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Impact of the In Vitro Diagnostic Regulation (IVDR) on the Conduct of Clinical Trials in the EU and CRO Outsourcing

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Sample Pages

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 Managing Member with the Life Science Strategy Group, LLC (LSSG). Mr. Meyer leads LSSG's biopharmaceutical services consulting division which serves the leading global contract research organizations (CROs), contract drug manufacturing organizations, drug discovery and diagnostics companies globally across all phases of the biopharmaceutical discovery, development and commercialization lifecycle.

Mr. Meyer has managed consulting engagements in a variety of areas including strategic planning, opportunity assessments, pricing analyses, forecasting, brand awareness and equity assessments, 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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Study Background

In Vitro Diagnostic (IVD) tests are critical to clinical trial operations, serving to help select patients in clinical trials, provide accurate efficacy results, monitor patient response, and more. In May of 2022, the In Vitro Diagnostics Regulation (IVDR) in the European Union and the European Economic Area (EU/EEA) went into effect, seeking to ensure higher patient safety for medical devices, requiring device manufacturers to conduct more stringent safety and performance studies for said devices. As a result, current and pending drug clinical trials utilizing IVD tests now must also adhere to the IVDR. Compliance among clinical drug trials with the IVDR means IVDs used in clinical trials providing a diagnostic test result that will influence patient medical management must go through a Performance Study, which requires submission of a Performance Study Application (PSA). However, this process is currently complex and uncoordinated, resulting in delays in clinical trials and patients waiting longer to participate in clinical trials, or even not participating at all.

This landmark report includes 90 biopharmaceutical participants from the United States and Europe and explores the impact of these delays on clinical trial CRO partnerships, with detailed findings on potential strategies and/or shifts to be implemented by biopharmaceutical companies to mitigate the current and expected delays caused by the IVDR.

In the report, Life Science Strategy Group also provides commentary and interpretation of the data, which reflects more than 30 years of experience consulting to many of the leading global biopharmaceutical companies, clinical development CROs and CRO industry analysts. As such, for the purposes of this report, we are looking through the lens of our clients – specifically, what are the preferences among biopharmaceutical respondents for CRO partnerships and clinical trial site locations and how might these preferences change for clinical trials ongoing in the EU/EEA that are/will be impacted by the IVDR.

Report Methodology

Methodology

The primary research for this report was fielded via an internet survey in November and December 2023 and draws from ninety (N=90) biopharmaceutical industry professionals from the United States and Europe responsible for clinical development and services outsourcing across a variety of clinical activity in early and late phase development. Respondent position titles include Manager/Senior Manager through President/Vice President with functional roles in clinical pharmacology, development, operations, project management, and sourcing/procurement, among others. All study participants were prescreened by LSSG to ensure a high level of involvement, knowledge, and decision-making influence or authority for clinical services outsourcing to CROs. This included confirming consistency of answers for related questions, validation of companies, and knowledge-based quality control questions.

Study respondents were asked to provide information about current and future shifts in CRO outsourcing, given the recent In Vitro Diagnostics Regulation (IVDR) affecting clinical trials in the European Union. This included estimates of delays and preferences among clinical trial site countries, CRO partners, and any other changes in clinical development outsourcing trends associated with the IVDR. To draw deeper conclusions, the data from this study was segmented by company size and geography of respondents. LSSG also included its experience and knowledge about the global biopharmaceutical and CRO industries, preferences and outsourcing practices.

All data analysis and reporting was performed by LSSG consultants. For analysis, n<15 is considered directional.

