



CLINICAL LEADER

# Phase II/III Clinical Study Trends & Market Outlook

*Excerpt from ISR Reports*

*Phase II/III Market Outlook: 2022-2026*

October, 2022

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This is an excerpt from ISR Report’s full **Phase II/III Market Outlook: 2022-2026** report. Learn more and find the full report at [research.isrreports.com](https://research.isrreports.com).



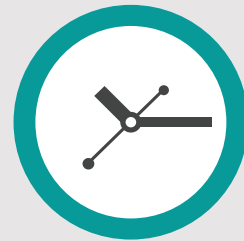
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# Methodology



Data collected  
in Q1 & Q2,  
2022



20-minute web-based  
quantitative online survey



132 respondents  
worldwide

# Demographics



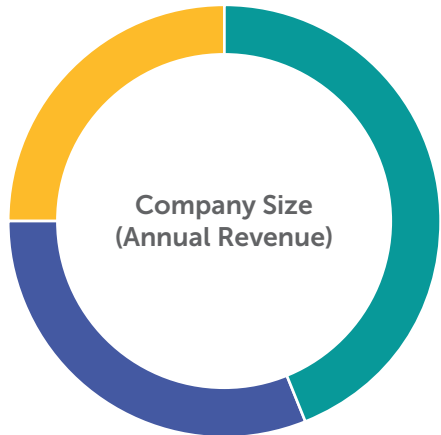
C-Level - 12%

President - 1%

Vice President - 21%

Director - 49%

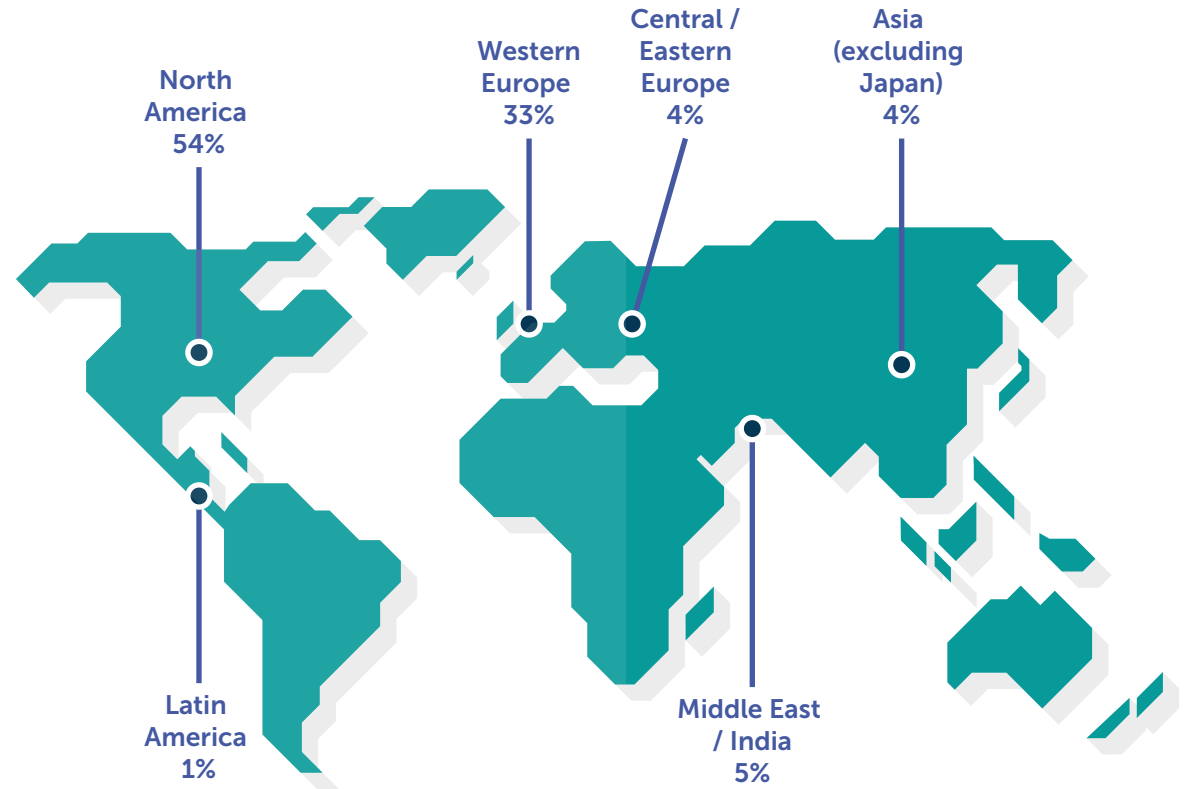
Manager - 17%



Large Companies (R&D \$1B or more) - 44%

Mid-Size Companies (R&D \$100M-\$999M) - 31%

Small Companies (R&D less than \$100M) - 25%



# Participant Criteria

Respondents were required to pass several screening criteria to qualify and participate in this survey:

- Must work for a pharmaceutical or biotech company.
- Must work in clinical operations/project management, medical, outsourcing/procurement, R&D management, or executive management.
- Must have responsibility for outsourced Phase II/III drug development activities within the past 18 months.
- Must play a role in gathering information about service providers, selecting service providers, and/or managing service provider activities.

Notes:

- For a more robust view of the Phase II/III market, we included several charts from ISR's 2022 *Phase II/III CRO Benchmarking (14th Edition)* report. Therefore, provider name changes and merger activity that occurred shortly before, during, or since data collection for the CRO Quality Benchmarking report are not reflected.
- Visual and written content from prior iterations of the *Phase II/III Market Outlook* research is also included in this report for additional context.

