



LIFE SCIENCE
STRATEGY GROUP

Real-World Evidence – A Market at an Inflection Point and its impact on the CRO Industry

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About the Author

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

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Mr. Meyer is a Founder and Principal Consultant with the Life Science Strategy Group, LLC (LSSG). With nearly 20 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 pharmaceutical discovery, development and commercialization.

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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Goal and Objectives

GOAL

- To better understand Biopharma's utilization of real-world evidence to support development and commercial activities and trends going forward, identify perceived market leaders and understand implications on the future evolution of the CRO industry.

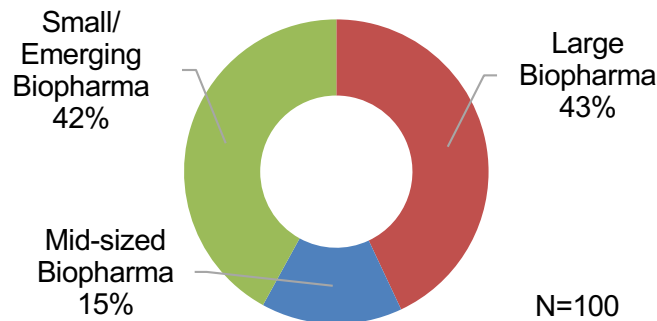
METHODOLOGY

- The primary research for this report was fielded in the first half of 2019. Study participants (N=100) are all involved with drug development and/or post-marketing approval/ commercialization stages of the product lifecycle and employed by a biopharmaceutical company.
- All study participants were prescreened by LSSG to ensure a high level of involvement and/or key decision-making authority for real-world evidence. All data analysis and reporting was performed by LSSG.

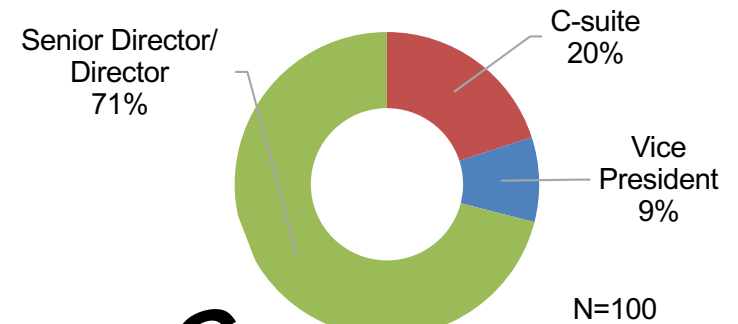
Respondent Demographics

- Respondents are located within North America (77%) and Europe (23%).
- All respondents have visibility into or responsibility for a budget that is allocated to RWE studies and/or services.

Company Type*



Position Level

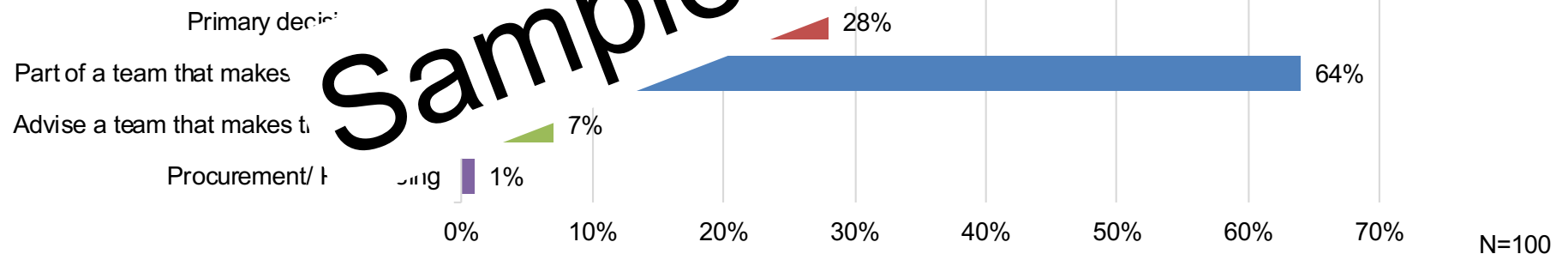


*Large Biopharma (greater than \$1.5 Billion in annual R&D spend)

Mid-sized Biopharma (greater than \$500 Million, but less than \$1.5 Billion in annual R&D spend)

Small/Emerging Biopharma (less than \$500 Million in annual R&D spend)

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Q. Where are you located?