Terminology and Segmentation

Terminology

For the purposes of this report, the below acronyms are defined as the following:

- ***IVD*** – *defined as In Vitro Diagnostics: tests done on samples such as blood or tissue taken from a human body to detect disease or other conditions*
- ***IVDR*** *– defined as In Vitro Diagnostics Regulation: a regulation passed in the EU that requires IVDs used in clinical trials that provide a diagnostic test result influencing patient medical management must submit a Performance Study Application.*
- ***PSA*** *– defined as Performance Study Application: a submission for a Performance Study as required by the IVDR.*
- ***EEA*** *– defined as those countries within the European Economic Area, including the EU and Iceland, Liechtenstein, and Norway.*

Segmentation

Respondents were classified into the following segments:

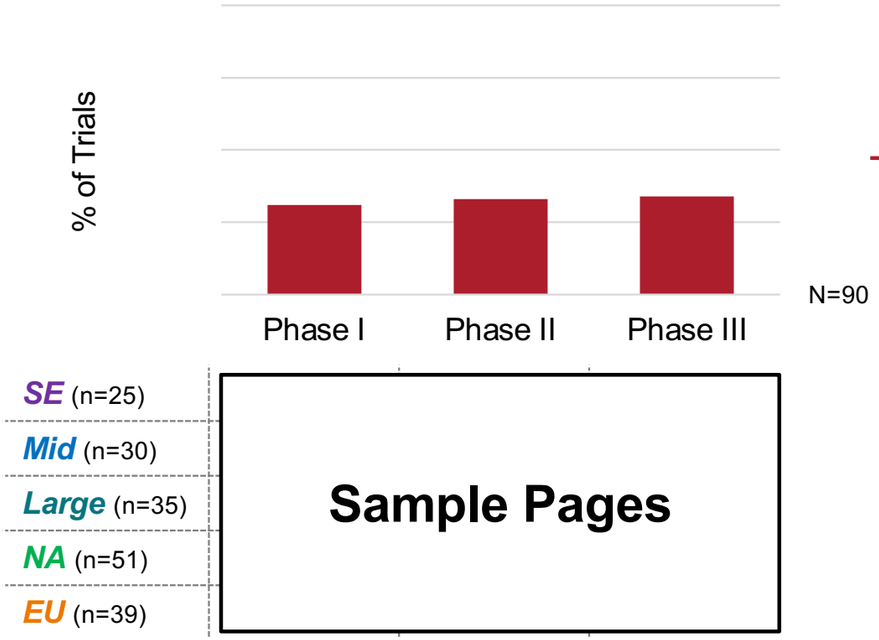
- ***Small/Emerging (SE) Biopharma*** – Respondents working at biopharmaceutical companies with an annual R&D budget between $0 and $300 Million
- ***Mid-size (Mid) Biopharma*** – Respondents working at biopharmaceutical companies with an annual R&D budget between $300 Million and $1.5 Billion
- ***Large Biopharma*** – Respondents working at biopharmaceutical with an annual R&D budget over $1.5 Billion
- ***North America (NA)*** – Respondents located in the United States and Canada
- ***Europe (EU)*** – Respondents located in Europe

Across all phases of development, roughly XXX of respondents' clinical trials currently involve IVDs. Respondents expect this to increase by approximately XX% in the next 2-3 years.

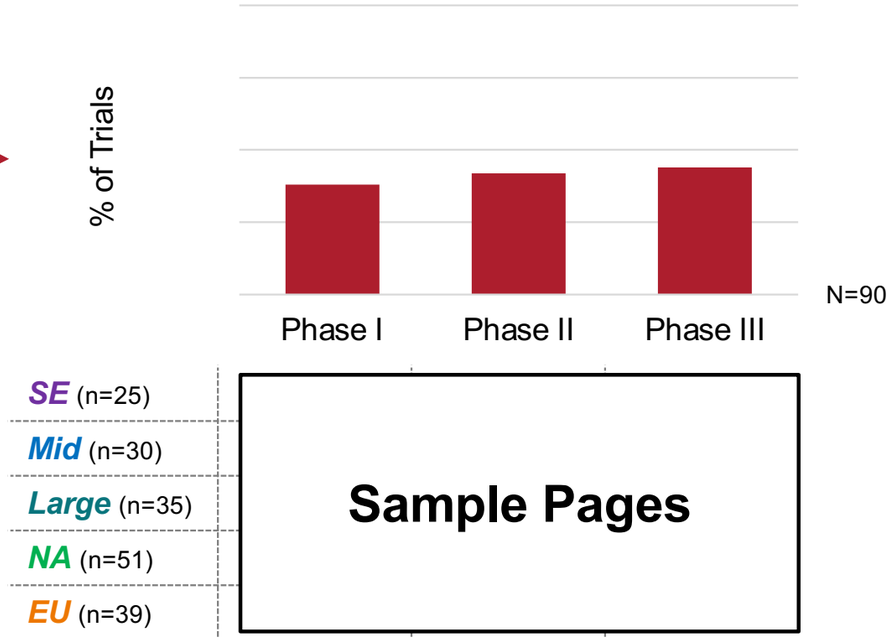
Percentage of Clinical Trials Involving IVDs