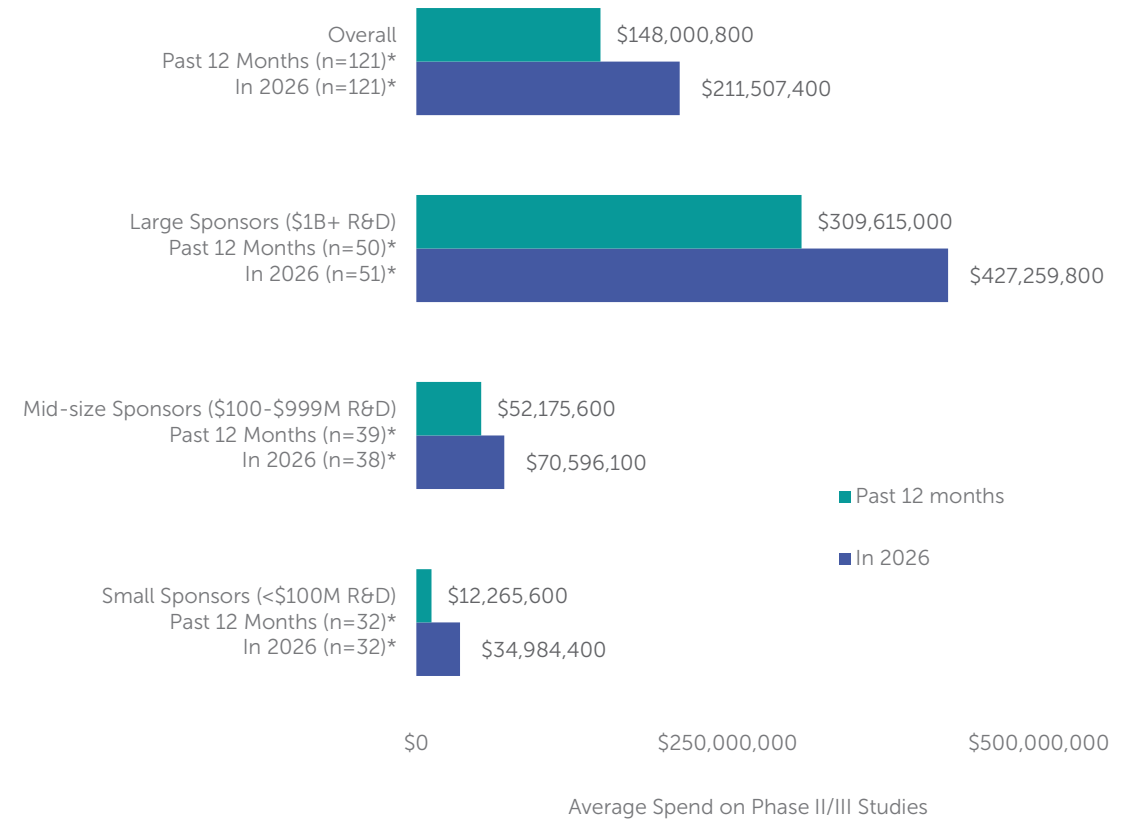
# Spend on Phase II/III Studies

As noted in prior years, average annual spend on Phase II/III studies mirrors sponsor size. Survey participants across all organization sizes expect spend on Phase II/III studies to increase in the coming years. Respondents at companies that spend less than \$100 million on R&D predict the largest proportional increase in spend while those at mid-size organizations expect average growth rates similar to those at large organizations.

Over half of this year’s respondents who expect an increase in spend credit the anticipated increase to *Pipeline success/more compounds to study* (71%) and *Company growth/success* (64%). In addition to organizational growth, market trends are also driving spending on Phase II/III studies. Roughly two out of five survey participants also listed *Rising cost of research* (46%), *Increasing trial complexity* (42%), and *Increasing trial size* (35%) as influential factors (see ‘Market Dynamics’ section of Study Data).

**“How much, in US dollars, has your company spent on Phase II/III studies in the past 12 months? Your best estimate is fine.”**

**“How much, in US dollars, would you estimate your company will spend on Phase II/III studies in 2026?”**



\*Outliers and respondents unable to estimate have been excluded

# Value of Average Outsourced Phase II/III Study

According to this year's respondents, the average value of the typical Phase II/III study their company outsources is about \$32 million. Large sponsors tend to outsource more expensive studies (\$47 million on average) compared to small and mid-size sponsors (\$19 million and \$22 million on average, respectively).

*"From your experience, in US dollars, what would you estimate is the value of the average Phase II/III study your company outsources? As a reminder, please consider only full-service outsourced clinical projects for this estimate." (n=123, outliers and respondents unable to estimate have been excluded)*



