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Chinese Innovative Biopharmaceutical Clinical Development, Outsourcing and CRO Utilization Practices, Outlook and Implications for Global CROs

April 2023

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

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I. Study Background

Study Background

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It's no secret that the developing Chinese biopharmaceutical market is high on the radar for many of the leading Global CROs due to its size and the future opportunity it presents. It's also no surprise that many of the Top-10 CROs have been making investments in the region for nearly a decade to "plant the seeds" for future success. However, published information quantifying the domestic Chinese biopharma industry and its outsourcing practices has been relatively unavailable – until today. This research report aims to fill this gap by providing groundbreaking insights into the current state and potential of the Chinese biopharmaceutical services industry.

The landmark report with more than 100 innovative Chinese biopharma professionals explores the many of the latest trends in clinical development in China, the impact of these trends on expected activities, the types of trials being conducted, and the shifts expected over the next few years. Furthermore, the report examines the clinical development budgets of Chinese biopharmaceutical companies and expected growth. It goes further to quantify the use of clinical research services offered by both local vendors and global, Top-10 CROs, providing an understanding of the extent to which outsourcing is used today and in the future.

In the report, Life Science Strategy Group provides its own commentary and interpretation of the data, which reflects more than 20 years of experience consulting to many of the leading Top-10 global CROs and CRO industry analysts. As such, for the purposes of this report, we are looking through the lens of our clients – specifically, what is the current state of the market today, how is it evolving and what are the implications for the future.

Overall, this groundbreaking research report provides a comprehensive analysis of Chinese biopharmaceutical clinical development trends, budgets, and growth, as well as outsourcing practices and CRO utilization. It will be of great interest to biopharmaceutical services industry executives, analysts, and leading global CROs seeking to understand the current state of the market and identify future opportunities.

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III. Methodology

Methodology

The primary research for this report was fielded via native language internet surveys in February and March 2023 and draws from more than one hundred Chinese biopharmaceutical industry professionals (N=101) responsible for clinical development budgets and clinical services outsourcing across a wide array of clinical development activities. Respondent positions include Manager/Senior Manager through President/Vice President of Clinical Development and Clinical Operations departments, 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 development budgeting and 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 clinical development industry trends and general information about clinical development budgeting practices. They were also asked about the scope of their company's clinical trials by phase of development and use of clinical research services providers, selection criteria and unmet needs. To draw deeper conclusions, the data from this was segmented by company size and by use of vendor type. 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.

Terminology

Outsourcing partners were grouped into three main categories:

- **Local Vendors**, defined as those offering clinical development services in China only
- **Regional Vendors**, defined as those offering clinical development services in APAC region
- **Global Vendors**, defined as those offering clinical development services globally

Segmentation

Respondents were classified into the following segments:

- **Small/Emerging** – respondents working at Chinese biopharmaceutical companies with annual revenue of less than ¥1B
- **Medium/Large** – respondents working at Chinese biopharmaceutical companies with annual revenue of more than ¥1B
- **Local Vendor Users** – respondents using local CROs/vendors for clinical development services
- **Global Vendor Users** – respondents using global CROs/vendors for clinical development services