- Currently, a larger share of XXX respondents' Phase I clinical trials involve in vitro diagnostics (IVDs) than do XXX biopharma respondents.

Current Clinical Trials



Clinical Trials in the Next 2-3 Years



Q1. What percent of your/your company's current and planned clinical trials over the next 2-3 years involve/will involve an associated IVD?

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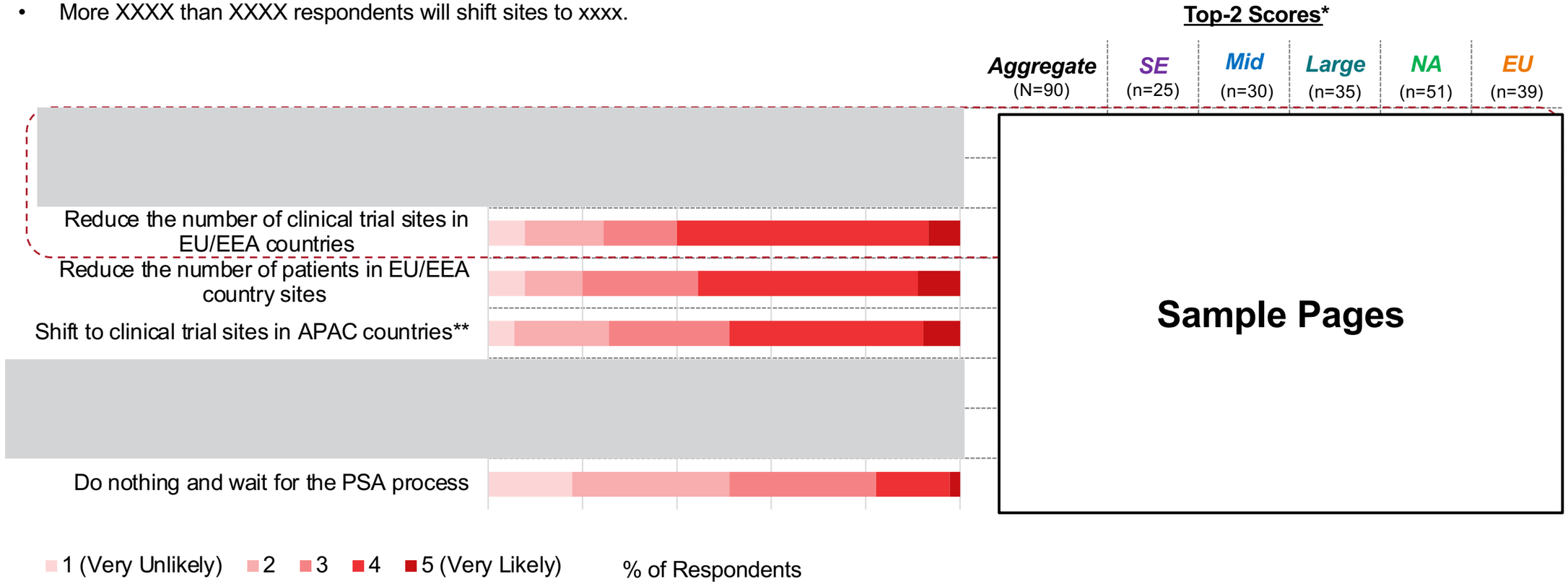
For future clinical trials, respondents expect to XXXXXXXX by shifting sites to X and Y the number in EU/EEA countries.