\*Outliers and respondents unable to estimate have been excluded

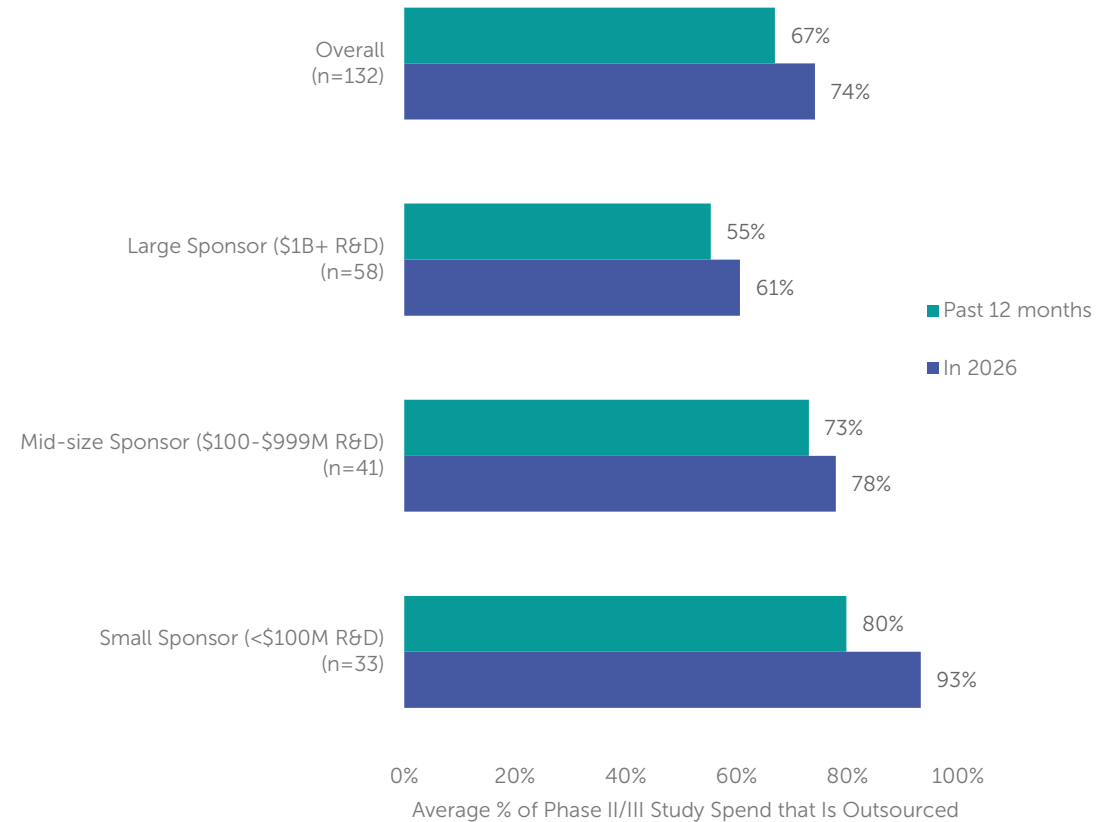
# Outsourced Proportion of Phase II/III Spend

Respondents reported that, on average, two-thirds of their company's spend on Phase II/III studies over the past year was outsourced. Larger companies conduct more Phase II/III work internally than small or mid-size sponsors. While roughly half of large sponsor Phase II/III spending was outsourced over the past 12 months (55%), survey participants at small and mid-size organizations reported that 80% and 73% was outsourced, respectively.

While respondents across all organization sizes anticipate that more Phase II/III spending will be outsourced by 2026, those at small companies expect the largest increase (13 percentage points on average). Approximately half of this year's survey participants who expect an increase in outsourcing cite *Pipeline success/more compounds to study* (56%), *More complex or large studies* (54%), and *Insufficient internal capacity* (47%) as reasons for their predicted increase in outsourcing (see 'Market Dynamics' section of Study Data).

***"Approximately, what percent of your company's spend on Phase II/III studies has been outsourced over the last 12 months?"***

***"Approximately, what percent of your company's spend on Phase II/III studies would you estimate will be outsourced in 2026?"***