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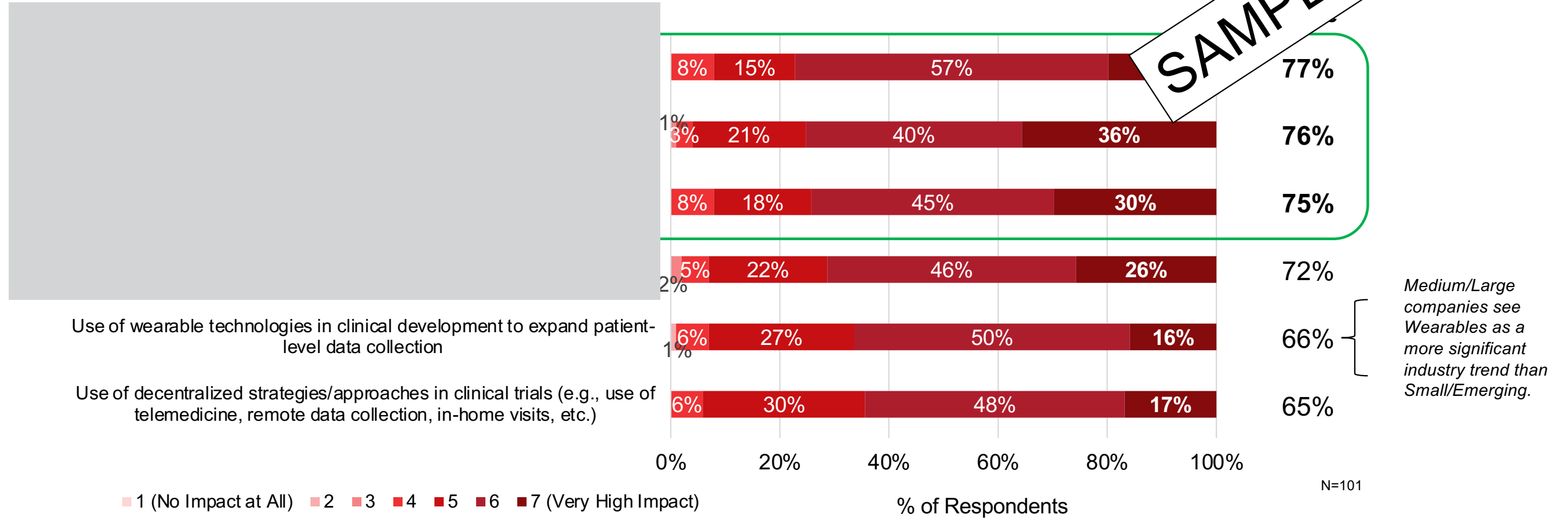
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IV. Detailed Findings

Use of X, Y and Z are top trends impacting clinical development in China over the next 2 years

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Impact of Industry Trends (Aggregate)



It will be increasingly important for global CROs to leverage X Y and Z to inform decision-making.

Q1. Please rate the impact of each of the following industry trends on your company's clinical development activities over the next 1-2 years. Please rate on a 1 to 7 scale, where 1=No Impact at All and 7=Very High Impact.

Most Chinese biopharma clinical trials are X, while Z are planned over the next 2 to 3 years.

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Percentage of Active Clinical Trials by Trial Type (Average)

	Local Trials		Regional Trials		Global Trials	
	Today	2-3 Years	Today	2-3 Years	Today	2-3 Years
Small/Emerging (n=51)	60%					
Medium/Large (n=50)	73%					
Local Vendor Users (n=97)	64%					
Global Vendor Users (n=58)	49%					

Note: Local Trials are defined as sites in China only, Regional Trials as sites in APAC region, and Global Trials as sites in NA, EU, APAC.