Likelihood to Take Select Actions Given Delays – Future Clinical Trials

- More X respondents will xxx in EU/EEA countries (XX% vs. XX%, respectively) and more Y than Z biopharma respondents will shift to clinical trial sites in the UK and non-EU/EEA countries (XX% vs. XX%, respectively).
- Compared to small/emerging and mid-size biopharma respondents, more yyy will shift sites to LATAM (XX% and XX% vs. XX% respectively) and APAC (XX% and XX% vs. XX%, respectively) countries.
- More XXXX than XXXX respondents will shift sites to xxxx.



Q6. [Show if Q2(future)a-c>0] Given the current delays and expectations of future delays, how likely are you to take each of the following actions for your clinical trials involving an IVD in EU/EEA countries? [Future Clinical Trials Over the Next 3 Years]

*Top-2 Score = Sum of options 4 & 5.
**Full answer options in appendix

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X are perceived to be market leaders in understanding and Z.

EU/EEA Regulatory Landscape Market Leaders

Perceived Market Leaders - Aggregate	Market Leaders - Segmentation	
Sample Pages • Precision for Medicine (n=6) • Propharma (n=4) • CTI (n=2) • WuXi AppTec (n=2) Includes n>1	***SE*** (n=25)	Sample Pages
	Mid (n=30)	
	Large (n=35)	
	NA (n=51)	
	EU (n=39)	

- No significant segmentation differences.

Q15. Which clinical development CROs, consultancies and other vendors do you perceive to be the market leader(s) in understanding and advising its customers about the evolving regulatory landscape and requirements in EU/EEA countries specifically related to the clinical trials involving in vitro diagnostics (IVDR), the EU Clinical Trial Regulation (CTR), and EU Clinical Trial Information System (CTIS)?

N=90

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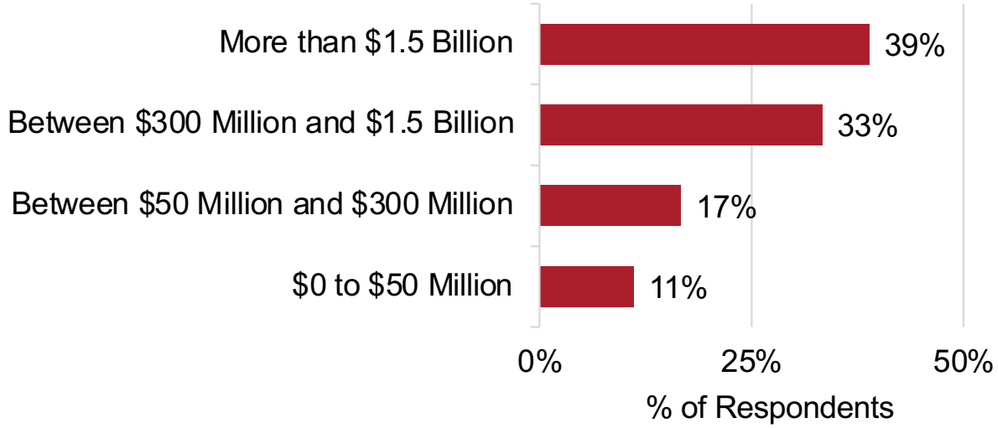
V. Respondent Demographics

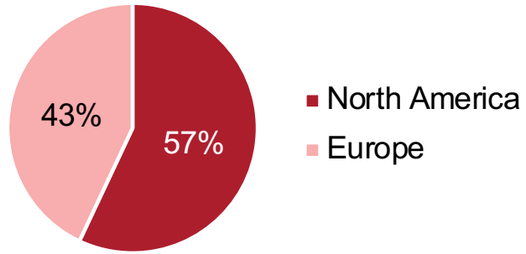
Respondent Demographics

- All respondents work in Biopharmaceutical companies.