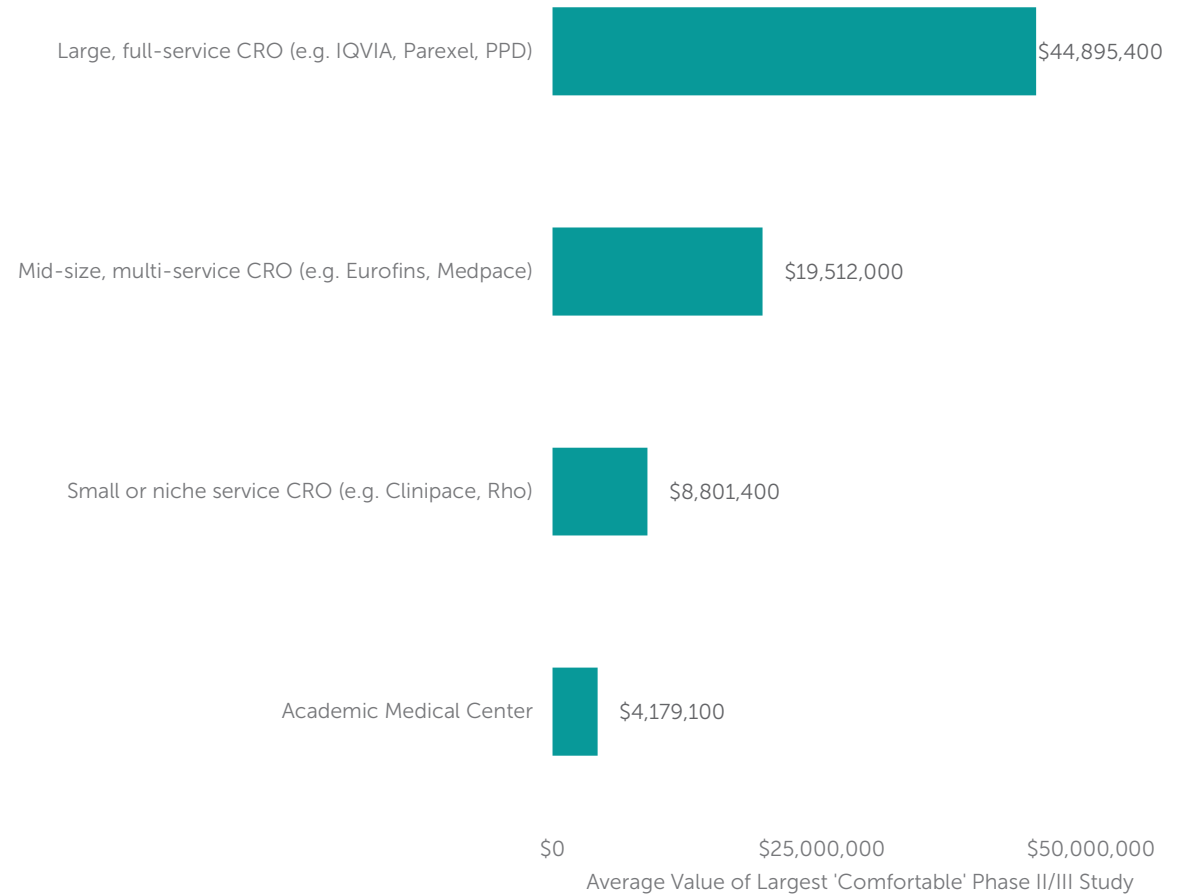


# Largest Study Comfortable Awarding to Each Provider Type

Respondents are more comfortable awarding larger Phase II/III studies to large CROs. On average, survey participants indicated they would feel comfortable engaging a full-service provider for efforts just shy of \$45 million, while mid-size, multi-service CROs would be allocated studies less than half that value (\$19.5 million on average). Respondents were comfortable awarding roughly \$9 million Phase II/III studies to small or niche CROs, and Academic Medical Centers would receive the smallest value efforts up to \$4 million.

A notable 85% of respondents “Agree-Strongly Agree” that the size of the study influences which CROs are considered for contract award (see ‘Trends and Predictions’ section of Study Data). The average values for the largest “comfortable” study reported this year closely mirror the data from 2020 (within +/- \$500K for all except mid-size CROs), indicating little variability in sponsor approaches for selecting Phase II/III providers.

***“Please indicate the largest Phase II/III study (in US dollars) you would be comfortable awarding to each of the provider types listed below. Please include all pass-through costs and investigator fees in your estimate.” (n=120-123, outliers and respondents unable to estimate have been excluded)***



# Outsourced Spend by Provider Type

Across all respondents, half of Phase II/III outsourcing spend goes to large, full-service CROs (51%). This proportion increases among large sponsors, which allocate three out of five outsourcing dollars to big providers. Use of mid-size, multi-service providers is slightly higher among mid-size and small sponsors (33% and 32%, respectively) than those at large companies (19%). Small sponsors allocate more Phase II/III spend to small CROs than mid-size or large sponsors, but all equally engage Academic Medical Centers for their outsourcing needs. On average, respondents expect the proportion of outsourcing spend allocated to each provider type to remain relatively steady over the coming years (see 'Market Dynamics' section of Study Data).