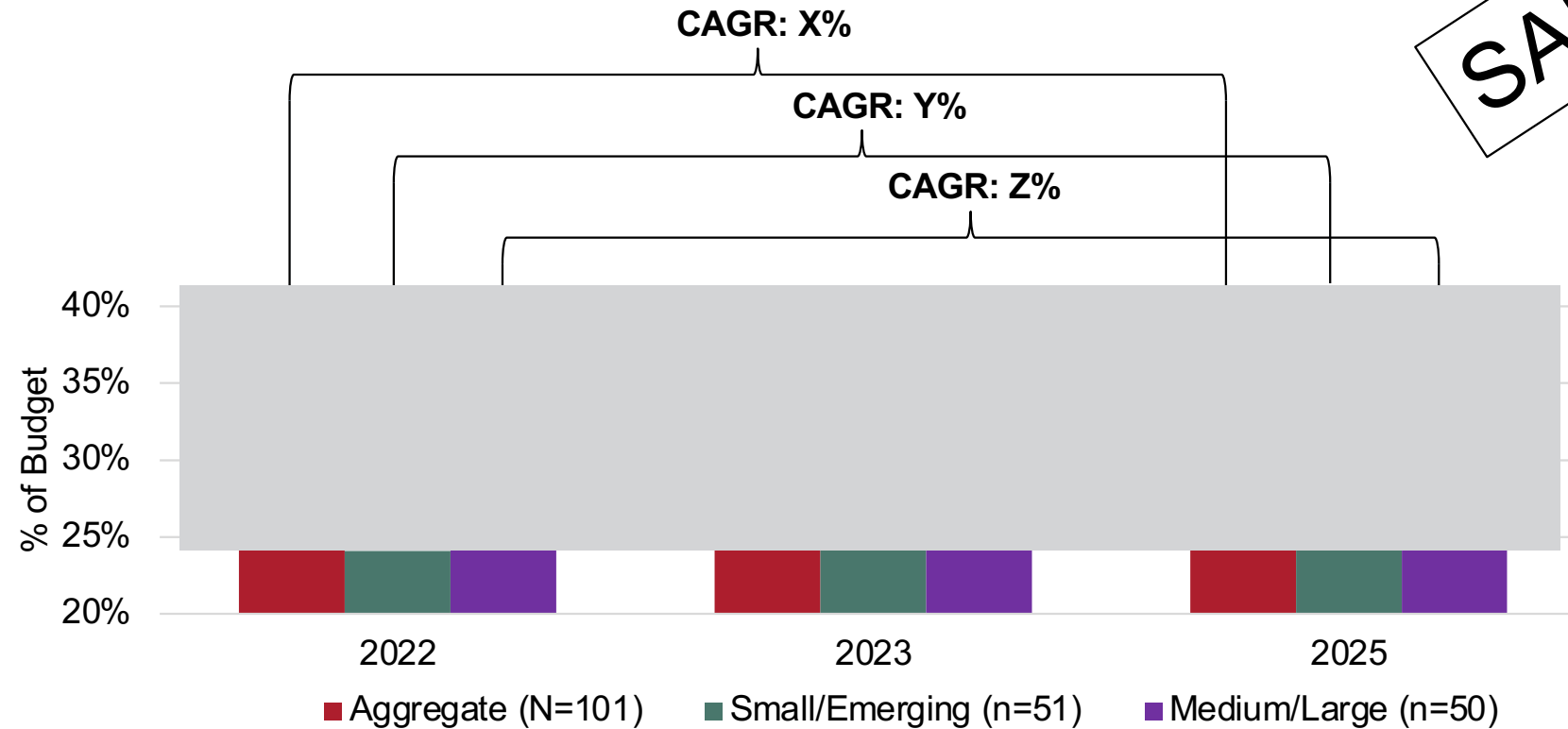
Rapid (5-year horizon) and extensive globalization of Chinese biopharma's clinical trials is Z. Global CROs targeting Chinese biopharma will need A, B and C to access the majority of the clinical development opportunity.

Q5a. What percent of your company's active clinical trials fit within each of the following categories? Please have responses sum to 100%.

Outsourcing growth by Small/Emerging Chinese biopharma companies is X and Y (CAGR: A% and B%).

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Clinical Development Budget Spent on Outsourcing (Company Size Segment)



