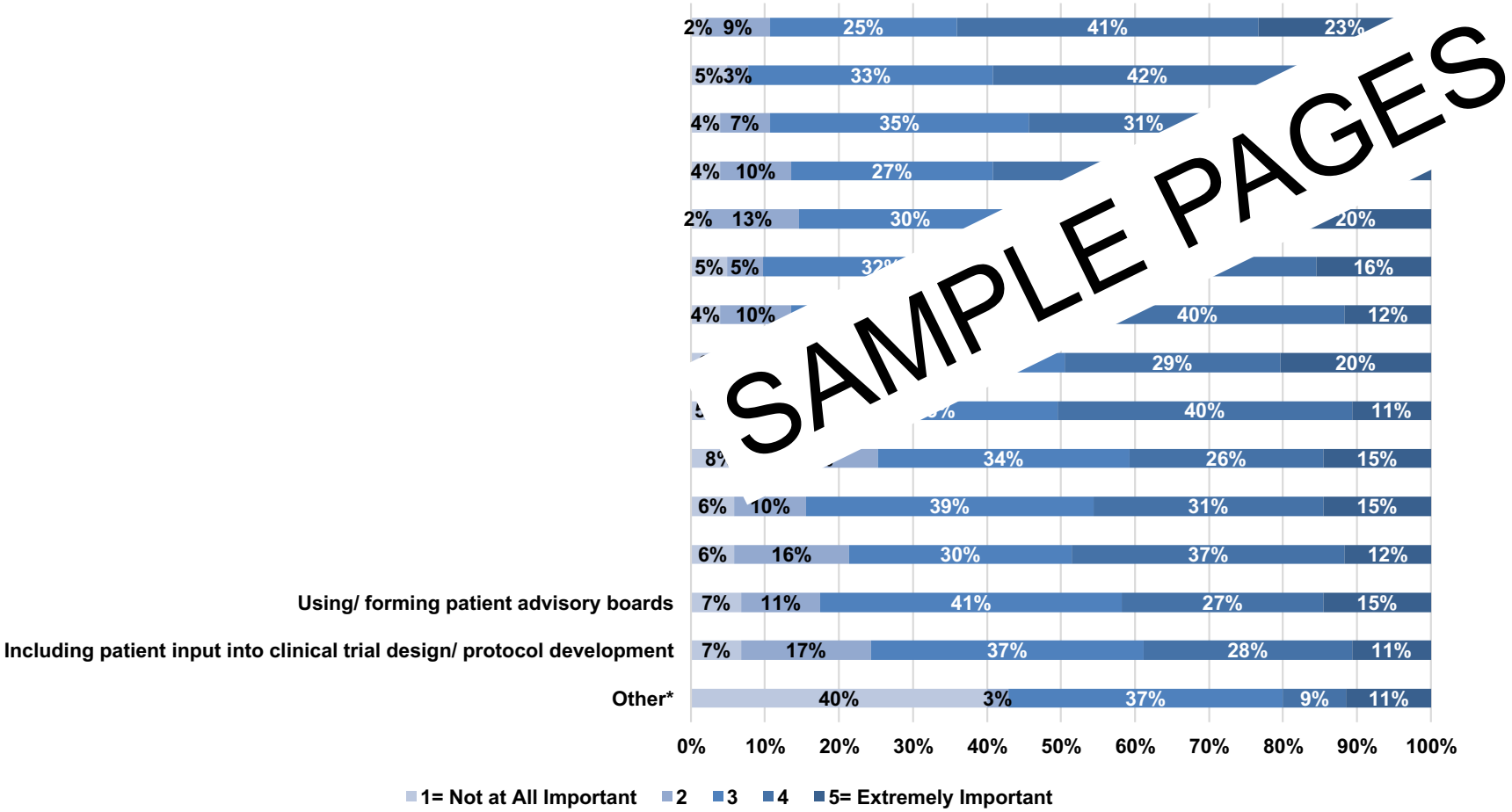
While most patient-centric approaches for clinical development are X, implementing Y is the most important (average 3.7 on a scale of 1-5, with 64% of respondents scored 4 or 5).