Prior research indicates that large CROs are leveraged for their *Global footprint* and *Breadth of service*, while mid-size providers stand out for *Quality* and *Project management*. Small CROs provide sponsors with *Specialized focus* and *Local knowledge*, while *KOL Access* and *Strong investigator relationships* were differentiators for academic medical centers (see 'Market Dynamics' section of Study Data).

***“Please estimate the percent of your company’s Phase II/III outsourcing spend with each of the following types of service providers. Your best estimate is fine. Columns must total 100%.”***



# Decision-making Influence by Role

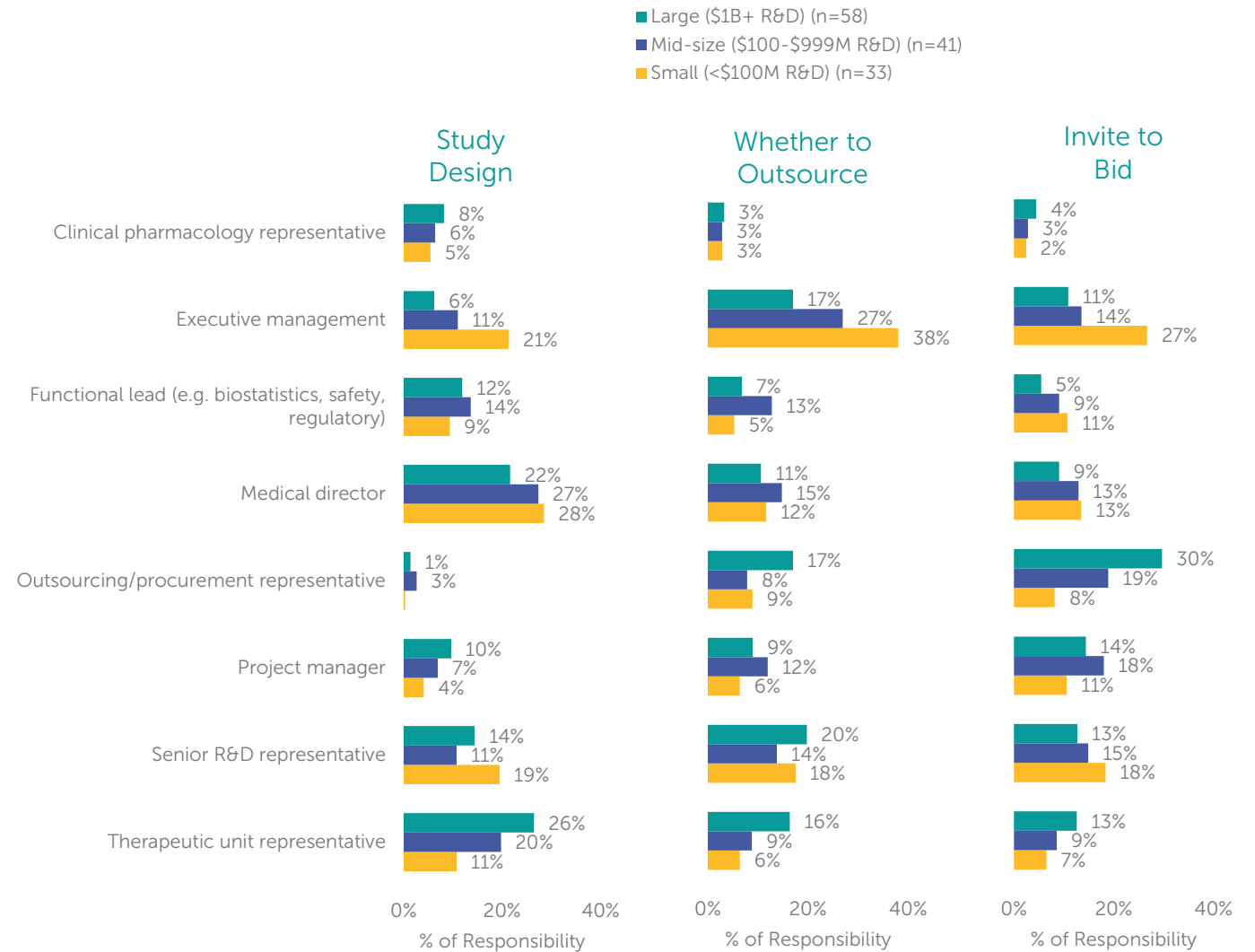
This research takes a deep dive into influence by role during the process of designing and executing an outsourced Phase II/III study. Many different roles play a part (but not equally) and the roles with the most responsibility vary by task.