Q. Which best describes the company you work for?

Q. Please indicate your position level or equivalent.

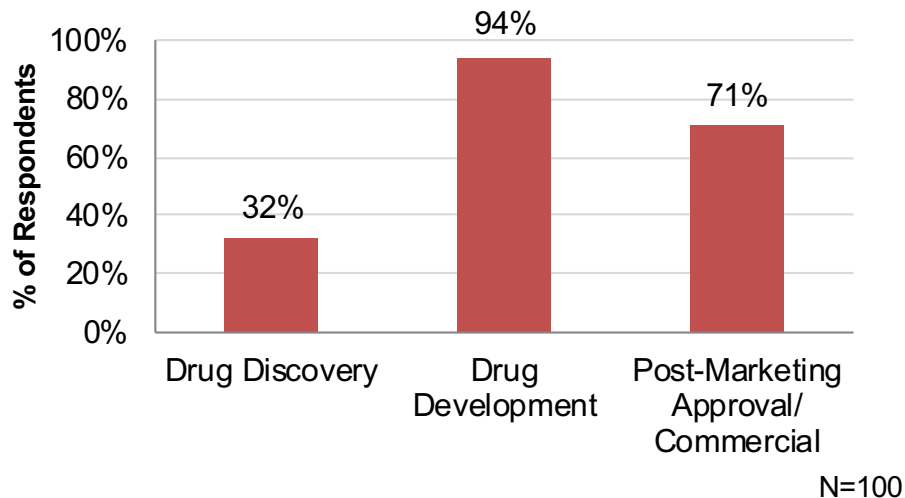
Q. How would you describe your role (or potential role) as it pertains to identifying and selecting external partners/vendors/sources for your/your company's RWE needs?

Q. Do you have visibility into or responsibility for a budget that is allocated to RWE studies and/or services?

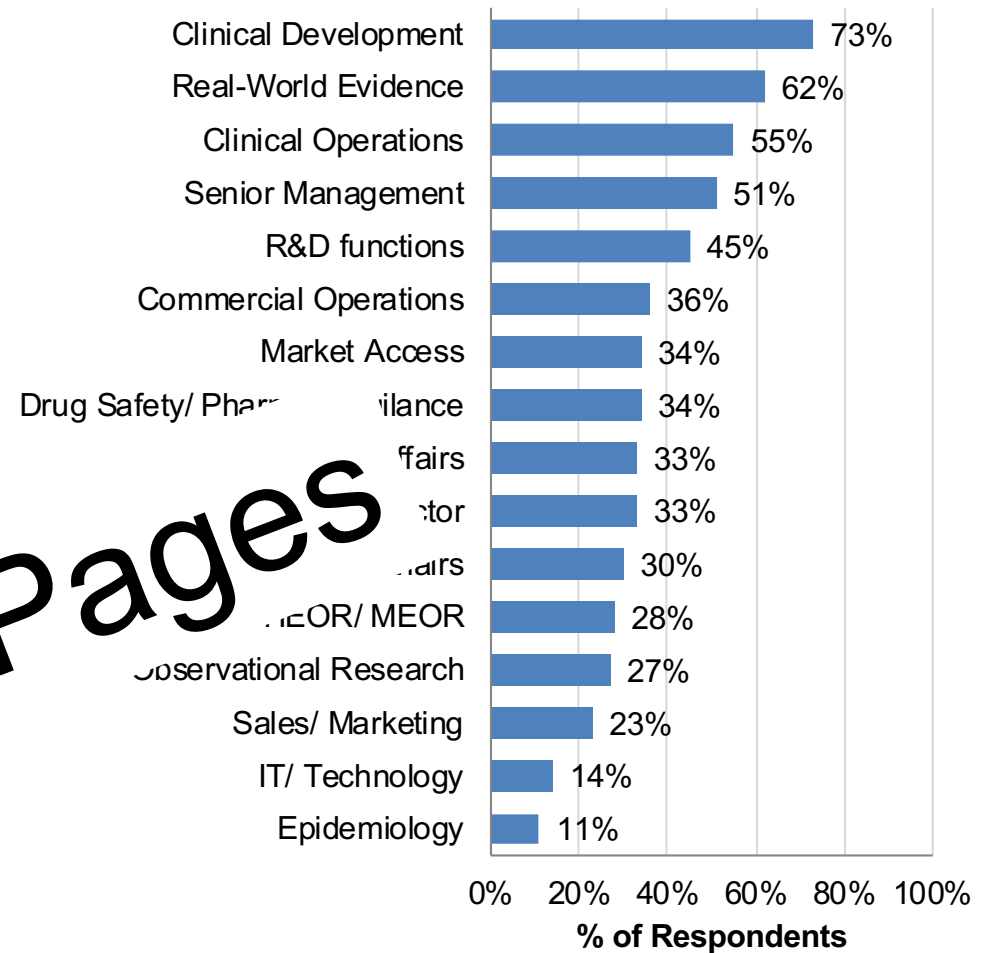
Source: Life Science Strategy Group, LLC