IMPORTANCE OF PATIENT-CENTRIC APPROACHES FOR CLINICAL DEVELOPMENT



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Q2: How important are each of the following activities in support of your company's efforts to adopt and implement a patient-centric approach to clinical development? Please rate on a 5 to 1 scale, where 5=Extremely Important and 1=Not at all Important

Source: Life Science Strategy Group, LLC

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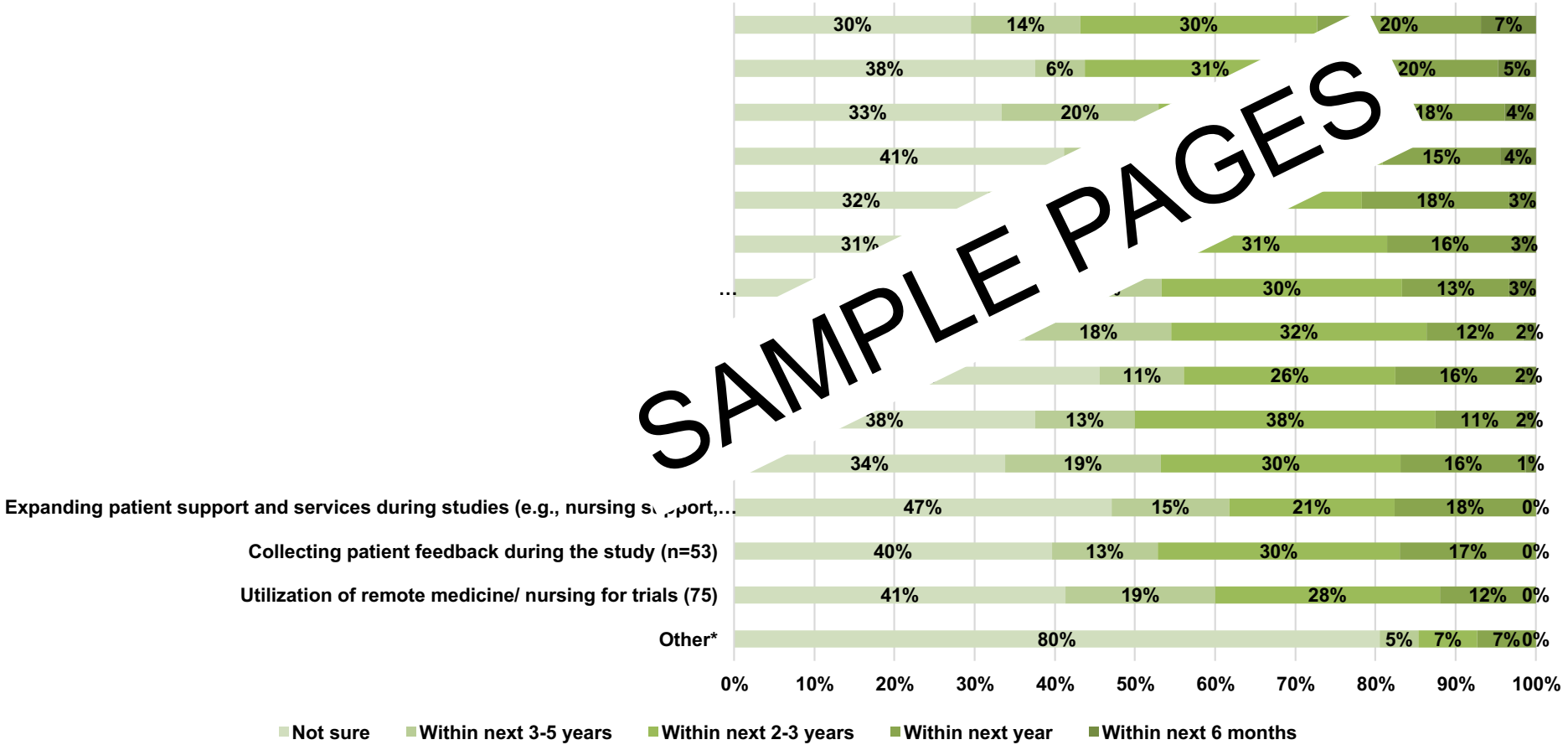
Half of respondents expect to X and Y within the next 1-3 years including adaptive-design clinical trials, A, B and C.

ANTICIPATION OF IMPLEMENTING PATIENT-CENTRIC APPROACHES FOR CLINICAL DEVELOPMENT



Q4: For those areas that your company is considering, or not currently considering, when do you anticipate your company will begin implementation, if at all?