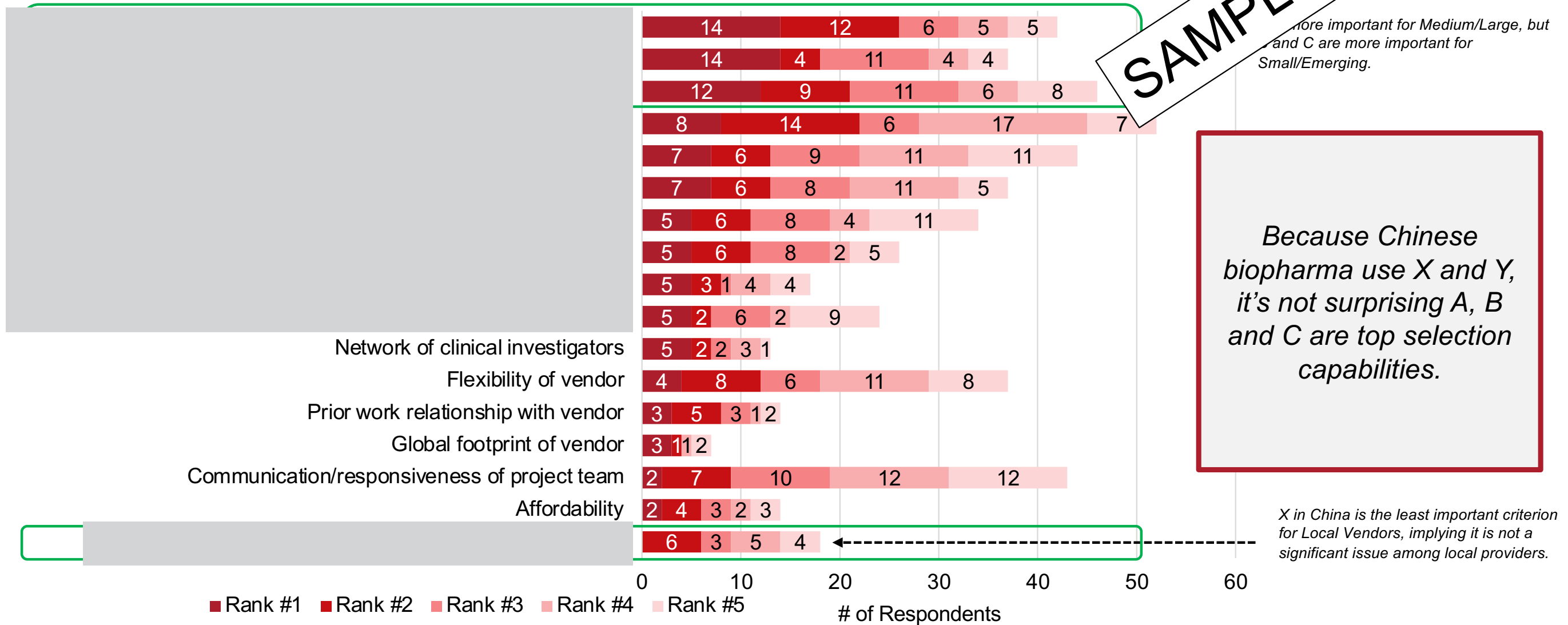
Clinical development outsourcing levels by Chinese biopharma reflect X and Y in North America and Europe. There is considerable Z for A and B outsourcing as the industry Z.

Q6. Please estimate the percentage of your company's annual total clinical development budget that was spent on outsourced clinical development services (vs. spent internally) in the following years.

Chinese biopharma rank A, B and C as the most important attributes/capabilities when selecting a local vendor.

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Important Attributes for Local Vendor Selection (Aggregate)



more important for Medium/Large, but A and C are more important for Small/Emerging.

Because Chinese biopharma use X and Y, it's not surprising A, B and C are top selection capabilities.

X in China is the least important criterion for Local Vendors, implying it is not a significant issue among local providers.

Q11a. Please rank order the importance of the following attributes and capabilities if/when selecting a Local Provider (e.g., offers clinical development services in China only) for outsourced clinical development services? Please rank your top 5.

Top local vendor unmet needs focus on A, B and C, while global vendor needs center on X, Y and Z

Top Unmet Needs when Outsourcing Clinical Development Services (Aggregated)

Local Vendors (N=101)	Global Vendors (N=101)
Key Finding: X and Y.	Key Finding: A and B.

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[Redacted content]

- Lack of expertise (n=4)
- Imperfect solutions that lack innovation (n=4)

- **Timely and good communication (n=12)**
- **Efficient project management team (n=8)**

"Respondent quote about unmet needs."
-Emerging Biopharma

"Insufficient X and Y ability."
-Large Biopharma

"Vendors do not have sufficient Z of B."
-Small Biopharma

"Vendors have a certain degree of X, but not Y or Z in their A."
- Large Biopharma

*Global CROs are X to Y in China because Z, A and B of their customers needed to deliver D and E solutions.**

Note: All respondents were given the chance to list unmet needs for each vendor type. If they had none, they were instructed to enter N/A.

Note: Unmet needs with <4 mentioned for Local Vendors and <8 mentions for Global Vendors not included.

Q12. What are your company's top unmet needs when outsourcing clinical development services to each of the following vendor types? Please list.