Respondent Demographics

Primary Areas of Responsibility



Functional Areas with Responsibility/ Significant Influence



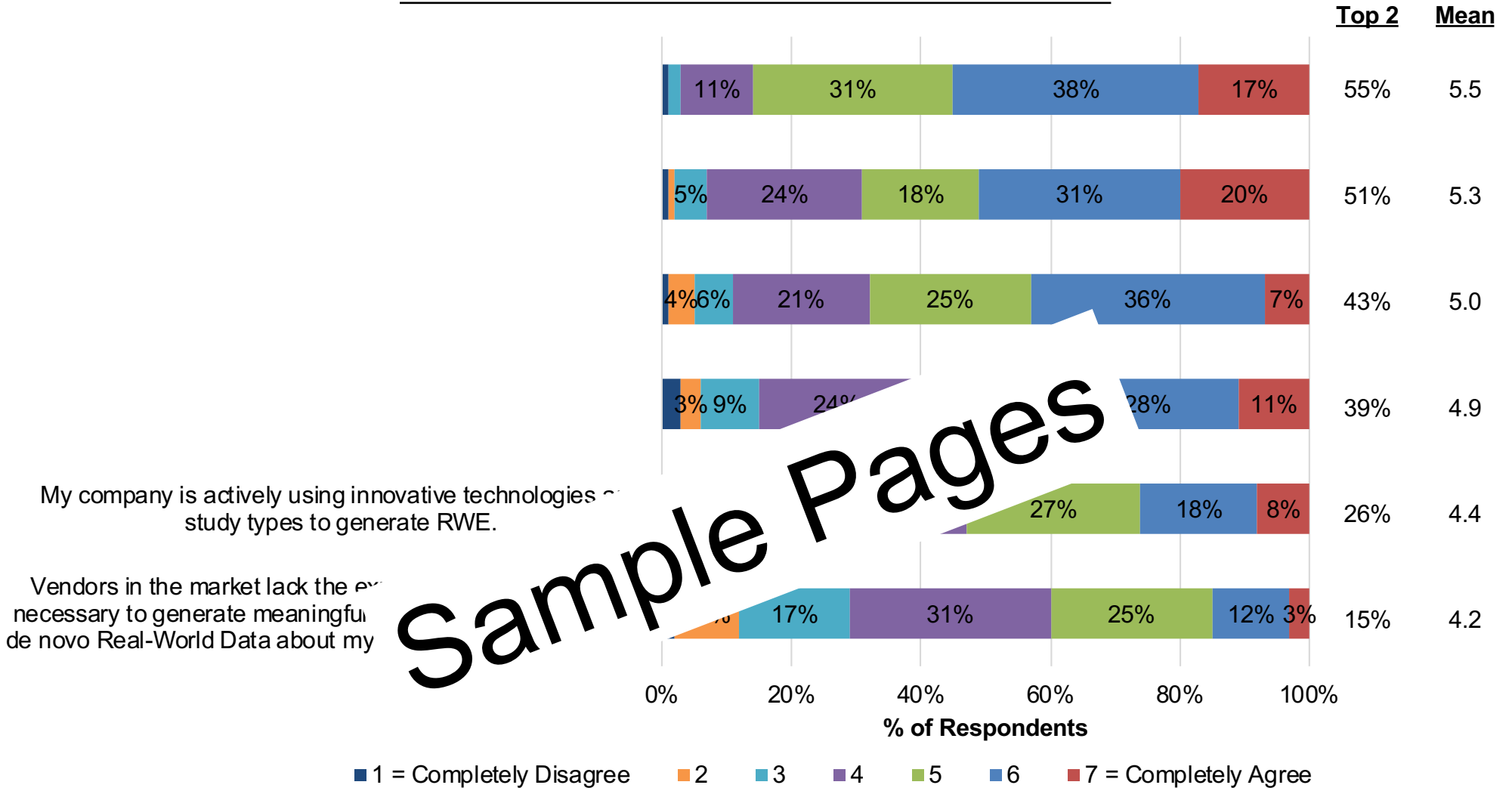
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Q. Which of the following functional areas are you responsible for, are part of your functional activities or where you have significant influence? Please select all that apply.
 Q. What stage(s) of the product lifecycle are your primary area(s) of responsibility? Please select all that apply.