Source: Life Science Strategy Group, LLC

While A is a concern, other challenges include X, Y and Z.

Greatest Challenges	# of Mentions
xxxxx	
xxxxxxx	
Unclear efficacy and safety outcomes of validation	
xxxxx	10
Patient compli	10
Regul ping data, diary data to FDA-	8
	7
	4
Patient communication hurdles	3

"The "development engine" is r elopment; change is difficult."

Biotech, North America

s meaningful, but very hard to reduce to data and accept."

- Small-Sized Pharma/ Biotech, North America

"Certain regulatory hurdles preclude us from interacting with p nts on a certain level. Also need to consider regulatory-driven la HIPAA, etc., that could impact our ability to freely c patients."

- Mid-Siz rica

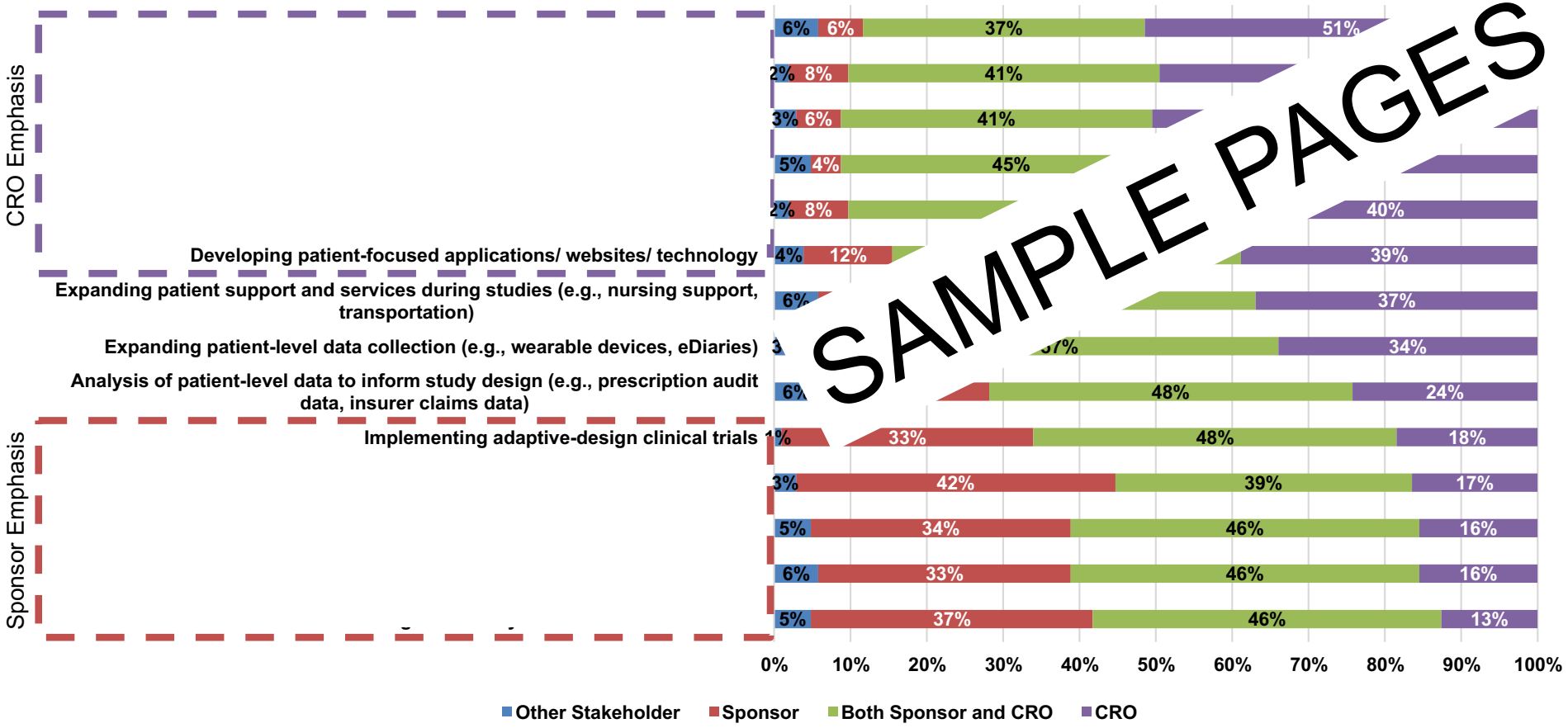
"Media often m ia is more concerned with making m cures to patients in need. The tru but it is a challenging topic especially ays us as being "monetary-centric" more so – Mid-Sized Pharma/ Biotech, North America

Q6: What are the greatest challenges facing your company in its efforts to identify and implement patient-centric clinical development strategies?