Overall, the medical director and therapeutic unit representative roles have the most influence over the design of the Phase II/III study. On average, executive management has the largest say in outsourcing decisions, study budgets, and final CRO selection. The outsourcing/procurement representative role has the most oversight on average regarding which CROs are invited to bid, though influence is spread relatively equally across many roles for both inviting CROs to bid and making the final selection. The project manager role has some influence over budgeting, and PMs are primarily responsible for managing CRO delivery, on average.



Interesting trends emerge when decision-making influence is viewed through the lens of organization size. At small and mid-size sponsors, the medical director has the most responsibility on average for **designing** the Phase II/III study, while respondents at large companies allocate slightly more design responsibility to a therapeutic unit representative. Executive management drives **outsourcing** and budgeting decisions at small and mid-size organizations, but influence over both of these functions is split relatively equally across many roles at large sponsors. Large sponsors lean primarily on outsourcing/procurement representatives to determine which CROs to **invite to bid**. The C-Suite owns the biggest part of this decision at small companies, and mid-size sponsors involve many stakeholders in CRO consideration. Please see 'Provider Perceptions and Selection' section of Study Data for detailed breakdowns.

*“Decision making for Phase II/III studies can be complicated and highly variable from company to company. The grid below indicates six (6) different responsibilities associated with the conduct of Phase II/III studies. It also shows nine (9) different roles that may or may not own or share these responsibilities. Based on your experience, please indicate how these responsibilities are spread across these roles. Each column must total 100%, completely allocating the ownership of that responsibility.” (n=132)*