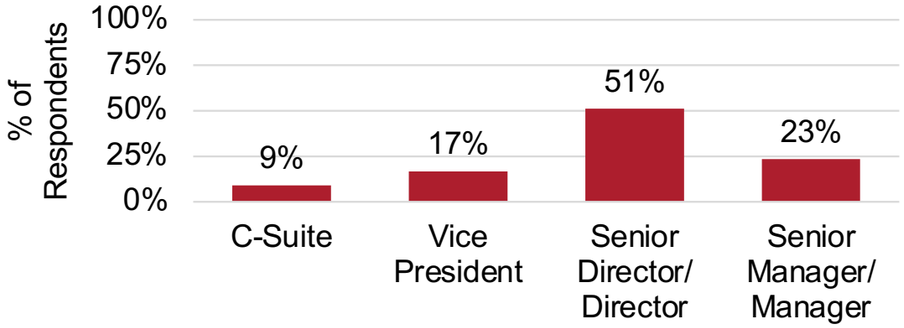
Company Size



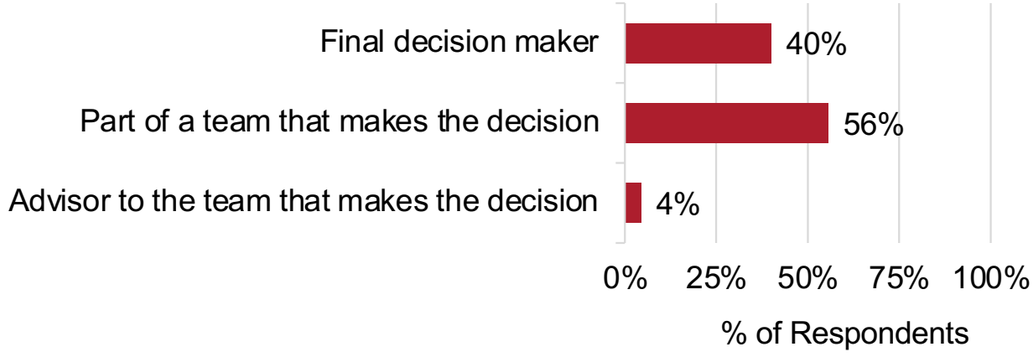
Involvement by Phase



Position Level



Role in Decision Making



S1. Where are you located?
S2. Which best describes the type of company that you currently work for?
S3. Please estimate your company's total R&D budget (not for your specific role, but the company in total) for the fiscal year?
S4. Which best describes your position level or equivalent?
S10. Which of the following best describes your role in the evaluation and selection process for clinical development services offered by Contract Research Organizations (CROs) for your/your company's clinical trials involving an associated IVD?