Source: Life Science Strategy Group, LLC

Most respondents agree that the Sponsor and CRO should work on X and Y throughout a trial. Sponsors should be more responsible for A. CROs should focus on B.

PRIMARY RESPONSIBILITY OF NECESSARY ACTIVITIES AND THOUGHT LEADERSHIP



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Q7: For each of the following activities in support of patient-centric clinical development, which stakeholder should take primary responsibility for necessary activities and thought leadership?

Source: Life Science Strategy Group, LLC

Sponsors need CROs to provide them with a X for their clinical studies that include Y.
Sponsors rely on the CRO's X and appreciate the knowledge of B.

Greater flexibility and adaptability

"Greater flexibility and willingness to adapt to unusual study designs. Have a menu of ready solutions based on past experience. Don't charge me for development of what you already know."
- Small-Sized Pharma/ Biotech, North America

Gather and share patient-centric information

"Form a center of expertise that can advise, formulate and implement strategies."
- Small-Sized Pharma/ Biotech, North America

Share Z

"Be proactive in sharing learnings from work across sponsors; propose ideas and demonstrated successes."
- Large-Sized Pharma/ Biotech, North America

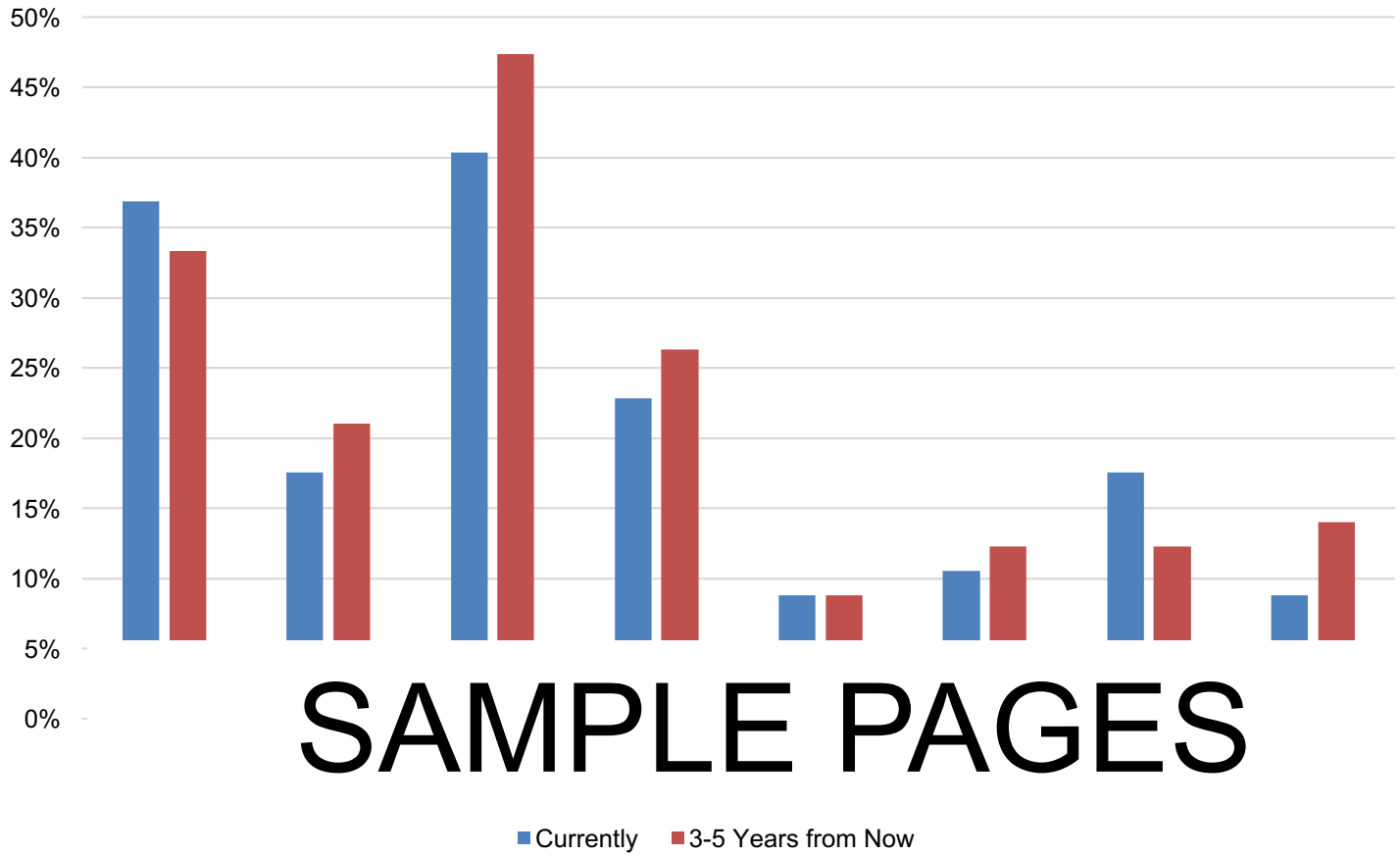
Regular X and Y

"1. If the ... and hold at least one patient advisory ... use what they think will work. 2. Make sure they have ... practices both within and across therapeutic areas."
- Small-Sized Pharma/ Biotech, North America

Q10: How can CROs best help your company execute its patient-centric clinical development strategies?
Source: Life Science Strategy Group, LLC

Forty percent (currently) and 47% (within 3-5 years) X is best prepared for engaging with patient advocacy groups. Y came in second place with 37% (currently) and 33% (within 3-5 years).

BEST PREPARED CRO FOR *ENGAGING WITH PATIENT ADVOCACY GROUPS*



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Q9: Which CROs are CURRENTLY best prepared to support your company's efforts to implement and execute patient-centric clinical development strategies in each of the following areas? Which CROs will be best prepared 3 to 5 years from now?

Source: Life Science Strategy Group, LLC

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Appendix - Overview of Questions

1. What is your company's general attitude toward adopting and implementing a patient-centric approach to clinical development?
2. How important are each of the following activities in support of your company's efforts to adopt and implement a patient-centric approach to clinical development?