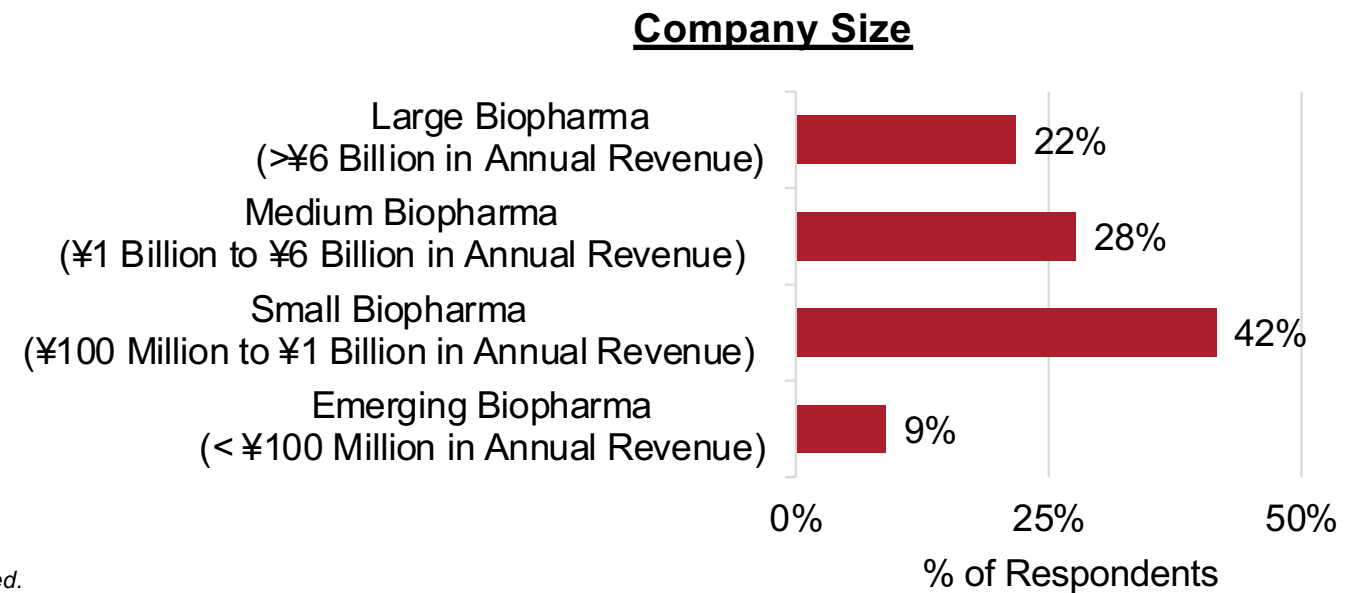
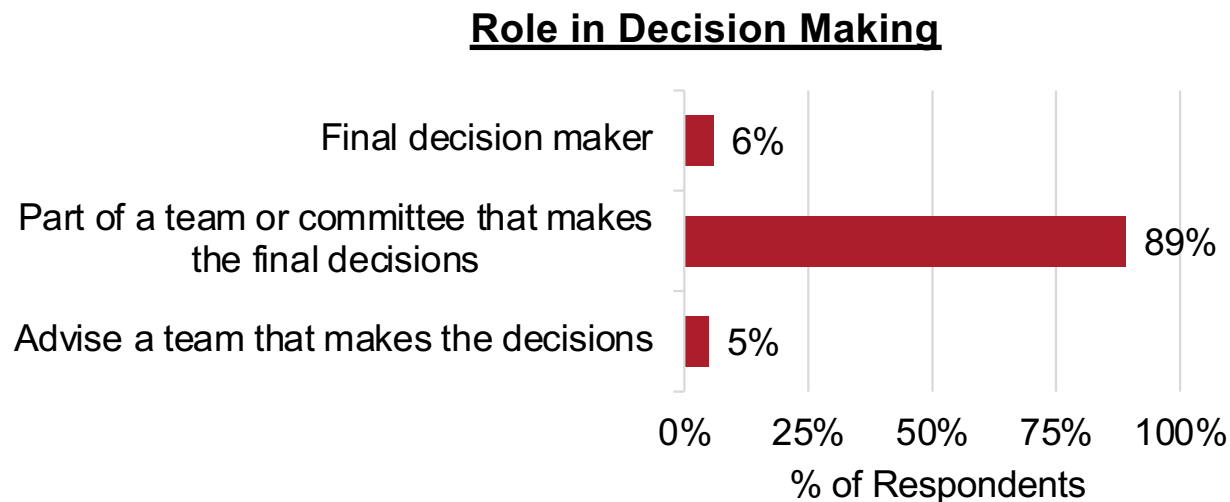
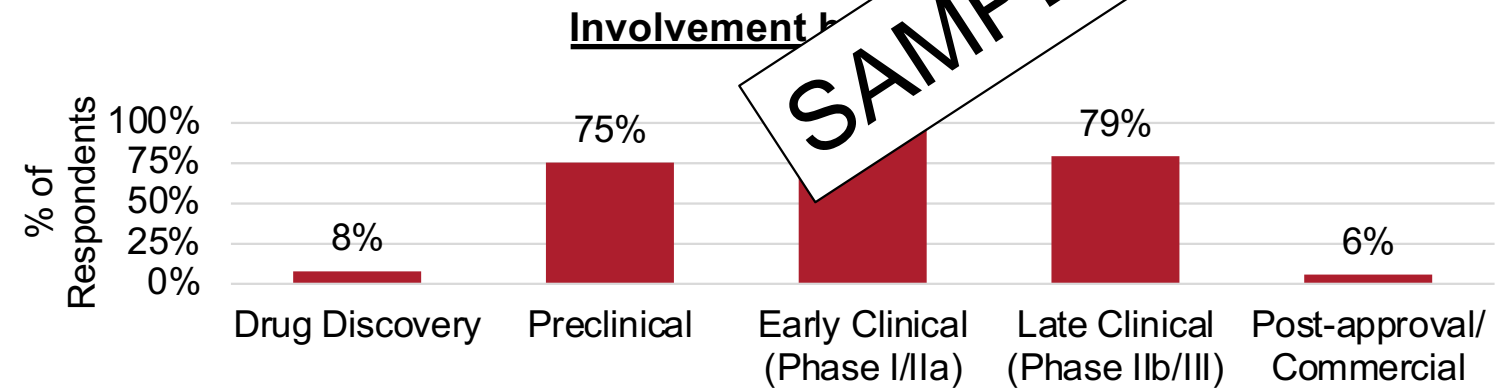