N=90

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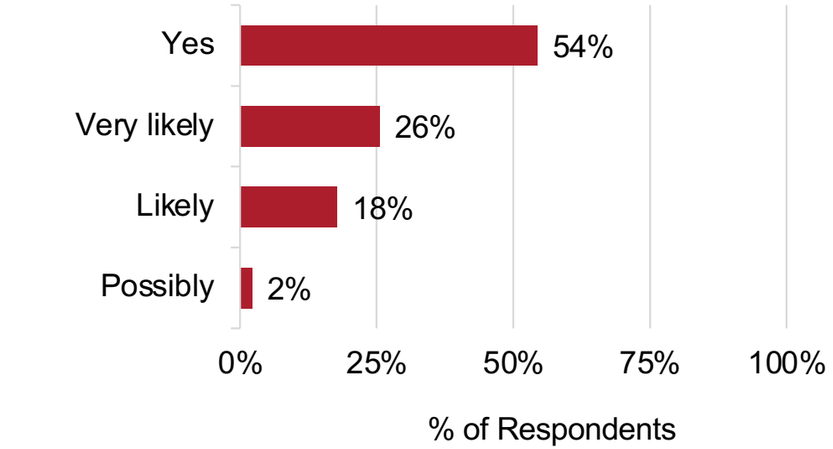
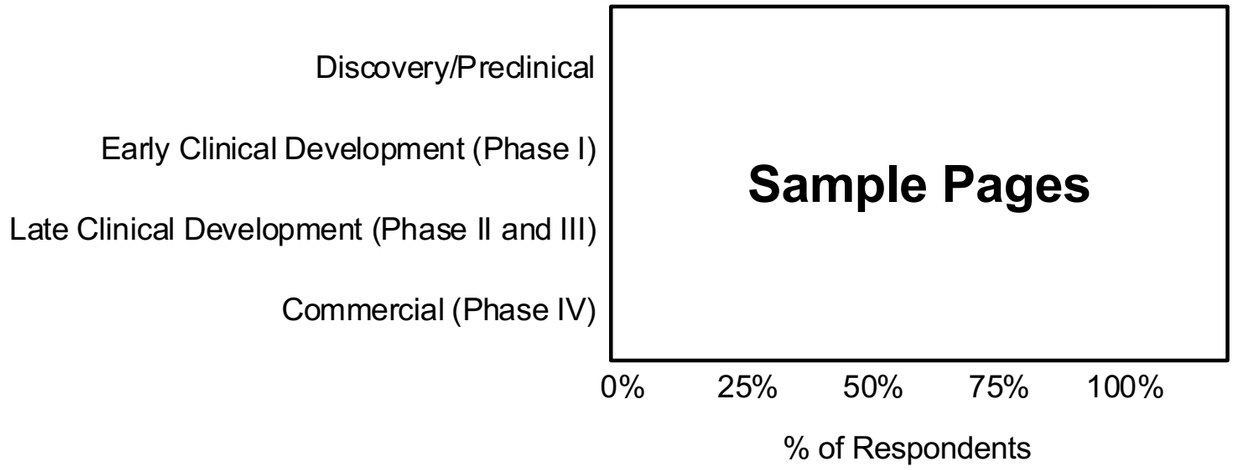
Respondent Demographics

- Respondents' clinical trials are either currently being conducted in the EU, or they are considering EU countries for their clinical programs over the next 3 years.

IVD Involvement in Current or Considered EU Trials



Developmental Stage of Functional Responsibilities



S5. Which describe the developmental stage(s) of your functional responsibilities at your company?
S7. Are any of the clinical trials that you are responsible/part of your functional responsibilities currently being conducted in European Union (EU) countries, or are EU countries being considered for your clinical programs over the next 3 years?
S9. Do any of the clinical trials that you are currently conducting or considering conducting over the next 3 years in EU countries include an associated in vitro diagnostic (IVD) that will help direct treatment decisions?