Source: Life Science Strategy Group, LLC

Companies are learning, gaining more experience and increasing financial investment in RWE-based strategies in support of the product lifecycle.

Attitudes Towards the Generation and Use of RWE



Q. To what degree do you agree or disagree with each of the following statements? Please use a scale of 1 to 7 on the slider, where 1=Completely Disagree and 7=Completely Agree.

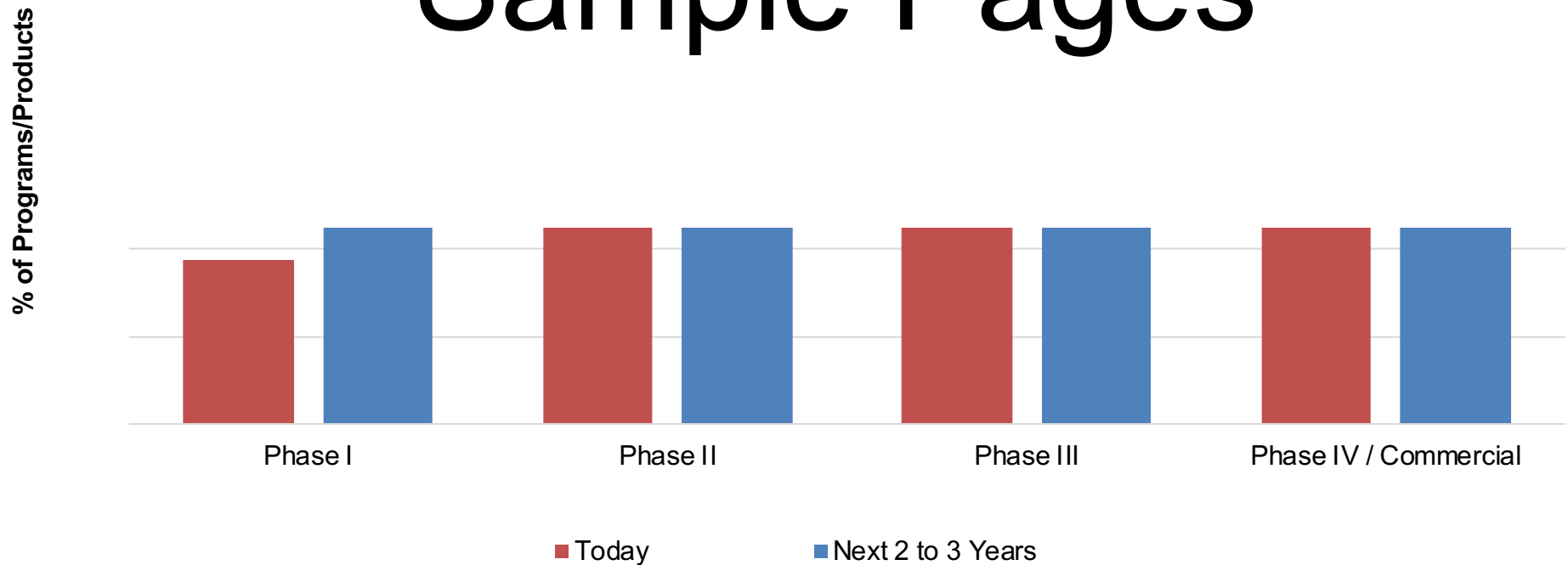
Source: Life Science Strategy Group, LLC