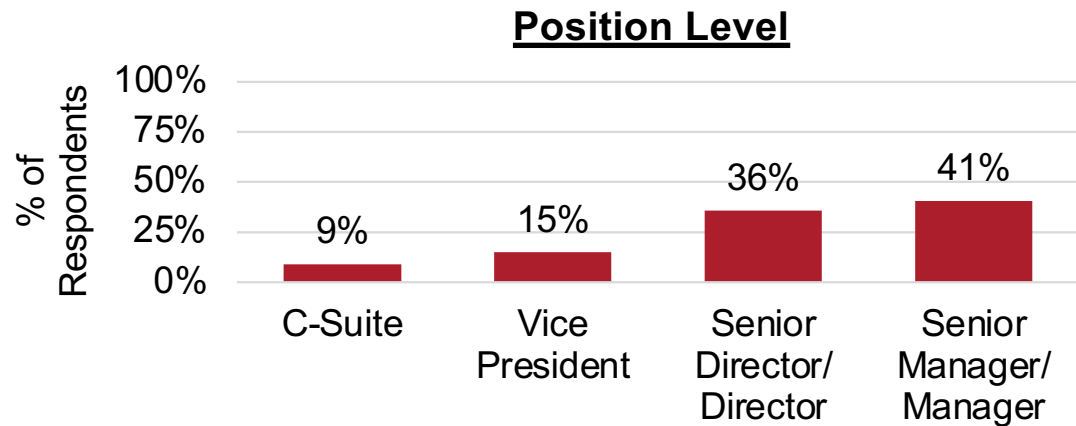
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V. Respondent Demographics