N=90

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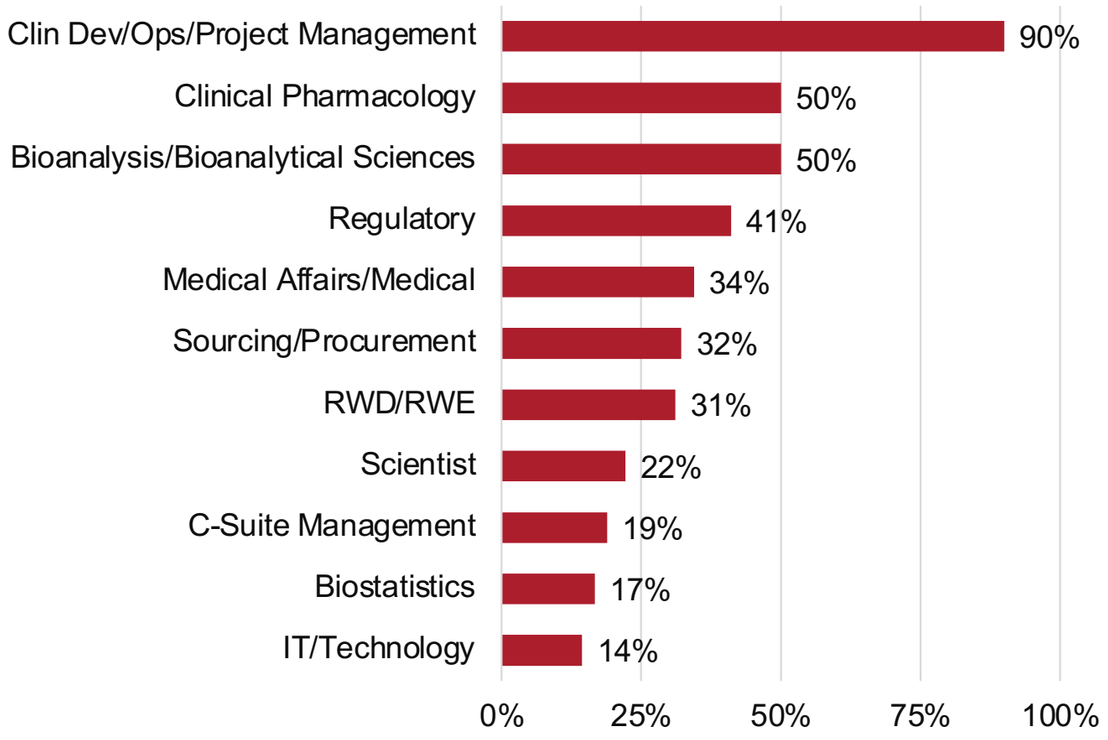
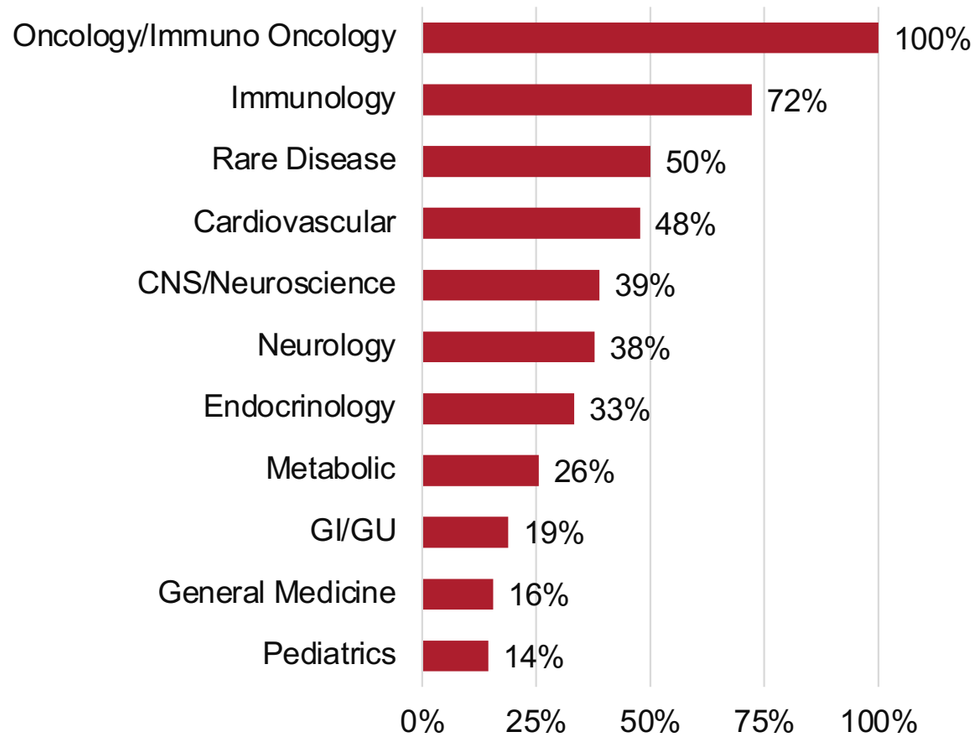
Respondent Demographics

Functional Area(s)



Other includes drug product development (n=1)

Therapeutic Area(s)



Other includes vaccines (n=2), infectious diseases (n=2), and hematology (n=1)

N=90

S6. Which best describes your primary functional role(s) at your company?
S8. In which therapeutic areas are the trials that you are currently conducting or considering conducting in EU countries over the next 3 years include?