N=100

Generation and use of RWE is expected to XXX over the next two to three years in support of development and post-approval programs. Growth will be Y within X and Y.

RWE Generation and Utilization in Support of Development and Commercial Activities

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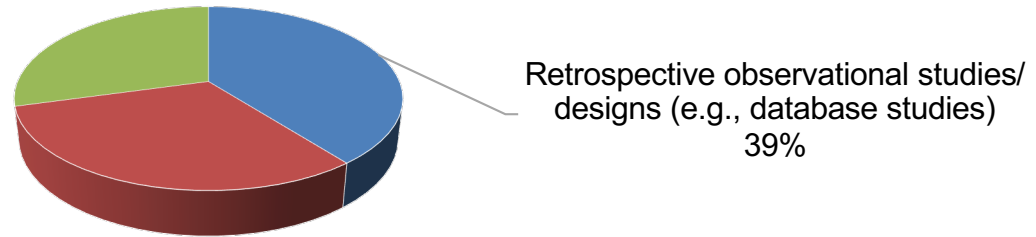
N=100

Q. What percent of your company's developmental programs and commercial products currently generate and/or utilize RWE? What percent will generate and/or utilize RWE in the next 2 to 3 years?

Source: Life Science Strategy Group, LLC

Nearly xx percent of respondents see shifts in the xxx RWE, including xxx.

Current RWE Study Design



N=100

xx%

of respondents see shifts in study types for RWE generation, including xxxxx in:

- xxxx
- Utilization of EHR data/ registry data
- xxxx
- Prospective studies
- xxxx
- xxxx
- xxxx
- Virtual trials

“xxxxxxxxxxxxxxxxxxxxxx.”

-VP, Emerging/ Small Biopharma (NA)

“RWD generation has improved with newer technologies as data quality informs decisions. RWE is an evolving tool. esp... disease entities to improve drug develop...”

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...value of early stage R&D costs.”

-VP, Mid-sized Biopharma (Europe)

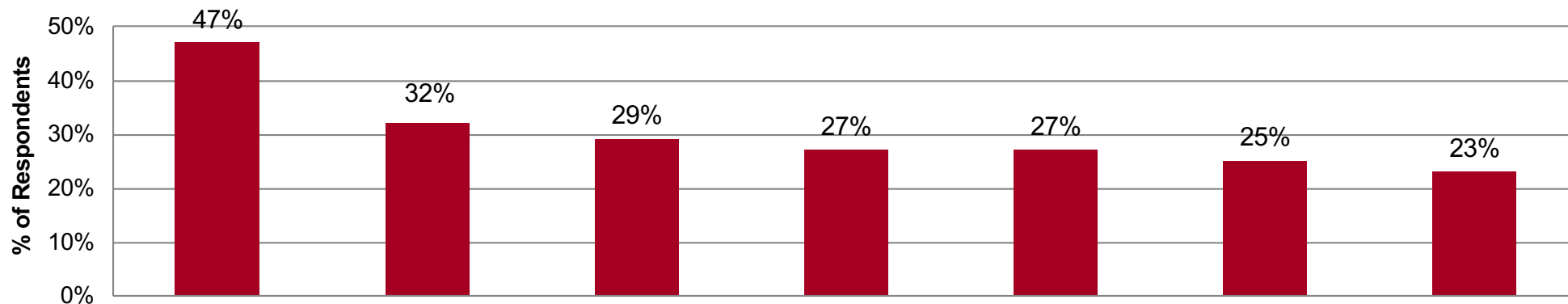
Q. For which of the following applications are you/your company using RWE today? Please select all that apply.