Respondent Demographics

- Respondents have functional responsibilities in clinical development at their company.
- All respondents are located and work at innovative biopharmaceutical companies located in China.

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S1. Where are you personally located? S1a. Please specify where in the Asia Pacific region you are personally located.
 S2. Where is your company headquartered? S2a. Please specify where in the Asia Pacific region your company is headquartered.
 S3. Which best describes the type of company that you currently work for?
 S4. Within what Phase(s) of drug development are you actively involved?
 S6. Which best describes your position level or equivalent?
 S9 What best describes your role as it relates to the identification, selection, and/or day-to-day interaction with clinical development service providers or other outsourcing partners in your primary functional area(s) of responsibility at your company?

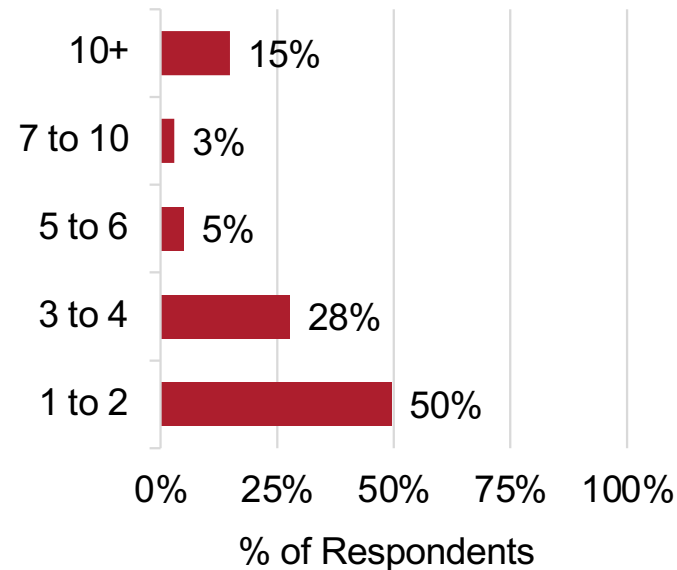
N=101

Respondent Demographics

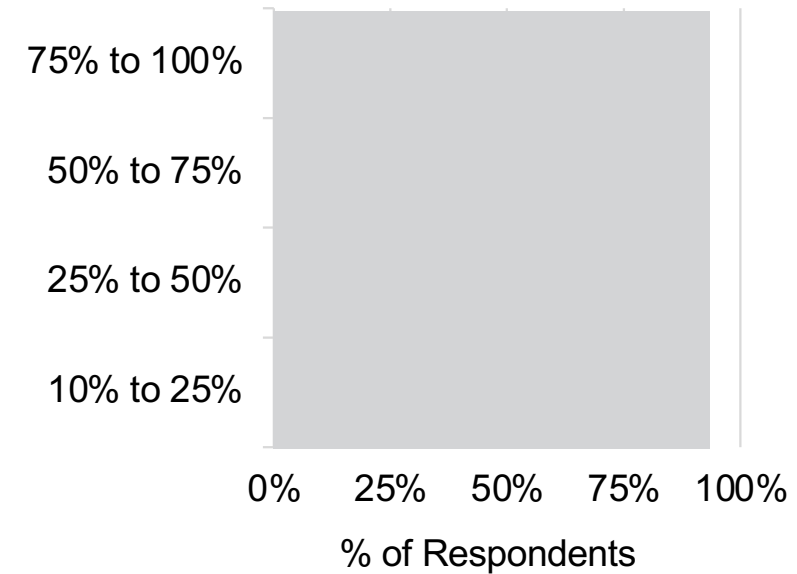
- Respondent companies have one or more active clinical programs and spend more than 10% of their annual development budget on external service providers.
- Most respondent companies outsource between X% and Y% of their annual clinical development budget to external providers.

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Number of Active Clinical Trials



% of Annual Clinical Development Budget Spent on Outsourcing



- **Local Vendor Users** comprise 96% of the respondent sample.
- **Global Vendor Users** comprise 57% of the respondent sample.

S7. How many active clinical programs in Phase 1 to Phase 3 is your company currently conducting?

S8. Please estimate the percent of your company's total annual clinical development budget that will be spent on services provided by external clinical development service providers (vs. internal spending).

S10. Which type of outsourced clinical development services vendor(s) does your company use to support its active clinical trials?