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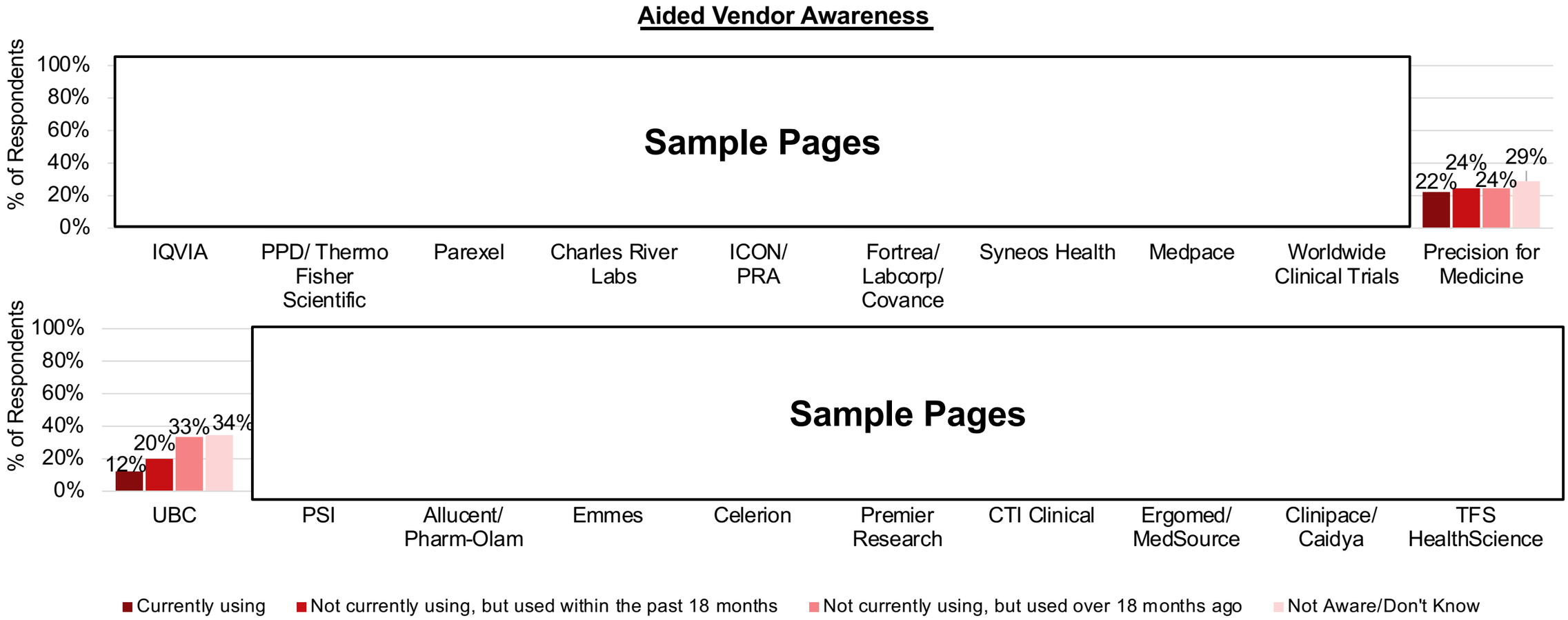
Respondent Demographics



N=90

S11. What best describes your experience/familiarity with each of the following CROs/vendors for their clinical development services?

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