Q. What percent of your/your company's current studies generating RWE are of each of the following types? How do you expect this to change 2-3 years from now?

Source: Life Science Strategy Group, LLC

Cost, access to the right RWD, understanding the value of RWE and expertise are common barriers to the generation and use of RWE.

Barriers to Generation and Use of RWE in Support of Product Development*



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"[Barriers include] xxa, lack of internal expertise, and customer preference for xxx."

-VP, Large Biopharma (Europe)

"[Barriers include] xxx, xxx data, and xxx that would impact commercial products."

-C-suite, Small/ Emerging Biopharma (NA)

*Note: Top 7 most mentioned hurdles/ barriers

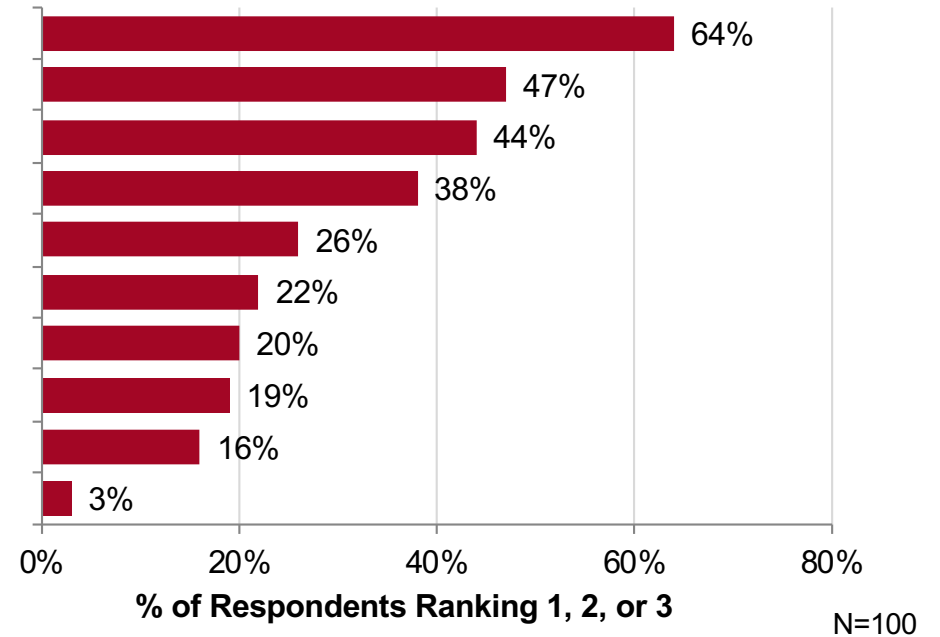
Q. What are the top 3 hurdles or barriers to utilizing/generating RWE in support of your **commercial products**?

Q. What are the top 3 hurdles or barriers to utilizing/generating RWE in support of your **development programs**?

Source: Life Science Strategy Group, LLC

Vendors are selected based x, y and z. Less importance is placed on a, b and c.

Importance of RWE Services Vendor Selection Criteria



- The exponential growth in the volume and types of RWD is driving demand for vendors that are expert in all facets of the data (e.g., access, validation, analysis, etc.)
- Typical vendor selection criteria, such as price, are relatively less important when selecting vendors, especially for those that are

Sample Pages