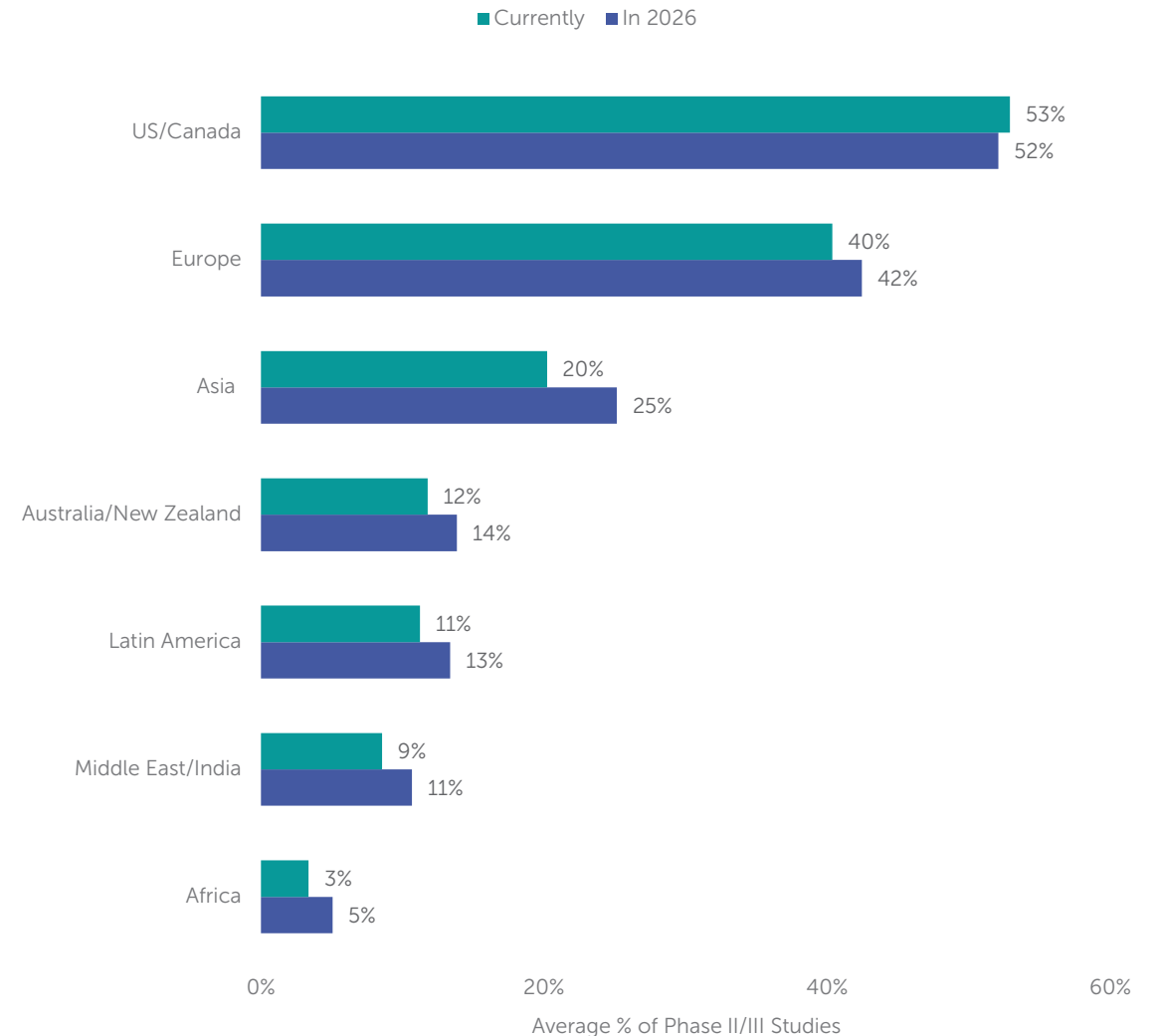


# Locations of Phase II/III Studies

Nearly three-fourths of respondents' Phase II/III studies recruit from multiple countries, on average (72%, see 'Trends and Predictions' section of Study Data). Survey participants reported that roughly half of their Phase II/III studies are conducted in North America. Two out of five studies have a European component and one-fifth are conducted in Asia, on average. Respondents project slight increases in the proportion of studies executed in every region outside of the US/Canada, which is expected to remain steady.

Respondents were asked to rate providers' overall performance on Phase II/III trials by region. Covance/Labcorp, ICON (including PRA), Medpace, Parexel, and Worldwide Clinical Trials received their most positive ratings on average for their North America offices, while Eurofins, IQVIA, PPD, and Syneos Health received higher performance scores for their European operations compared to their work in other geographies (see 'Trends and Predictions' section of Study Data). None of the providers received their highest ratings for Asia-Pacific, highlighting an opportunity area for differentiation in the region with the largest anticipated increase in Phase II/III studies in 2026 (+5 percentage points in Asia).

***"Please estimate the percent of your company's Phase II/III studies that are / will be executed in the following regions, currently and in 2026. As studies often take place in multiple geographies, percentages do not need to = 100%. Your best estimates are fine."*** (n=132)



# Service Provider Size Trends

Four out of five respondents agree that study size influences the CROs considered for outsourcing Phase II/III services (85%). As noted previously, survey participants are more comfortable awarding higher dollar figure studies to large, full-service CROs. Despite only accounting for 14% of outsourcing spend on average, most respondents consider smaller, niche CROs to offer high levels of therapeutic expertise and quality customer service.

***“Please indicate your level of agreement with the following statements.” (n=132)***



# About Industry Standard Research

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