3. To what degree is your company implementing/ using the following activities in its clinical development activities?
4. For those areas that your company is considering, or not currently considering, when do you anticipate your company will begin implementation, if at all?
5. In what therapeutic areas is your company the most active with regard to developing and implementing patient-centric clinical development strategies?
6. What are the greatest challenges facing your company in its efforts to identify and implement patient-centric clinical development strategies?
7. For each of the following activities in support of patient-centric clinical development, which stakeholder should take primary responsibility for necessary activities and thought leadership?
8. For each of the following activities in support of patient-centric clinical development, why should the CRO take responsibility and/ or thought leadership? What specifically should they do?
9. For each of the following activities in support of patient-centric clinical development, which CROs are CURRENTLY best prepared to support your company's efforts to implement and execute patient-centric clinical development strategies in each of the following areas? Which CROs will be best prepared 3 to 5 years from now?
10. How can CROs best help your company execute its patient-centric clinical development strategies?

Source: Life Science Strategy Group, LLC

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About Life Science Strategy, LLC

About Life Science Strategy Group, LLC

Life Science Strategy Group, LLC (LSSG) is a life science consultancy specializing in strategic consulting, market research engagements and syndicated publications across a variety of therapeutic, technology and service markets. Our core leadership team brings more than 40 years of combined experience conducting strategic consulting engagements in the following areas:

- Pharmaceutical
- Biotechnology
- Medical Devices
- Contract Research
- Diagnostics
- Drug Discovery

LSSG brings extensive breadth and depth of life science knowledge combined with seasoned consultants specializing in strategic and new product planning and commercialization strategy. We provide actionable and insightful strategic consulting results backed by data-driven market research.

"Solid, responsive, and dependable. That's why we work with LSSG."
VP Business Intelligence, Global Top–5 CRO

For more information on the Life Science Strategy Group's consulting and market research services, please contact us at info@lifesciencestrategy.com or call toll free at **1 (800) 941–6373**.

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